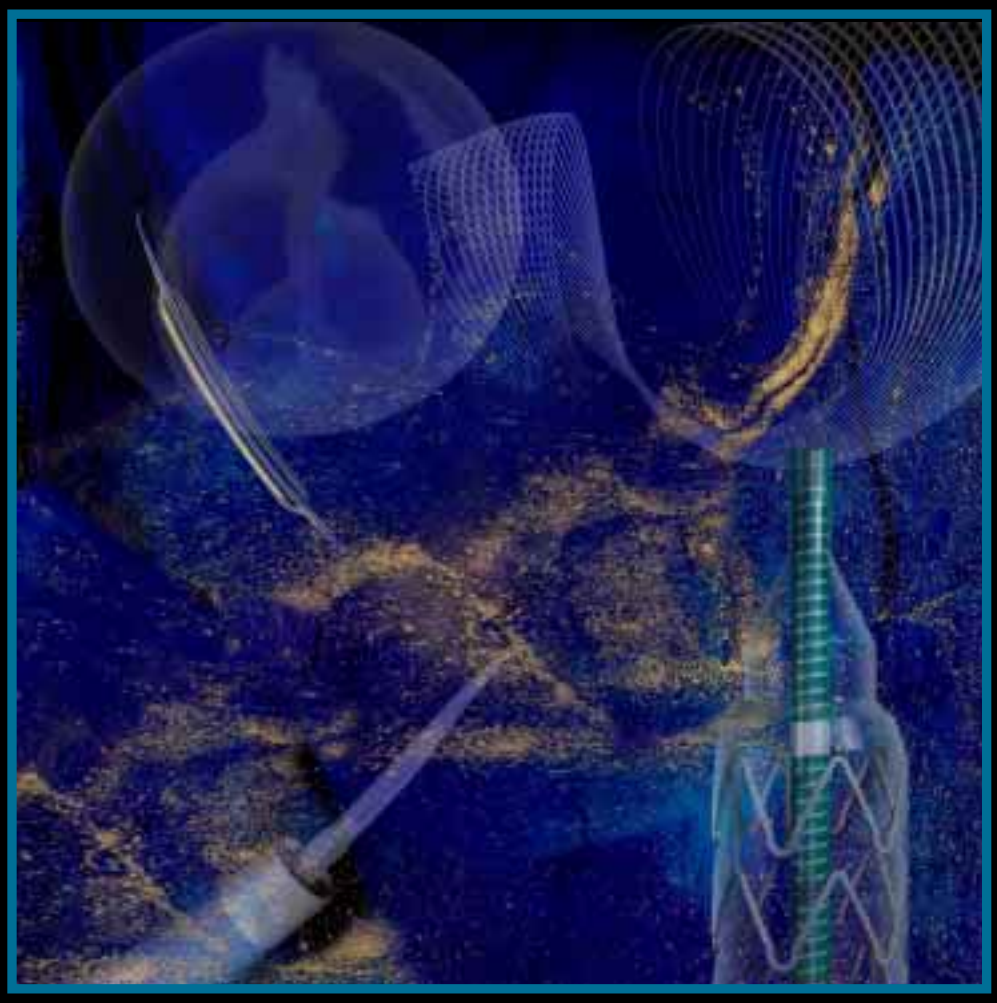

VASCULAR INTERVENTION

2001 PRODUCT CATALOG

GUIDANT

IT'S A GREAT TIME TO BE ALIVE℠

ORDERING INFORMATION

Return Policy

1. Guidant Corporation's Vascular Intervention division will accept return of any undamaged and unused standard catalog item within 90 days of invoice date. Defective product can be returned at any time, with an Authorized Return Goods Number (RGA).
2. Returned product is subject to examination for acceptable condition or alleged defects.
3. Acceptable returned product will be credited to customer account subject to a restocking fee.
4. A Returned Goods Authorization Number is required for all returns and replacements. This number can be obtained by calling your account representative, or Customer Service at 800 227-9902.
5. The RGA Number must be clearly marked on the outside of all boxes returned. A copy of the packing slip and/or Purchase Order Number should be included with the merchandise.

Shipping Policy

Guidant Corporation's Vascular Intervention division offers a variety of shipping options, including overnight delivery. All shipment charges are paid by Guidant. Please specify your shipping preference when placing your order with Guidant Customer Service Representatives.

WARNING: Manufactured with CFC-113, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

Guidant Corporation's Vascular Intervention division is diligently working to eliminate the use of CFC-113 in the manufacturing process.

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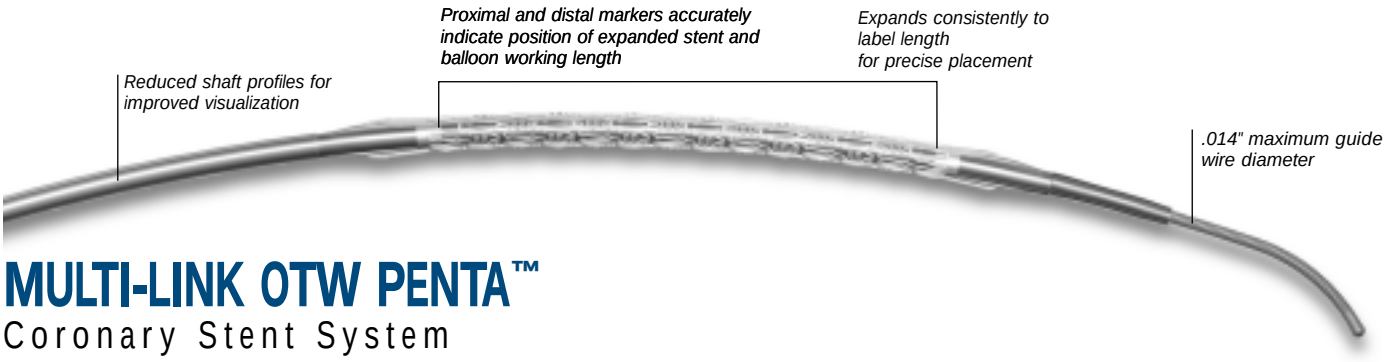

MULTI-LINK OTW PENTA™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1008056-08	00802526257315	2.75	8	.041	8	16
1008057-08	00802526257377	3.00	8	.041	8	16
1008058-08	00802526257452	3.50	8	.044	8	16
1008059-08	00802526257537	4.00	8	.046	8	16
1008056-13	00802526257322	2.75	13	.041	8	16
1008057-13	00802526257384	3.00	13	.041	8	16
1008058-13	00802526257469	3.50	13	.044	8	16
1008059-13	00802526257544	4.00	13	.046	8	16
1008056-15	00802526257339	2.75	15	.041	8	16
1008057-15	00802526257391	3.00	15	.041	8	16
1008058-15	00802526257476	3.50	15	.044	8	16
1008059-15	00802526257551	4.00	15	.046	8	16
1008056-18	00802526257346	2.75	18	.041	8	16
1008057-18	00802526257407	3.00	18	.041	8	16
1008058-18	00802526257483	3.50	18	.044	8	16
1008059-18	00802526257568	4.00	18	.046	8	16
1008056-23	00802526257353	2.75	23	.041	8	16
1008057-23	00802526257414	3.00	23	.041	8	16
1008058-23	00802526257490	3.50	23	.044	8	16
1008059-23	00802526257575	4.00	23	.046	8	16
1008056-28	00802526257360	2.75	28	.041	8	16
1008057-28	00802526257421	3.00	28	.041	8	16
1008058-28	00802526257506	3.50	28	.044	8	16
1008059-28	00802526257582	4.00	28	.046	8	16
1008057-33	00802526257438	3.00	33	.041	8	16
1008058-33	00802526257513	3.50	33	.044	8	16
1008059-33	00802526257599	4.00	33	.046	8	16
1008057-38	00802526257445	3.00	38	.041	8	16
1008058-38	00802526257520	3.50	38	.044	8	16
1008059-38	00802526257605	4.00	38	.046	8	16

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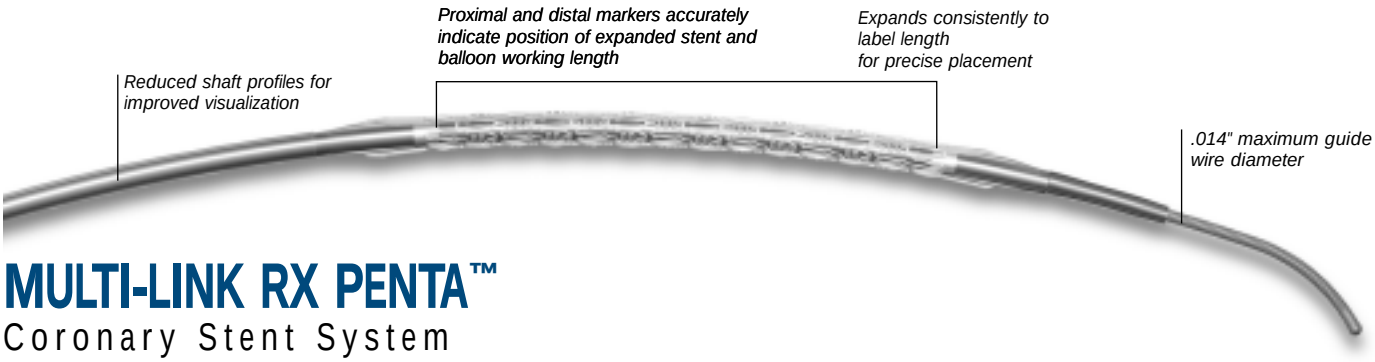

MULTI-LINK RX PENTA™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)
1008051-08	00802526256950	2.75	8	.041	8	16
1008052-08	00802526257018	3.00	8	.041	8	16
1008053-08	00802526257094	3.50	8	.044	8	16
1008054-08	00802526257179	4.00	8	.046	8	16
1008051-13	00802526256967	2.75	13	.041	8	16
1008052-13	00802526257025	3.00	13	.041	8	16
1008053-13	00802526257100	3.50	13	.044	8	16
1008054-13	00802526257186	4.00	13	.046	8	16
1008051-15	00802526256974	2.75	15	.041	8	16
1008052-15	00802526257032	3.00	15	.041	8	16
1008053-15	00802526257117	3.50	15	.044	8	16
1008054-15	00802526257193	4.00	15	.046	8	16
1008051-18	00802526256981	2.75	18	.041	8	16
1008052-18	00802526257049	3.00	18	.041	8	16
1008053-18	00802526257124	3.50	18	.044	8	16
1008054-18	00802526257209	4.00	18	.046	8	16
1008051-23	00802526256998	2.75	23	.041	8	16
1008052-23	00802526257056	3.00	23	.041	8	16
1008053-23	00802526257131	3.50	23	.044	8	16
1008054-23	00802526257216	4.00	23	.046	8	16
1008051-28	00802526257001	2.75	28	.041	8	16
1008052-28	00802526257063	3.00	28	.041	8	16
1008053-28	00802526257148	3.50	28	.044	8	16
1008054-28	00802526257223	4.00	28	.046	8	16
1008052-33	00802526257070	3.00	33	.041	8	16
1008053-33	00802526257155	3.50	33	.044	8	16
1008054-33	00802526257230	4.00	33	.046	8	16
1008052-38	00802526257087	3.00	38	.041	8	16
1008053-38	00802526257162	3.50	38	.044	8	16
1008054-38	00802526257247	4.00	38	.046	8	16
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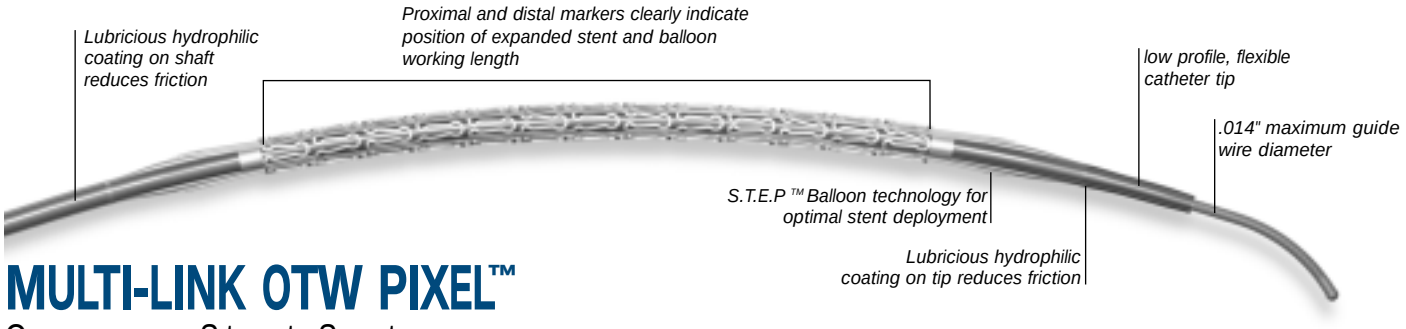

MULTI-LINK OTW PIXEL™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1007830-08	00802526257797	2.00	8	.036	7	16
1007831-08	00802526257834	2.25	8	.036	7	16
1007832-08	00802526257889	2.50	8	.037	7	16
1007830-13	00802526257803	2.00	13	.036	7	16
1007831-13	00802526257841	2.25	13	.036	7	16
1007832-13	00802526257896	2.50	13	.037	7	16
1007830-18	00802526257810	2.00	18	.036	7	16
1007831-18	00802526257858	2.25	18	.036	7	16
1007832-18	00802526257902	2.50	18	.037	7	16
1007830-23	00802526257827	2.00	23	.036	7	16
1007831-23	00802526257865	2.25	23	.036	7	16
1007832-23	00802526257919	2.50	23	.037	7	16
1007830-28	00802526261152	2.00	28	.036	7	16
1007831-28	00802526257872	2.25	28	.036	7	16
1007832-28	00802526257926	2.50	28	.037	7	16

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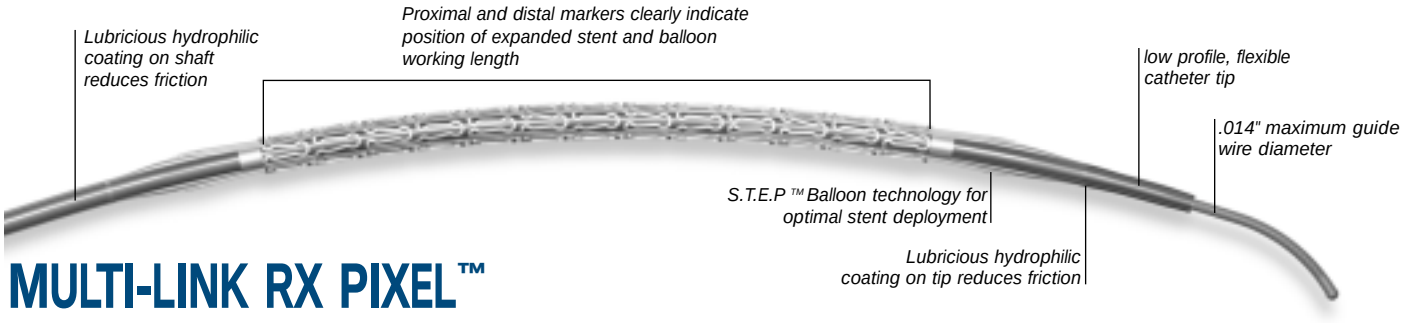
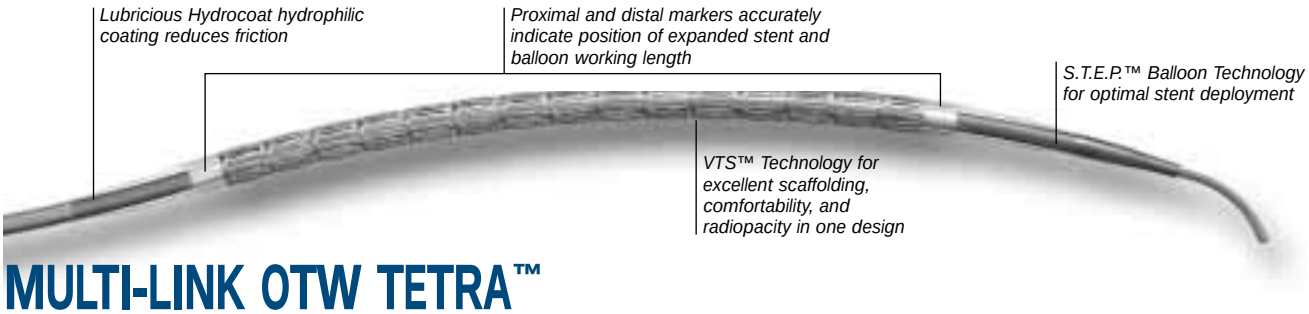


MULTI-LINK RX PIXEL™

Coronary Stent System (additional part numbers on next page)

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1005730-08	00802526257643	2.00	8	.036	7	16
1005731-08	00802526257698	2.25	8	.036	7	16
1005732-08	00802526257742	2.50	8	.037	7	16
1005730-13	00802526257650	2.00	13	.036	7	16
1005731-13	00802526257704	2.25	13	.036	7	16
1005732-13	00802526257759	2.50	13	.037	7	16
1005730-18	00802526257667	2.00	18	.036	7	16
1005731-18	00802526257711	2.25	18	.036	7	16
1005732-18	00802526257766	2.50	18	.037	7	16
1005730-23	00802526257674	2.00	23	.036	7	16
1005731-23	00802526257728	2.25	23	.036	7	16
1005732-23	00802526257773	2.50	23	.037	7	16
1005730-28	00802526257681	2.00	28	.036	7	16
1005731-28	00802526257735	2.25	28	.036	7	16
1005732-28	00802526257780	2.50	28	.037	7	16

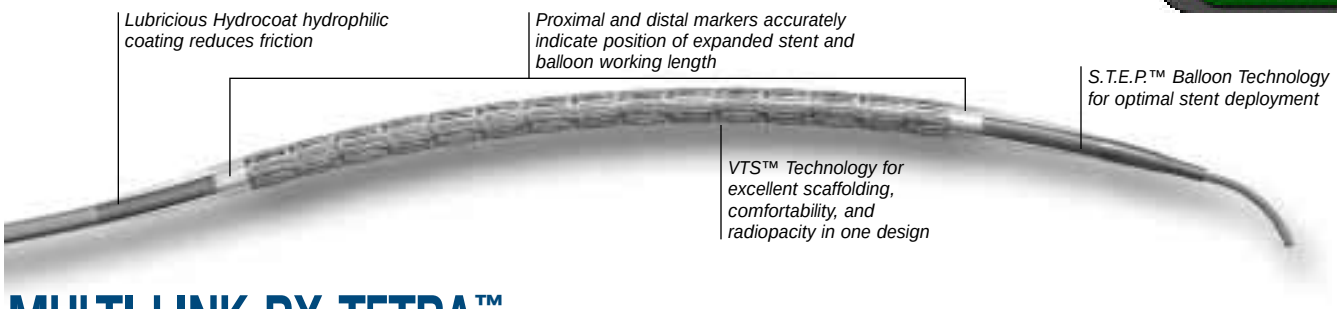


MULTI-LINK OTW TETRA™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1005880-08	00802526222948	2.50	8	.041	8	16
1005881-08	00802526222689	2.75	8	.042	8	16
1005882-08	00802526222733	3.00	8	.044	8	16
1005883-08	00802526222801	3.50	8	.045	8	16
1005884-08	00802526222870	4.00	8	.048	8	16
1005880-13	00802526222641	2.50	13	.041	8	16
1005881-13	00802526222696	2.75	13	.042	8	16
1005882-13	00802526222740	3.00	13	.044	8	16
1005883-13	00802526222818	3.50	13	.045	8	16
1005884-13	00802526222887	4.00	13	.048	8	16
1005880-18	00802526222658	2.50	18	.041	8	16
1005881-18	00802526222702	2.75	18	.042	8	16
1005882-18	00802526222757	3.00	18	.044	8	16
1005883-18	00802526222825	3.50	18	.045	8	16
1005884-18	00802526222894	4.00	18	.048	8	16
1005880-23	00802526222665	2.50	23	.041	8	16
1005881-23	00802526222719	2.75	23	.042	8	16
1005882-23	00802526222764	3.00	23	.044	8	16
1005883-23	00802526222832	3.50	23	.045	8	16
1005884-23	00802526222900	4.00	23	.048	8	16
1005880-28	00802526222672	2.50	28	.041	8	16
1005881-28	00802526222726	2.75	28	.042	8	16
1005882-28	00802526222771	3.00	28	.044	8	16
1005883-28	00802526222849	3.50	28	.045	8	16
1005884-28	00802526222917	4.00	28	.048	8	16
1005882-33	00802526222788	3.00	33	.044	8	16
1005883-33	00802526222856	3.50	33	.045	8	16
1005884-33	00802526222924	4.00	33	.048	8	16
1005882-38	00802526222795	3.00	38	.044	8	16
1005883-38	00802526222863	3.50	38	.045	8	16
1005884-38	00802526222931	4.00	38	.048	8	16

Minimal I.D. of Guiding Catheter = .056″ Maximum Guide Wire = .014″

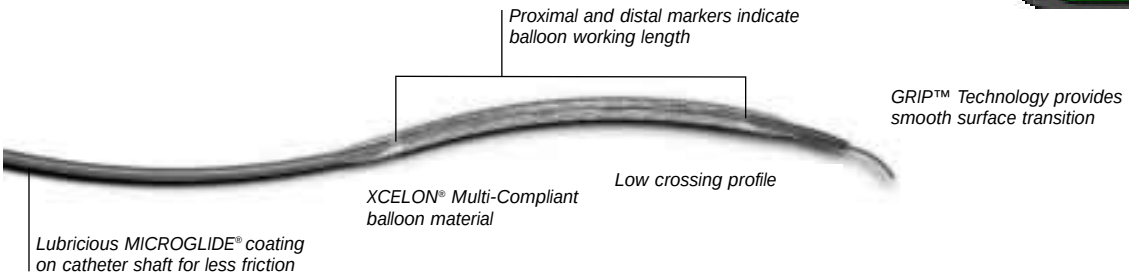


MULTI-LINK RX TETRA™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1005859-08	00802526220371	2.50	8	.041	8	16
1005860-08	00802526220425	2.75	8	.042	8	16
1005861-08	00802526220470	3.00	8	.044	8	16
1005862-08	00802526220548	3.50	8	.045	8	16
1005863-08	00802526220616	4.00	8	.048	8	16
1005859-13	00802526220388	2.50	13	.041	8	16
1005860-13	00802526220432	2.75	13	.042	8	16
1005861-13	00802526220487	3.00	13	.044	8	16
1005862-13	00802526220555	3.50	13	.045	8	16
1005863-13	00802526220623	4.00	13	.048	8	16
1005859-18	00802526220395	2.50	18	.041	8	16
1005860-18	00802526220449	2.75	18	.042	8	16
1005861-18	00802526220494	3.00	18	.044	8	16
1005862-18	00802526220562	3.50	18	.045	8	16
1005863-18	00802526220630	4.00	18	.048	8	16
1005859-23	00802526220401	2.50	23	.041	8	16
1005860-23	00802526220456	2.75	23	.042	8	16
1005861-23	00802526220500	3.00	23	.044	8	16
1005862-23	00802526220579	3.50	23	.045	8	16
1005863-23	00802526220647	4.00	23	.048	8	16
1005859-28	00802526220418	2.50	28	.041	8	16
1005860-28	00802526220463	2.75	28	.042	8	16
1005861-28	00802526220517	3.00	28	.044	8	16
1005862-28	00802526220586	3.50	28	.045	8	16
1005863-28	00802526220654	4.00	28	.048	8	16
1005861-33	00802526220524	3.00	33	.044	8	16
1005862-33	00802526220593	3.50	33	.045	8	16
1005863-33	00802526220661	4.00	33	.048	8	16
1005861-38	00802526220531	3.00	38	.044	8	16
1005862-38	00802526220609	3.50	38	.045	8	16
1005863-38	00802526220678	4.00	38	.048	8	16

Minimal I.D. of Guiding Catheter = .056″ Maximum Guide Wire = .014″

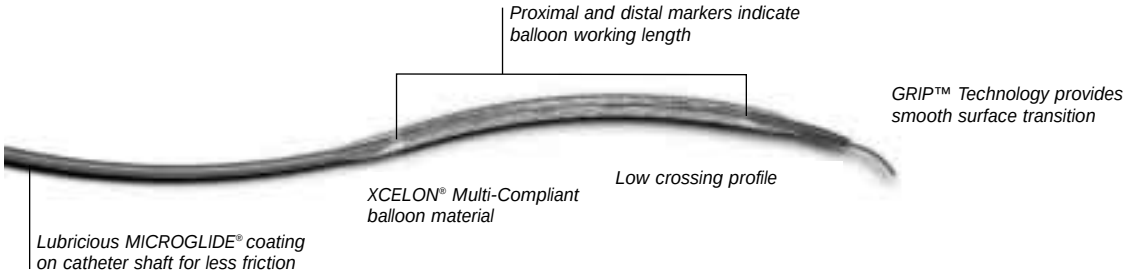


MULTI-LINK OTW ULTRA™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Minimal I.D. of Guiding Catheter (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1003389-13	00802526207358	3.50	13	.056	.066	9	14
1003390-13	00802526207365	4.00	13	.057	.066	9	14
1003391-13	00802526207372	4.50	13	.057	.066	9	14
1003392-13	00802526207389	5.00	13	.057	.075	9	14
1003389-18	00802526207396	3.50	18	.056	.066	9	14
1003390-18	00802526207402	4.00	18	.057	.066	9	14
1003391-18	00802526207419	4.50	18	.057	.066	9	14
1003392-18	00802526207426	5.00	18	.057	.075	9	14
1003389-28	00802526207433	3.50	28	.056	.066	9	14
1003390-28	00802526207440	4.00	28	.057	.066	9	14
1003391-28	00802526207457	4.50	28	.057	.066	9	14
1003392-28	00802526207464	5.00	28	.057	.075	9	14
1003389-38	00802526207471	3.50	38	.056	.066	9	14
1003390-38	00802526207488	4.00	38	.057	.066	9	14
1003391-38	00802526207495	4.50	38	.057	.066	9	14
1003392-38	00802526207501	5.00	38	.057	.075	9	14

Nominal Guide Wire = .014″

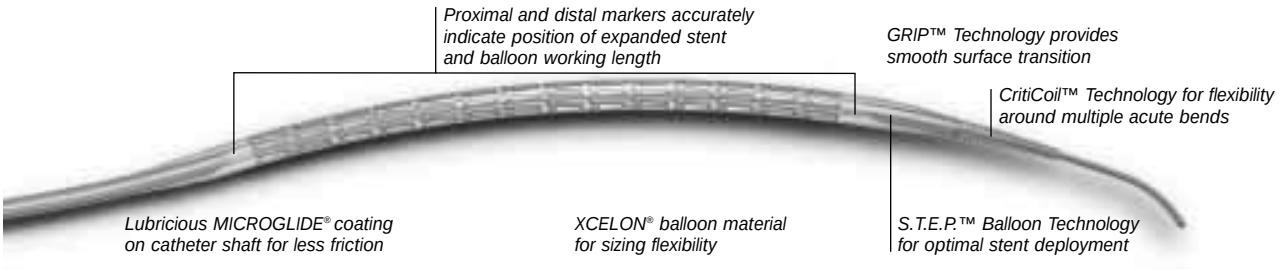


MULTI-LINK RX ULTRA™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Minimal I.D. of Guiding Catheter (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1003379-13	00802526207693	3.50	13	.056	.066	9	14
1003380-13	00802526207709	4.00	13	.057	.066	9	14
1003381-13	00802526207716	4.50	13	.057	.066	9	14
1003382-13	00802526207723	5.00	13	.057	.075	9	14
1003379-18	00802526207730	3.50	18	.056	.066	9	14
1003380-18	00802526207747	4.00	18	.057	.066	9	14
1003381-18	00802526207754	4.50	18	.057	.066	9	14
1003382-18	00802526207761	5.00	18	.057	.075	9	14
1003379-28	00802526207778	3.50	28	.056	.066	9	14
1003380-28	00802526207785	4.00	28	.057	.066	9	14
1003381-28	00802526207792	4.50	28	.057	.066	9	14
1003382-28	00802526207815	5.00	28	.057	.075	9	14
1003379-38	00802526207822	3.50	38	.056	.066	9	14
1003380-38	00802526207846	4.00	38	.057	.066	9	14
1003381-38	00802526207853	4.50	38	.057	.066	9	14
1003382-38	00802526207860	5.00	38	.057	.075	9	14

Maximum Guide Wire = .014″

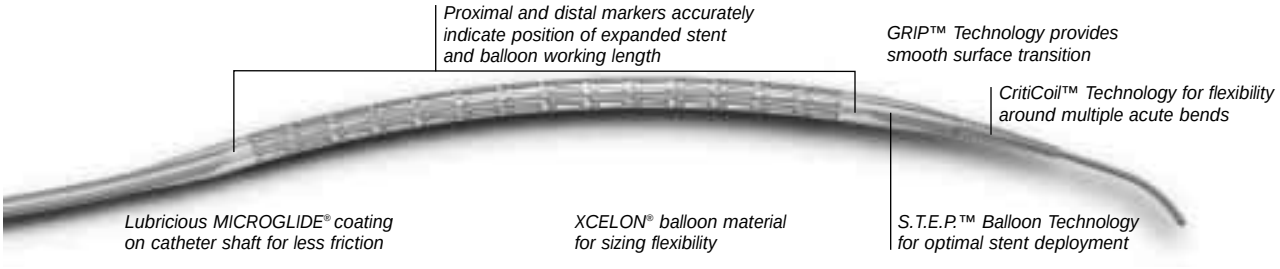


MULTI-LINK OTW TRISTAR™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1003468-08	00802526205774	2.50	8	.043	8	16
1003469-08	00802526205781	2.75	8	.044	8	16
1003470-08	00802526205798	3.00	8	.045	8	16
1003471-08	00802526205804	3.50	8	.048	8	16
1003472-08	00802526205811	4.00	8	.049	8	16
1003468-13	00802526205828	2.50	13	.043	8	16
1003469-13	00802526205835	2.75	13	.044	8	16
1003470-13	00802526205842	3.00	13	.045	8	16
1003471-13	00802526205859	3.50	13	.048	8	16
1003472-13	00802526205866	4.00	13	.049	8	16
1003468-18	00802526205873	2.50	18	.043	8	16
1003469-18	00802526205880	2.75	18	.044	8	16
1003470-18	00802526205897	3.00	18	.045	8	16
1003471-18	00802526205903	3.50	18	.048	8	16
1003472-18	00802526205910	4.00	18	.049	8	16
1003468-23	00802526205927	2.50	23	.043	8	16
1003469-23	00802526205934	2.75	23	.044	8	16
1003470-23	00802526205941	3.00	23	.045	8	16
1003471-23	00802526205958	3.50	23	.048	8	16
1003472-23	00802526205965	4.00	23	.049	8	16
1003468-28	00802526205972	2.50	28	.043	8	16
1003469-28	00802526205989	2.75	28	.044	8	16
1003470-28	00802526205996	3.00	28	.045	8	16
1003471-28	00802526206009	3.50	28	.048	8	16
1003472-28	00802526206016	4.00	28	.049	8	16
1003470-33	00802526206030	3.00	33	.045	8	16
1003471-33	00802526206047	3.50	33	.048	8	16
1003472-33	00802526206054	4.00	33	.049	8	16
1003470-38	00802526206085	3.00	38	.045	8	16
1003471-38	00802526206092	3.50	38	.048	8	16
1003472-38	00802526206108	4.00	38	.049	8	16

Minimal I.D. of Guiding Catheter = .064″ Maximum Guide Wire = .014″



MULTI-LINK RX TRISTAR™

Coronary Stent System

Stock Number	UPN Number	Stent Sizes Available (mm)	Stent Length (mm)	Crossing Profile (in)	Stent Nominal Pressure (atm)	Rated Burst Pressure (atm)
1003474-08	00802526206566	2.50	8	.043	8	16
1003475-08	00802526206573	2.75	8	.044	8	16
1003476-08	00802526206580	3.00	8	.045	8	16
1003477-08	00802526206597	3.50	8	.048	8	16
1003478-08	00802526206603	4.00	8	.049	8	16
1003474-13	00802526206610	2.50	13	.043	8	16
1003475-13	00802526206627	2.75	13	.044	8	16
1003476-13	00802526206634	3.00	13	.045	8	16
1003477-13	00802526206641	3.50	13	.048	8	16
1003478-13	00802526206658	4.00	13	.049	8	16
1003474-18	00802526206665	2.50	18	.043	8	16
1003475-18	00802526206672	2.75	18	.044	8	16
1003476-18	00802526206689	3.00	18	.045	8	16
1003477-18	00802526206696	3.50	18	.048	8	16
1003478-18	00802526206702	4.00	18	.049	8	16
1003474-23	00802526206719	2.50	23	.043	8	16
1003475-23	00802526206726	2.75	23	.044	8	16
1003476-23	00802526206733	3.00	23	.045	8	16
1003477-23	00802526206740	3.50	23	.048	8	16
1003478-23	00802526206757	4.00	23	.049	8	16
1003474-28	00802526206764	2.50	28	.043	8	16
1003475-28	00802526206771	2.75	28	.044	8	16
1003476-28	00802526206788	3.00	28	.045	8	16
1003477-28	00802526206795	3.50	28	.048	8	16
1003478-28	00802526206801	4.00	28	.049	8	16
1003476-33	00802526206818	3.00	33	.045	8	16
1003477-33	00802526206825	3.50	33	.048	8	16
1003478-33	00802526206832	4.00	33	.049	8	16
1003476-38	00802526206849	3.00	38	.045	8	16
1003477-38	00802526206856	3.50	38	.048	8	16
1003478-38	00802526206863	4.00	38	.049	8	16

Minimal I.D. of Guiding Catheter = .064″ Maximum Guide Wire = .014″

MULTI-LINK OTW PENTA™

Coronary Stent System

MULTI-LINK RX PENTA™

Coronary Stent System

℞ ONLY

INDICATIONS:

The MULTI-LINK OTW PENTA™ and MULTI-LINK RX PENTA™ Coronary Stent Systems are indicated for improving coronary luminal diameter in the following (See Individualization of Treatment):

- Patients with symptomatic ischemic heart disease due to discrete de novo or restenotic native coronary artery lesions (length < 25 mm) with reference vessel diameters ranging from 3.0 mm to 4.0 mm.
- Treatment of abrupt or threatened abrupt closure in patients with failed interventional therapy in lesions (< 35 mm in length) with reference vessel diameters ranging from 2.5 mm to 4.0 mm.

Long-term outcome for this permanent implant is unknown at present.

Note: The 2.5 mm and 2.75 mm diameters, and the 33 mm and 38 mm length stents, are solely indicated for use in patients with abrupt or threatened abrupt closure.

CONTRAINDICATIONS:

The MULTI-LINK RX PENTA™ and MULTI-LINK OTW PENTA™ Coronary Stent Systems are contraindicated for use in:

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

WARNINGS AND PRECAUTIONS:

WARNINGS:

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events.
- Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.

Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its Delivery System as removal may damage the stent and/or lead to stent embolization. Stent system is intended to perform as a system.
- Delivery System should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- Do not prepare or pre-inflate Delivery System prior to stent deployment other than as directed. Use balloon purging technique described in the section 9.3.2 Delivery System Preparation.
- The labeled stent diameter refers to expanded stent inner diameter. Previous coronary stent systems referred to outside diameter in the expanded state.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (See Stent/System Removal – Precautions.)
- Placement of a stent has the potential to compromise side branch patency.
- Do not exceed Rated Burst Pressure as indicated on product label. Balloon pressures should be monitored during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should any resistance be felt at any time during withdrawal of the Coronary Stent System, the entire system should be removed as a single unit.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Stent / System Removal - Precautions

Should any resistance be felt at any time during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the Delivery System to the guiding catheter; then remove the guiding catheter and Delivery System as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

- Care must be exercised when crossing a newly deployed stent with a coronary guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- Do not perform a magnetic resonance imaging (MRI) scan on patients post-stent implantation until the stent has completely endothelialized (eight weeks) to minimize the potential for migration. The stent may scans due to distortion of the magnetic field.

Potential Adverse Events:

Adverse events may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death • Dissection
- Drug reactions to anti-platelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery • Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

MULTI-LINK OTW PIXEL™

Coronary Stent System

MULTI-LINK RX PIXEL™

Coronary Stent System

℞ ONLY

INDICATIONS

The MULTI-LINK RX PIXEL™ and MULTI-LINK OTW PIXEL™ Coronary Stent Systems are indicated for improving coronary luminal diameter in the following (see Individualization of Treatment):

- Patients with abrupt or threatened abrupt closure with failed interventional therapy of de novo and restenotic native coronary artery lesions (length ≤ 25 mm) with reference vessel diameters from 2.0 to 2.5 mm.

Long-term outcome for this permanent implant is unknown at present.

CONTRAINDICATIONS

The MULTI-LINK RX PIXEL™ and MULTI-LINK OTW PIXEL™ Coronary Stent Systems are contraindicated for use in:

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

WARNINGS AND PRECAUTIONS

WARNINGS

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events.
- Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.

Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its Delivery System as removal may damage the stent and/or lead to stent embolization. Stent system is intended to perform as a system.
- Delivery System should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- Do not prepare or pre-inflate Delivery System prior to stent deployment other than as directed. Use balloon purging technique described in the section 9.3.2 Delivery System Preparation.
- The labeled stent diameter refers to expanded stent inner diameter. Previous coronary stent systems referred to outside diameter in the expanded state.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (See Stent System Removal – Precautions.)
- Placement of a stent has the potential to compromise side branch patency.
- Do not exceed Rated Burst Pressure as indicated on product label. Balloon pressures should be monitored during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should any resistance be felt at any time during withdrawal of the Coronary Stent System, the entire system should be removed as a single unit.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Stent System Removal - Precautions

Should any resistance be felt at any time during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the Delivery System to the guiding catheter; then remove the guiding catheter and Delivery System as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components. If it is necessary to retain guide wire position for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

- Care must be exercised when crossing a newly deployed stent with a coronary guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- Do not perform a magnetic resonance imaging (MRI) scan on patients post-stent implantation until the stent has completely endothelialized (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

Potential Adverse Events

Adverse events may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to anti-platelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

MULTI-LINK OTW TETRA™

Coronary Stent System

MULTI-LINK RX TETRA™

Coronary Stent System

℞ ONLY

INDICATIONS

The MULTI-LINK RX TETRA™ and MULTI-LINK OTW TETRA™ Coronary Stent System is indicated for improving coronary luminal diameter in the following (See Individualization of Treatment):

- Patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic native coronary artery lesions (length ≤ 25 mm) with reference vessel diameters ranging from 3.0 mm to 4.0 mm;
- Treatment of abrupt or threatened closure in patients with failed interventional therapy in lesions (≤ 35 mm in length) with reference vessel diameters ranging from 2.5 mm to 4.0 mm.

Long term outcome for this permanent implant is unknown at present.

Note: The 2.5 mm and 2.75 mm diameters, and the 33 mm and 38 mm length stents are solely indicated for use in patients with abrupt or threatened abrupt closure.

CONTRAINDICATIONS

The MULTI-LINK RX TETRA™ Coronary Stent System is contraindicated for use in:

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

WARNINGS AND PRECAUTIONS

(see also Individualization of Treatment)

WARNINGS

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events.
- Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.

Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product “Use By” date.
- Do not remove stent from its Delivery System as removal may damage the stent and/or lead to stent embolization. Stent system is intended to perform as a system.
- Delivery System should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from packaging, placement over guide wire and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Do not “roll” the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- Do not prepare or pre-inflate Delivery System prior to stent deployment other than as directed. Use balloon purging technique described in the section 9.3.2 Delivery System Preparation.
- THE WORKING LENGTH OF THE CATHETER HAS CHANGED FROM 137 CM TO 143 CM. THE PROXIMAL PORTION, FROM THE BRACHIAL AND FEMORAL MARKERS TO THE INFLATION PORT, IS LONGER THAN PREVIOUS CATHETERS.
- THE LABELED STENT DIAMETER REFERS TO EXPANDED STENT INNER DIAMETER. PREVIOUS CORONARY STENT SYSTEMS REFERRED TO OUTSIDE DIAMETER IN THE EXPANDED STATE.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (See Stent/System Removal - Precautions)
- Placement of a stent has the potential to compromise side branch patency.
- Do not exceed Rated Burst Pressure as indicated on product label. Balloon pressures should be monitored during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should any resistance be felt at any time during withdrawal of the Coronary Stent System, the entire system should be removed as a single unit.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Stent / System Removal - Precautions

Should any resistance be felt at any time during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the Delivery System to the guiding catheter; then remove the guiding catheter and Delivery System as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

- Care must be exercised when crossing a newly deployed stent with a coronary guide wire or balloon catheter to avoid disrupting the stent geometry.
- Do not perform a magnetic resonance imaging (MRI) scan on patients post-stent implantation until the stent has completely endothelialized (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

Potential Adverse Events

Adverse events (in alphabetical order) may be associated with the use of a coronary stent in native coronary arteries :

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to anti-platelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

MULTI-LINK RX ULTRA™

Coronary Stent System

MULTI-LINK OTW ULTRA™

Coronary Stent System

℞ ONLY

INDICATIONS:

The MULTI-LINK RX ULTRA™ and MULTI-LINK OTW ULTRA™ Coronary Stent Systems are indicated for improving coronary luminal diameter in the following (See Individualization of Treatment);

- Patients with symptomatic ischemic heart disease due to discrete de novo or restenotic native coronary artery lesions (length < 25 mm) with reference vessel diameters ranging from 3.5 mm to 5.0 mm.
- Treatment of abrupt or threatened abrupt closure in patients with failed interventional therapy in lesions (length < 35 mm) with reference vessel diameters ranging from 3.5 mm to 5.0 mm.

Long-term outcome for this permanent implant is unknown at present.

Note: The 38 mm length stents are solely indicated for use in patients with abrupt or threatened abrupt closure.

CONTRAINDICATIONS:

The MULTI-LINK RX ULTRA™ and MULTI-LINK OTW ULTRA™ Coronary Stent Systems are contraindicated for use in:

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

WARNINGS AND PRECAUTIONS:

WARNINGS:

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events.
- Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.

Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its Delivery System as removal may damage the stent and/or lead to stent embolization. Stent system is intended to perform as a system.
- Delivery System should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through the rotating hemostatic valve adapter and guiding catheter hub.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- Do not prepare or pre-inflate Delivery System prior to stent deployment other than as directed. Use balloon purging technique described in section 9.3.2 Delivery System Preparation.
- The working length of the catheter has been changed from 137 cm to 143 cm. The proximal portion, from the brachial and femoral markers to the inflation port, is longer than previous catheters.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chance of dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (See Stent/System Removal – Precautions.)
- Placement of a stent has the potential to compromise side branch patency.
- Do not exceed Rated Burst Pressure as indicated on product label. Balloon pressures should be monitored during inflation. Use of pressures higher than specified on the product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should any resistance be felt at any time during withdrawal of the Coronary Stent System, the entire system should be removed as a single unit.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Stent / System Removal - Precautions

Should any resistance be felt at any time during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the Delivery System to the guiding catheter; then remove the guiding catheter and Delivery System as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components. If it is necessary to retain guide wire position for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

- Care should be exercised when crossing a newly deployed stent with a coronary guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- Do not perform a magnetic resonance imaging (MRI) scan on patients post-stent implantation until the stent has completely endothelialized (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

Potential Adverse Events

Adverse events may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to anti-platelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery.

MULTI-LINK OTW TRISTAR™

Coronary Stent System

MULTI-LINK RX TRISTAR™

Coronary Stent System

℞ ONLY

INDICATIONS

The ACS MULTI-LINK OTW TRISTAR™ and ACS MULTI-LINK RX TRISTAR™ Coronary Stent System is indicated for improving coronary luminal diameter in the following (See Individualization of Treatment):

- Patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic native coronary artery lesions (length ≤ 25 mm) with reference diameters ranging from 3.0 mm to 4.0 mm;
- Treatment of abrupt or threatened abrupt closure in patients with failed interventional therapy in lesions (≤ 35 mm in length) with reference diameters ranging from 2.5 mm to 4.0 mm.

Long term outcome (beyond 6 months) for this permanent implant is unknown at present.

Note: The 2.5 mm and 2.75 mm diameters, and the 33 mm and 38 mm length stents are solely indicated for use in patients with abrupt or threatened abrupt closure.

CONTRAINDICATIONS

The ACS MULTI-LINK RX TRISTAR™ Coronary Stent System is contraindicated for use in:

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

WARNINGS AND PRECAUTIONS

(see also Individualization of Treatment)

WARNINGS

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events.
- Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.

Stent Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note product "Use By" date.
- **Do not remove stent from its Delivery System** as removal may damage the stent and/or lead to stent embolization. Stent system is intended to perform as a system.
- Delivery System should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- **Do not prepare or pre-inflate Delivery System prior to stent deployment** other than as directed. Use balloon purging technique described in the section 9.3.2 Delivery System Preparation.
- **THE WORKING LENGTH OF THE CATHETER HAS CHANGED FROM 137CM TO 143CM. THE PROXIMAL PORTION, FROM THE BRACHIAL AND FEMORAL MARKERS TO THE INFLATION PORT, IS LONGER THAN PREVIOUS CATHETERS.**
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (See Stent/System Removal - Precautions)
- Placement of a stent has the potential to compromise side branch patency.
- **Do not exceed Rated Burst Pressure as indicated on product label.** Balloon pressures should be monitored during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should **any resistance** be felt **at any time** during withdrawal of the Coronary Stent System, the entire system should be **removed as a single unit.**
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Stent / System Removal - Precautions

Should **any resistance** be felt **at any time** during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be **removed as a single unit.**

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the Delivery System to the guiding catheter; then remove the guiding catheter and Delivery System as a **single unit.**

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent artery/lesion access, leave the guide wire in place and remove all other system components.

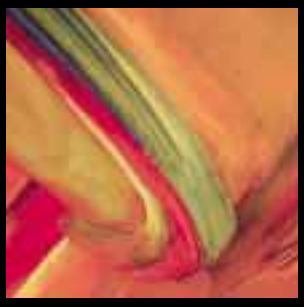
Post Implant - Precautions

- Care must be exercised when **crossing a newly deployed stent** with a coronary guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- Do not perform a **magnetic resonance imaging** (MRI) scan on patients post-stent implantation until the stent has completely endothelialized (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

Potential Adverse Events

Adverse events (in alphabetical order) may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to anti-platelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery



ANGIOPLASTY SYSTEMS

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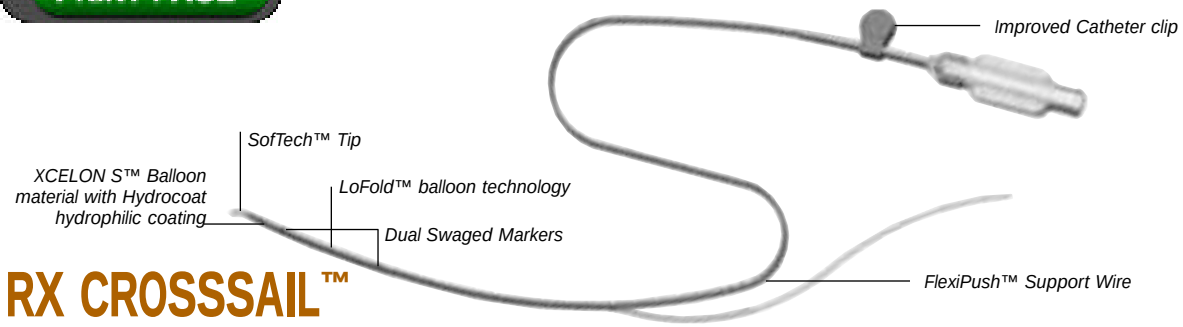

RX CROSSSAIL™

Coronary Dilatation Catheter

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Proximal-Distal Shaft Diameters (F)
10 mm						
1005294-10	00802526193811	1.50	.024	8	14	2.6-2.6/2.4
1005296-10	00802526193828	2.00	.024	8	14	2.6-2.6/2.4
1005298-10	00802526193835	2.50	.024	8	14	2.6-2.6/2.4
1005299-10	00802526193842	2.75	.024	8	14	2.6-2.6/2.4
1005300-10	00802526193859	3.00	.024	8	14	2.6-2.6/2.4
1005302-10	00802526193866	3.50	.026	8	14	2.6-2.6/2.6
1005304-10	00802526193873	4.00	.026	8	14	2.6-2.6/2.8
15 mm						
1005296-15	00802526193880	2.00	.024	8	14	2.6-2.6/2.4
1005297-15	00802526193897	2.25	.024	8	14	2.6-2.6/2.4
1005298-15	00802526193903	2.50	.024	8	14	2.6-2.6/2.4
1005299-15	00802526193910	2.75	.024	8	14	2.6-2.6/2.4
1005300-15	00802526193927	3.00	.024	8	14	2.6-2.6/2.4
1005301-15	00802526193934	3.25	.026	8	14	2.6-2.6/2.6
1005302-15	00802526193941	3.50	.026	8	14	2.6-2.6/2.6
1005303-15	00802526193958	3.75	.026	8	14	2.6-2.6/2.8
1005304-15	00802526193965	4.00	.026	8	14	2.6-2.6/2.8
20 mm						
1005294-20	00802526193972	1.50	.024	8	14	2.6-2.6/2.4
1005296-20	00802526193989	2.00	.024	8	14	2.6-2.6/2.4
1005297-20	00802526193996	2.25	.024	8	14	2.6-2.6/2.4
1005298-20	00802526194009	2.50	.024	8	14	2.6-2.6/2.4
1005299-20	00802526194016	2.75	.024	8	14	2.6-2.6/2.4
1005300-20	00802526194023	3.00	.024	8	14	2.6-2.6/2.4
1005301-20	00802526194030	3.25	.026	8	14	2.6-2.6/2.6
1005302-20	00802526194047	3.50	.026	8	14	2.6-2.6/2.6
1005303-20	00802526194054	3.75	.026	8	14	2.6-2.6/2.8
1005304-20	00802526194061	4.00	.026	8	14	2.6-2.6/2.8
1005305-20	00802526194078	4.50	.026	8	14	2.6/2.8
1005306-20	00802526194085	5.00	.026	8	14	2.6/2.8
30 mm						
1005296-30	00802526194092	2.00	.024	8	14	2.6-2.6/2.4
1005298-30	00802526194108	2.50	.024	8	14	2.6-2.6/2.4
1005299-30	00802526194115	2.75	.024	8	14	2.6-2.6/2.4
1005300-30	00802526194122	3.00	.024	8	14	2.6-2.6/2.6
1005302-30	00802526194139	3.50	.026	8	14	2.6-2.6/2.8
1005304-30	00802526194146	4.00	.026	8	14	2.6-2.6/2.8
40 mm						
1005298-40	00802526194153	2.50	.024	8	14	2.6-2.6/2.4
1005300-40	00802526194160	3.00	.024	8	14	2.6-2.6/2.6
1005302-40	00802526194177	3.50	.026	8	14	2.6-2.6/2.8
1005304-40	00802526194184	4.00	.026	8	14	2.6-2.6/2.8

Usable Catheter Working Length = 143 cm

Maximum Guide Wire = .014″

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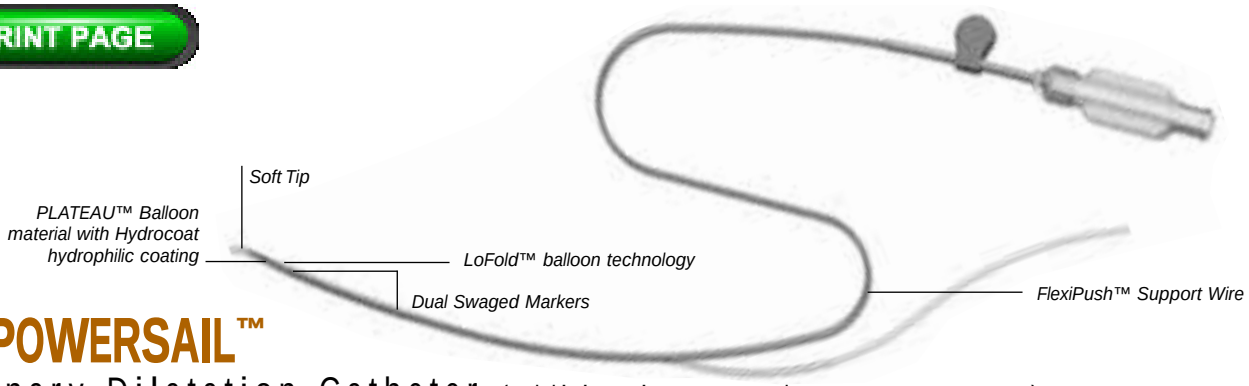

RX POWERSAIL™

Coronary Dilatation Catheter (additional part numbers on next page)

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Proximal-Distal Shaft Diameters (F)
8 mm						
1005519-08	00802526251399	2.00	.026	10	18	2.6/2.6
1005520-08	00802526251436	2.25	.026	10	18	2.6/2.6
1005521-08	00802526253744	2.50	.026	10	18	2.6/2.6
1005522-08	00802526253799	2.75	.026	10	18	2.6/2.6
1005523-08	00802526253843	3.00	.026	10	18	2.6/2.6
1005524-08	00802526253898	3.25	.026	10	18	2.6/2.6
1005525-08	00802526253942	3.50	.026	10	18	2.6/2.6
1005526-08	00802526254000	3.75	.026	10	18	2.6/2.6
1005527-08	00802526254055	4.00	.026	10	18	2.6/2.6
13 mm						
1005519-13	00802526251405	2.00	.026	10	18	2.6/2.6
1005520-13	00802526251443	2.25	.026	10	18	2.6/2.6
1005521-13	00802526253751	2.50	.026	10	18	2.6/2.6
1005522-13	00802526253805	2.75	.026	10	18	2.6/2.6
1005523-13	00802526253850	3.00	.026	10	18	2.6/2.6
1005524-13	00802526253904	3.25	.026	10	18	2.6/2.6
1005525-13	00802526253959	3.50	.026	10	18	2.6/2.6
1005526-13	00802526254017	3.75	.026	10	18	2.6/2.6
1005527-13	00802526254062	4.00	.026	10	18	2.6/2.6
1005528-13	00802526254116	4.50	.026	10	18	2.6/2.6
1005529-13	00802526254147	5.00	.026	10	18	2.6/2.6
15 mm						
1005521-15	00802526253768	2.50	.026	10	18	2.6/2.6
1005522-15	00802526253812	2.75	.026	10	18	2.6/2.6
1005523-15	00802526253867	3.00	.026	10	18	2.6/2.6
1005524-15	00802526253911	3.25	.026	10	18	2.6/2.6
1005525-15	00802526253966	3.50	.026	10	18	2.6/2.6
1005526-15	00802526254024	3.75	.026	10	18	2.6/2.6
1005527-15	00802526254079	4.00	.026	10	18	2.6/2.6
18 mm						
1005517-18	00802526224065	1.50	.026	10	18	2.6/2.6
1005519-18	00802526224072	2.00	.026	10	18	2.6/2.6
1005520-18	00802526224089	2.25	.026	10	18	2.6/2.6
1005521-18	00802526224096	2.50	.026	10	18	2.6/2.6
1005522-18	00802526224102	2.75	.026	10	18	2.6/2.6
1005523-18	00802526224119	3.00	.026	10	18	2.6/2.6
1005524-18	00802526224133	3.25	.026	10	18	2.6/2.6
1005525-18	00802526224140	3.50	.026	10	18	2.6/2.6
1005526-18	00802526224157	3.75	.026	10	18	2.6/2.6
1005527-18	00802526224164	4.00	.026	10	18	2.6/2.6
1005528-18	00802526224171	4.50	.026	10	18	2.6/2.6
1005529-18	00802526224188	5.00	.026	10	18	2.6/2.6

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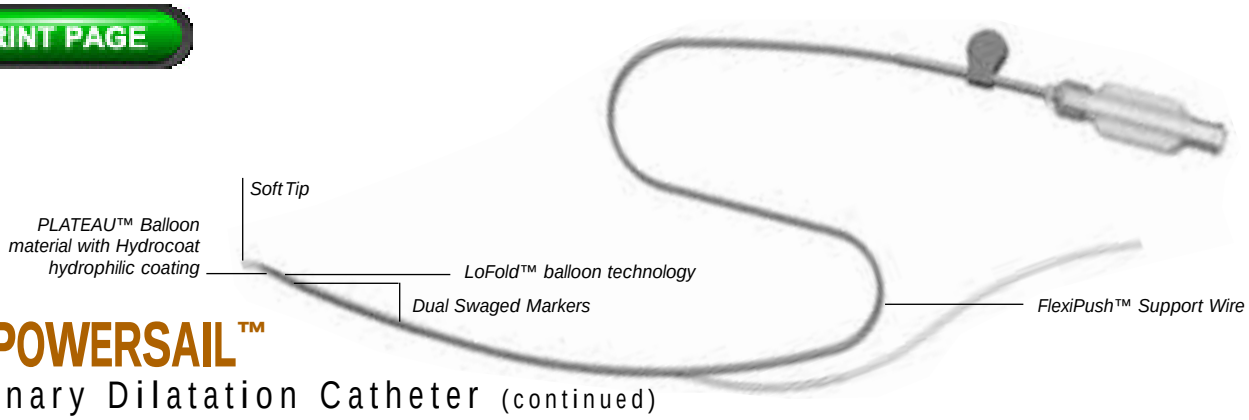

RX POWERSAIL™

Coronary Dilatation Catheter (continued)

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Proximal-Distal Shaft Diameters (F)
23 mm						
1005519-23	00802526251412	2.00	.026	10	18	2.6/2.6
1005520-23	00802526251450	2.25	.026	10	18	2.6/2.6
1005521-23	00802526253775	2.50	.026	10	18	2.6/2.6
1005522-23	00802526253829	2.75	.026	10	18	2.6/2.6
1005523-23	00802526253874	3.00	.026	10	18	2.6/2.6
1005524-23	00802526253928	3.25	.026	10	18	2.6/2.6
1005525-23	00802526253973	3.50	.026	10	18	2.6/2.6
1005526-23	00802526254031	3.75	.026	10	18	2.6/2.6
1005527-23	00802526254086	4.00	.026	10	18	2.6/2.6
1005528-23	00802526254123	4.50	.026	10	18	2.6/2.6
1005529-23	00802526254154	5.00	.026	10	18	2.6/2.6
28 mm						
1005519-28	00802526251429	2.00	.026	10	18	2.6/2.6
1005520-28	00802526253737	2.25	.026	10	18	2.6/2.6
1005521-28	00802526253782	2.50	.026	10	18	2.6/2.6
1005522-28	00802526253836	2.75	.026	10	18	2.6/2.6
1005523-28	00802526224126	3.00	.026	10	18	2.6/2.6
1005524-28	00802526253935	3.25	.026	10	18	2.6/2.6
1005525-28	00802526253980	3.50	.026	10	18	2.6/2.6
1005526-28	00802526254048	3.75	.026	10	18	2.6/2.6
1005527-28	00802526254093	4.00	.026	10	18	2.6/2.6
1005528-28	00802526254130	4.50	.026	10	18	2.6/2.6
1005529-28	00802526254161	5.00	.026	10	18	2.6/2.6
33 mm						
1005523-33	00802526253881	3.00	.026	10	18	2.6/2.6
1005525-33	00802526253997	3.50	.026	10	18	2.6/2.6
1005527-33	00802526254109	4.00	.026	10	18	2.6/2.6

Not in FMR

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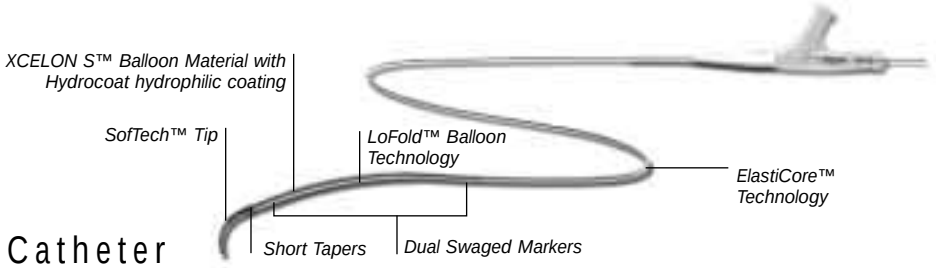

OTW OPENSAIL™

Coronary Dilatation Catheter

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Proximal-Distal Shaft Diameters (F)
10 mm						
1005307-10	00802526219443	1.50	.024	8	14	3.2-3.3/2.4
1005309-10	00802526219511	2.00	.024	8	14	3.2-3.3/2.4
1005311-10	00802526219580	2.50	.024	8	14	3.2-3.3/2.4
1005312-10	00802526219634	2.75	.024	8	14	3.2-3.3/2.4
1005313-10	00802526219672	3.00	.024	8	14	3.2-3.3/2.4
1005315-10	00802526219757	3.50	.026	8	14	3.2-3.3/2.6
1005317-10	00802526219832	4.00	.026	8	14	3.2-3.3/2.8
15 mm						
1005309-15	00802526219528	2.00	.024	8	14	3.2-3.3/2.4
1005310-15	00802526219566	2.25	.024	8	14	3.2-3.3/2.4
1005311-15	00802526219597	2.50	.024	8	14	3.2-3.3/2.4
1005312-15	00802526219641	2.75	.024	8	14	3.2-3.3/2.4
1005313-15	00802526219689	3.00	.024	8	14	3.2-3.3/2.4
1005314-15	00802526219733	3.25	.026	8	14	3.2-3.3/2.6
1005315-15	00802526219764	3.50	.026	8	14	3.2-3.3/2.6
1005316-15	00802526219818	3.75	.026	8	14	3.2-3.3/2.8
1005317-15	00802526219849	4.00	.026	8	14	3.2-3.3/2.8
20 mm						
1005307-20	00802526219467	1.50	.024	8	14	3.2-3.3/2.4
1005309-20	00802526219535	2.00	.024	8	14	3.2-3.3/2.4
1005310-20	00802526219573	2.25	.024	8	14	3.2-3.3/2.4
1005311-20	00802526219603	2.50	.024	8	14	3.2-3.3/2.4
1005312-20	00802526219658	2.75	.024	8	14	3.2-3.3/2.4
1005313-20	00802526219696	3.00	.024	8	14	3.2-3.3/2.4
1005314-20	00802526219740	3.25	.026	8	14	3.2-3.3/2.6
1005315-20	00802526219771	3.50	.026	8	14	3.2-3.3/2.6
1005316-20	00802526219825	3.75	.026	8	14	3.2-3.3/2.8
1005317-20	00802526219856	4.00	.026	8	14	3.2-3.3/2.8
1005318-20	00802526219887	4.50	.026	8	14	3.2-3.3/2.8
1005319-20	00802526219894	5.00	.026	8	14	3.2-3.3/2.8
30 mm						
1005309-30	00802526219542	2.00	.024	8	14	3.2-3.3/2.4
1005311-30	00802526219610	2.50	.024	8	14	3.2-3.3/2.4
1005312-30	00802526219665	2.75	.024	8	14	3.2-3.3/2.4
1005313-30	00802526219702	3.00	.024	8	14	3.2-3.3/2.6
1005315-30	00802526219788	3.50	.026	8	14	3.2-3.3/2.8
1005317-30	00802526219863	4.00	.026	8	14	3.2-3.3/2.8
40 mm						
1005311-40	00802526219627	2.50	.024	8	14	3.2-3.3/2.4
1005313-40	00802526219719	3.00	.024	8	14	3.2-3.3/2.6
1005315-40	00802526219795	3.50	.026	8	14	3.2-3.3/2.8
1005317-40	00802526219870	4.00	.026	8	14	3.2-3.3/2.8

Usable Catheter Working Length = 143 cm

Maximum Guide Wire = .014″

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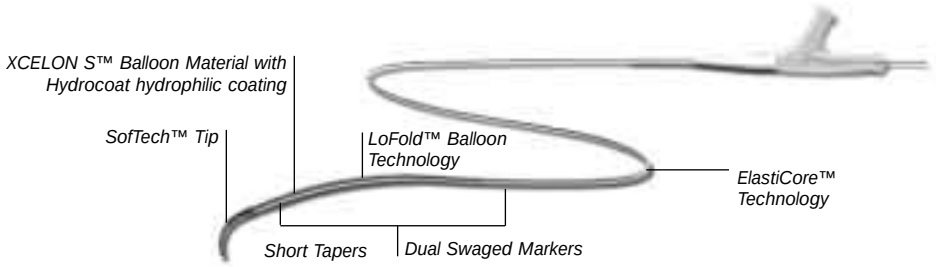

OTW HIGHSAIL™

Coronary Dilatation Catheter

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Proximal-Distal Shaft Diameters (F)
8 mm						
1005558-08	00802526254185	2.00	.026	10	18	3.2/2.6
1005559-08	00802526254239	2.25	.026	10	18	3.2/2.6
1005560-08	00802526254284	2.50	.026	10	18	3.2/2.6
1005561-08	00802526254345	2.75	.026	10	18	3.2/2.6
1005562-08	00802526254406	3.00	.026	10	18	3.2/2.6
1005563-08	00802526254475	3.25	.026	10	18	3.2/2.6
1005564-08	00802526254536	3.50	.026	10	18	3.2/2.6
1005565-08	00802526254604	3.75	.026	10	18	3.2/2.6
1005566-08	00802526254666	4.00	.026	10	18	3.2/2.6
13 mm						
1005558-13	00802526254192	2.00	.026	10	18	3.2/2.6
1005559-13	00802526254246	2.25	.026	10	18	3.2/2.6
1005560-13	00802526254291	2.50	.026	10	18	3.2/2.6
1005561-13	00802526254352	2.75	.026	10	18	3.2/2.6
1005562-13	00802526254413	3.00	.026	10	18	3.2/2.6
1005563-13	00802526254482	3.25	.026	10	18	3.2/2.6
1005564-13	00802526254543	3.50	.026	10	18	3.2/2.6
1005565-13	00802526254611	3.75	.026	10	18	3.2/2.6
1005566-13	00802526254673	4.00	.026	10	18	3.2/2.6
1005567-13	00802526254734	4.50	.026	10	18	3.2/2.6
1005568-13	00802526254772	5.00	.026	10	18	3.2/2.6
15 mm						
1005560-15	00802526254307	2.50	.026	10	18	3.2/2.6
1005561-15	00802526254369	2.75	.026	10	18	3.2/2.6
1005562-15	00802526254420	3.00	.026	10	18	3.2/2.6
1005563-15	00802526254499	3.25	.026	10	18	3.2/2.6
1005564-15	00802526254550	3.50	.026	10	18	3.2/2.6
1005565-15	00802526254628	3.75	.026	10	18	3.2/2.6
1005566-15	00802526254680	4.00	.026	10	18	3.2/2.6
18 mm						
1005556-18	00802526254178	1.50	.026	10	18	3.2/2.6
1005558-18	00802526254208	2.00	.026	10	18	3.2/2.6
1005559-18	00802526254253	2.25	.026	10	18	3.2/2.6
1005560-18	00802526254314	2.50	.026	10	18	3.2/2.6
1005561-18	00802526254376	2.75	.026	10	18	3.2/2.6
1005562-18	00802526254437	3.00	.026	10	18	3.2/2.6
1005563-18	00802526254505	3.25	.026	10	18	3.2/2.6
1005564-18	00802526254567	3.50	.026	10	18	3.2/2.6

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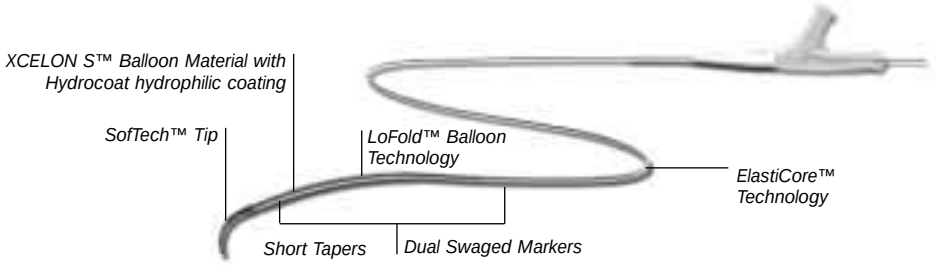
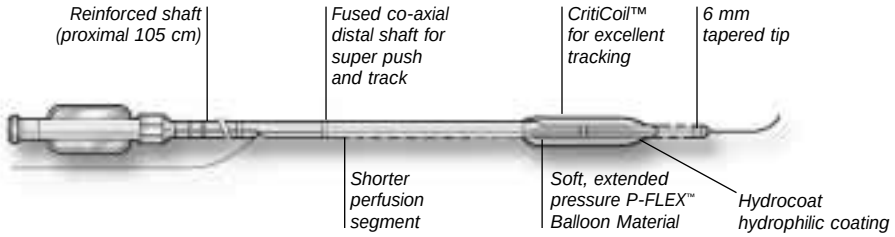


OTW HIGHSAIL™ (continued)

Coronary Dilatation Catheter

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Proximal-Distal Shaft Diameters (F)
1005565-18	00802526254635	3.75	.026	10	18	3.2/2.6
1005566-18	00802526254697	4.00	.026	10	18	3.2/2.6
1005567-18	00802526254741	4.50	.026	10	18	3.2/2.6
1005568-18	00802526254789	5.00	.026	10	18	3.2/2.6
23 mm						
1005558-23	00802526254215	2.00	.026	10	18	3.2/2.6
1005559-23	00802526254260	2.25	.026	10	18	3.2/2.6
1005560-23	00802526254321	2.50	.026	10	18	3.2/2.6
1005561-23	00802526254383	2.75	.026	10	18	3.2/2.6
1005562-23	00802526254444	3.00	.026	10	18	3.2/2.6
1005563-23	00802526254512	3.25	.026	10	18	3.2/2.6
1005564-23	00802526254574	3.50	.026	10	18	3.2/2.6
1005565-23	00802526254642	3.75	.026	10	18	3.2/2.6
1005566-23	00802526254703	4.00	.026	10	18	3.2/2.6
1005567-23	00802526254758	4.50	.026	10	18	3.2/2.6
1005568-23	00802526254796	5.00	.026	10	18	3.2/2.6
28 mm						
1005558-28	00802526254222	2.00	.026	10	18	3.2/2.6
1005559-28	00802526254277	2.25	.026	10	18	3.2/2.6
1005560-28	00802526254338	2.50	.026	10	18	3.2/2.6
1005561-28	00802526254390	2.75	.026	10	18	3.2/2.6
1005562-28	00802526254451	3.00	.026	10	18	3.2/2.6
1005563-28	00802526254529	3.25	.026	10	18	3.2/2.6
1005564-28	00802526254581	3.50	.026	10	18	3.2/2.6
1005565-28	00802526254659	3.75	.026	10	18	3.2/2.6
1005566-28	00802526254710	4.00	.026	10	18	3.2/2.6
1005567-28	00802526254765	4.50	.026	10	18	3.2/2.6
1005568-28	00802526254802	5.00	.026	10	18	3.2/2.6
33 mm						
1005562-33	00802526254468	3.00	.026	10	18	3.2/2.6
1005564-33	00802526254598	3.50	.026	10	18	3.2/2.6
1005566-33	00802526254727	4.00	.026	10	18	3.2/2.6



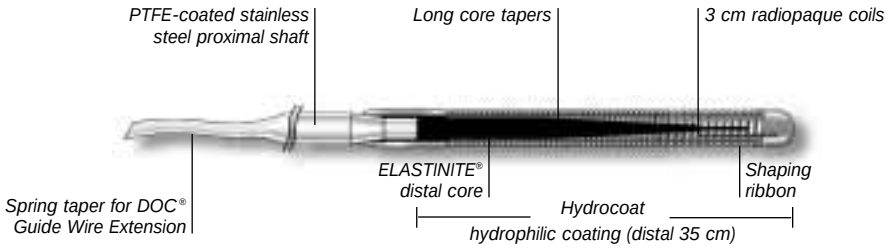
RX ESPRIT™

Coronary Dilatation Catheter with CROSSFLOW™ Perfusion Technology

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Proximal-Distal Shaft Diameters (F)
20 mm						
1001650-20U	00802526183058	2.00	.041	8	14	2.3/2.1-3.1/3.5
1001651-20U	00802526183065	2.25	.041	8	14	2.3/2.1-3.1/3.5
1001652-20U	00802526183072	2.50	.041	8	14	2.3/2.1-3.1/3.5
1001653-20U	00802526183089	2.75	.042	8	14	2.3/2.1-3.1/3.5
1001654-20U	00802526183096	3.00	.042	8	14	2.3/2.1-3.1/3.5
1001655-20U	00802526183102	3.25	.043	8	14	2.3/2.1-3.1/3.5
1001656-20U	00802526183119	3.50	.043	8	14	2.3/2.1-3.1/3.5
1001657-20U	00802526183126	3.75	.044	8	13	2.3/2.1-3.1/3.5
1001658-20U	00802526183133	4.00	.044	8	13	2.3/2.1-3.1/3.5
30 mm						
1001650-30U	00802526183560	2.00	.042	8	14	2.3/2.1-3.1/3.5
1001652-30U	00802526183607	2.50	.042	8	14	2.3/2.1-3.1/3.5
1001654-30U	00802526183645	3.00	.044	8	14	2.3/2.1-3.1/3.5
1001656-30U	00802526183683	3.50	.044	8	14	2.3/2.1-3.1/3.5
1001658-30U	00802526183720	4.00	.045	8	13	2.3/2.1-3.1/3.5

Usable Catheter Working Length = 137 cm

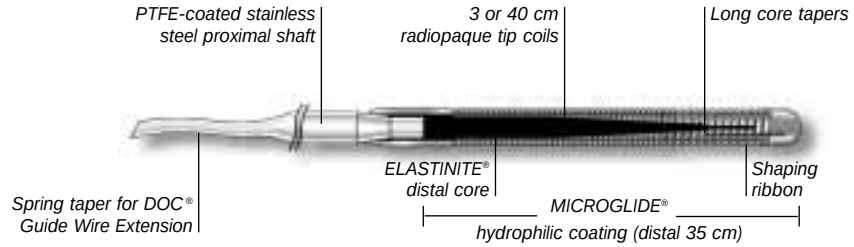
Maximum Guide Wire = .014″



HI-TORQUE BALANCE® .014″

Guide Wire with Hydrocoat hydrophilic coating

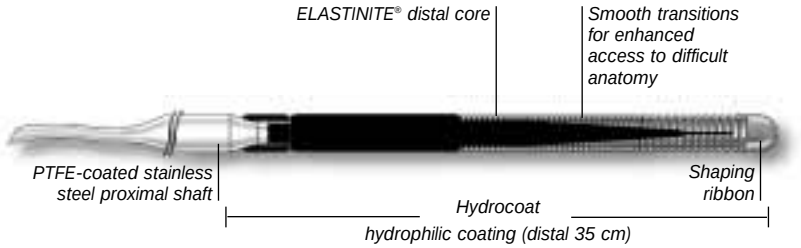
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
28000S-HC	00802526208928	3	Straight	190
28000JS-HC	00802526208935	3	‘J’	190
28001S-HC	00802526209048	3	Straight	300
28001JS-HC	00802526209055	3	‘J’	300



HI-TORQUE BALANCE® .014″

Guide Wire

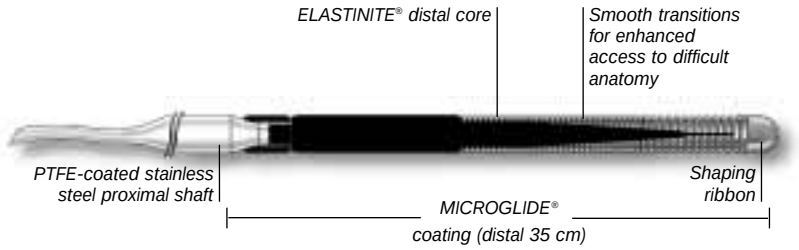
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
28000S	00802526208898	3	Straight	190
28000JS	00802526208867	3	‘J’	190
28100S	00802526208911	40	Straight	190
28100JS	00802526208904	40	‘J’	190
28001S	00802526209017	3	Straight	300
28001JS	00802526209000	3	‘J’	300
28101S	00802526209031	40	Straight	300
28101JS	00802526209024	40	‘J’	300



HI-TORQUE BALANCE MIDDLEWEIGHT™ .014″

Guide Wire with Hydrocoat hydrophilic coating

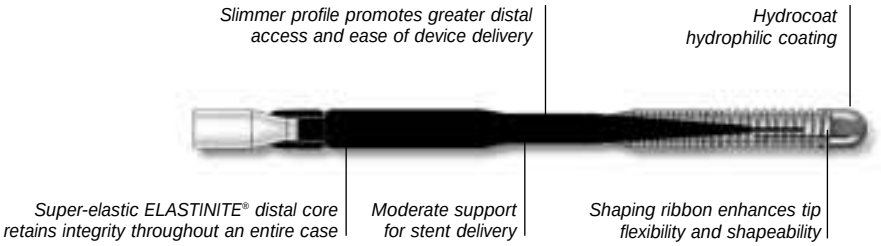
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1001780S-HC	00802526209208	3	Straight	190
1001780JS-HC	00802526209215	3	‘J’	190
1001782S-HC	00802526209260	3	Straight	300
1001782JS-HC	00802526209277	3	‘J’	300



HI-TORQUE BALANCE MIDDLEWEIGHT™ .014″

Guide Wire

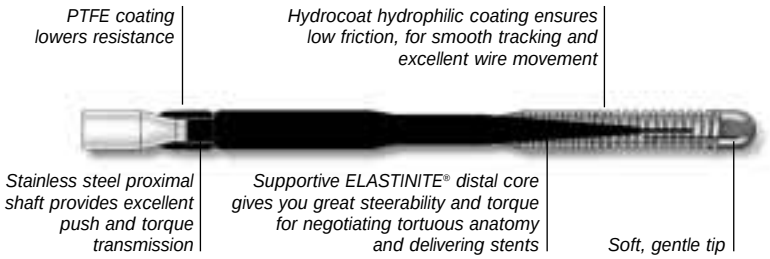
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1001780S	00802526209161	3	Straight	190
1001780JS	00802526209154	3	‘J’	190
1001782S	00802526209260	3	Straight	300
1001782JS	00802526209253	3	‘J’	300



HI-TORQUE BALANCE TREK™

Guide Wire with Hydrocoat hydrophilic coating

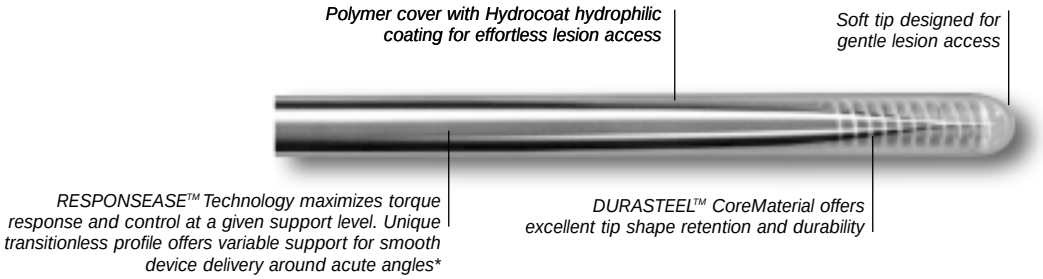
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Size (in)	Wire Length (cm)
1005159H	00802526210808	4.5	Straight	.014	190
1005159HJ	00802526210815	4.5	'J'	.014	190
1005160H	00802526210761	4.5	Straight	.014	300
1005160HJ	00802526210778	4.5	'J'	.014	300



HI-TORQUE BALANCE HEAVYWEIGHT™ .014″

Guide Wire with Hydrocoat hydrophilic coating

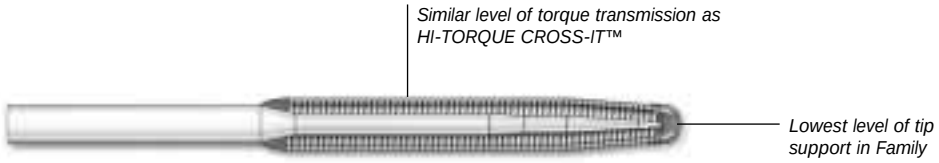
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1000462H	00802526210549	4.5	Straight	190
1000462HJ	00802526210556	4.5	'J'	190
1000463HS	00802526210648	4.5	Straight	300
1000463HJ	00802526210655	4.5	'J'	300



HI-TORQUE WHISPER™

MS Guide Wire with Hydrocoat hydrophilic coating

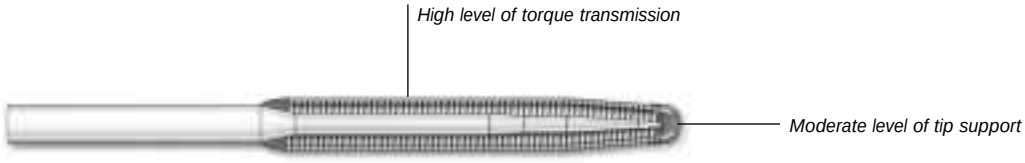
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Size (in)	Wire Length (cm)
1005357H	00802526212406	3	Straight		190
1005357HJ	00802526212413	3	J'		190
1005359H	00802526212369	3	Straight		300
1005359HJ	00802526212376	3	J'		300



HI-TORQUE CROSS-IT™ 100XT

Guide Wire with Hydrocoat hydrophilic coating

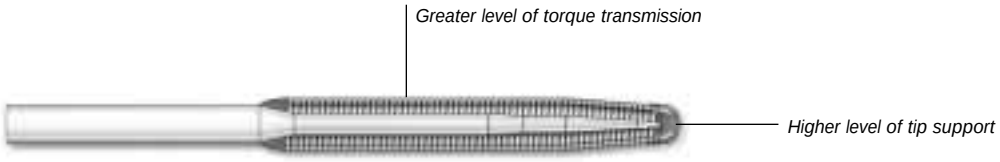
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Size (in)	Wire Length (cm)
1003309H	00802526210952	3	Straight	.014	190
1003309HJ	00802526210969	3	'J'	.014	190
1003310H	00802526210914	3	Straight	.014	300
1003310HJ	00802526210921	3	'J'	.014	300



HI-TORQUE CROSS-IT™ 200XT

Guide Wire with Hydrocoat hydrophilic coating

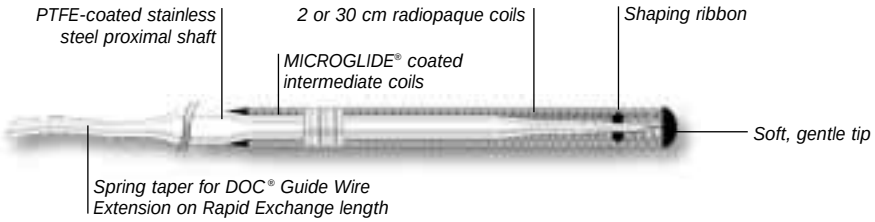
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Size (in)	Wire Length (cm)
1003312H	00802526211072	3	Straight	.014	190
1003312HJ	00802526211089	3	'J'	.014	190
1003313H	00802526211034	3	Straight	.014	300
1003313HJ	00802526211041	3	'J'	.014	300



HI-TORQUE CROSS-IT™ 300XT

Guide Wire with Hydrocoat hydrophilic coating

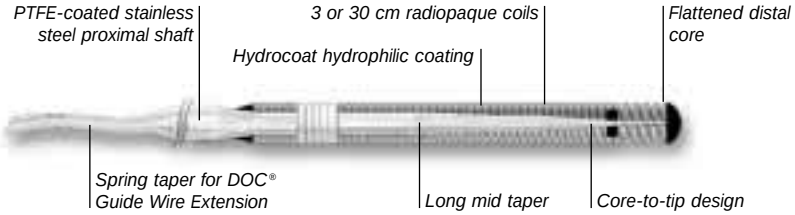
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Size (in)	Wire Length (cm)
1003315H	00802526211171	3	Straight	.014	190
1003315HJ	00802526211188	3	'J'	.014	190
1003316H	00802526211133	3	Straight	.014	300
1003316HJ	00802526211140	3	'J'	.014	300



HI-TORQUE FLOPPY II® .014″

Guide Wire

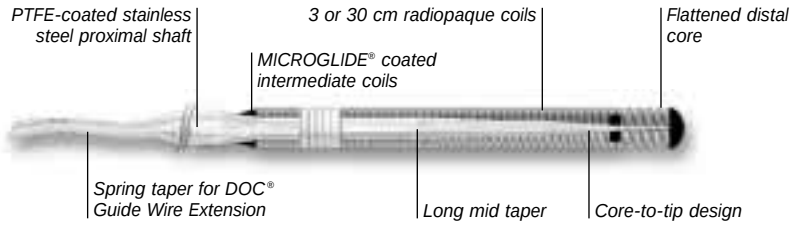
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
22339MS	00802526209604	2	Straight	190
22339MJS	00802526209574	2	‘J’	190
22339MS-903	00802526209611	30	Straight	190
22339MJS-903	00802526209598	30	‘J’	190
22359MS	00802526209765	2	Straight	300
22359MJS	00802526209758	2	‘J’	300
22359MS-903	00802526209772	30	Straight	300



HI-TORQUE TRAVERSE® .014″

Guide Wire with Hydrocoat hydrophilic coating

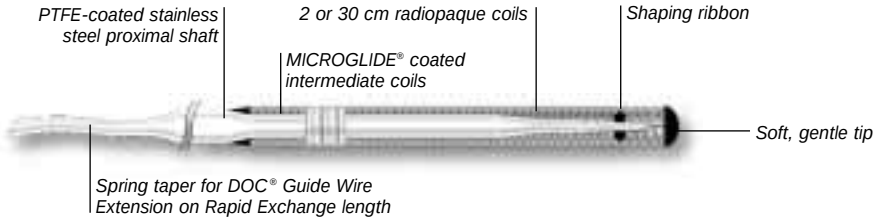
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
22349HS	00802526211935	3	Straight	190
22349HJS	00802526211911	3	‘J’	190
22349HS-903	00802526211942	30	Straight	190
22349HJS-903	00802526211928	30	‘J’	190
22379HS	00802526211966	3	Straight	300
22379HJS	00802526211959	3	‘J’	300
22379HS-903	00802526211973	30	Straight	300
22379HJS-903	00802526210402	30	‘J’	300



HI-TORQUE TRAVERSE® .014″

Guide Wire

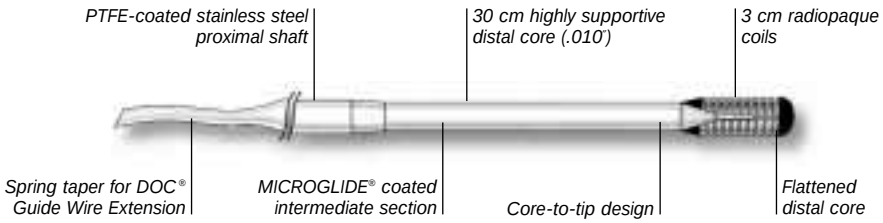
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
22349MS	00802526210273	3	Straight	190
22349MJS	00802526210259	3	‘J’	190
22349MS-903	00802526210280	30	Straight	190
22349MJS-903	00802526210266	30	‘J’	190
22379MS	00802526210389	3	Straight	300
22379MJS	00802526210365	3	‘J’	300
22379MS-903	00802526210396	30	Straight	300
22379MJS-903	00802526210372	30	‘J’	300



HI-TORQUE FLOPPY II® EXTRA SUPPORT .014″

Guide Wire

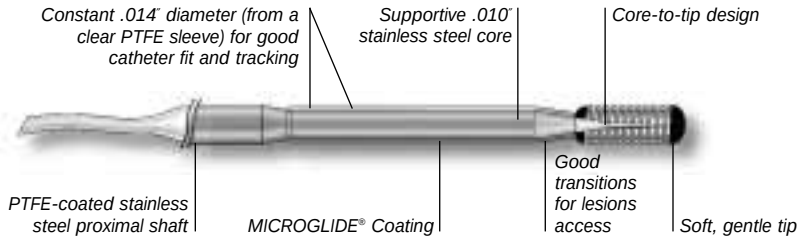
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
22299MS	00802526209369	2	Straight	190
22299MS-901	00802526209376	30	Straight	190
22359MS-901	00802526209482	2	Straight	300
22399MS	00802526209505	30	Straight	300



HI-TORQUE EXTRA S'PORT™ .014″

Guide Wire

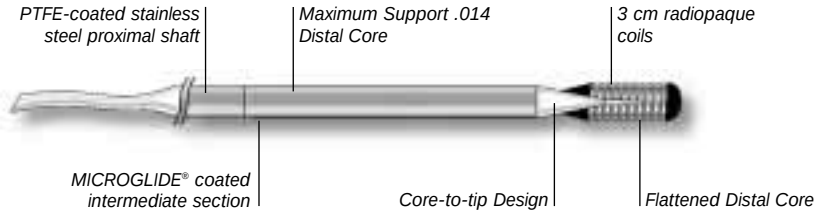
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
22225MS	00802526210051	3	Straight	190
22225MJS	00802526210044	3	'J'	190
22235MS	00802526210150	3	Straight	300
22235MJS	00802526210143	3	'J'	300



HI-TORQUE ALL STAR™ .014″

Guide Wire

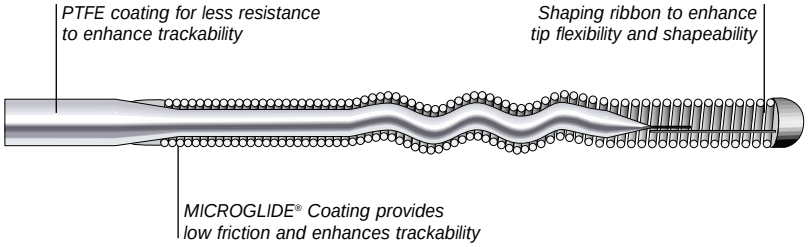
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1001740S	00802526208768	3	Straight	190
1001740JS	00802526208751	3	'J'	190
1001741S	00802526208775	3	Straight	300
1001741JS	00802526208782	3	'J'	300



HI-TORQUE IRON MAN™ .014″

Guide Wire

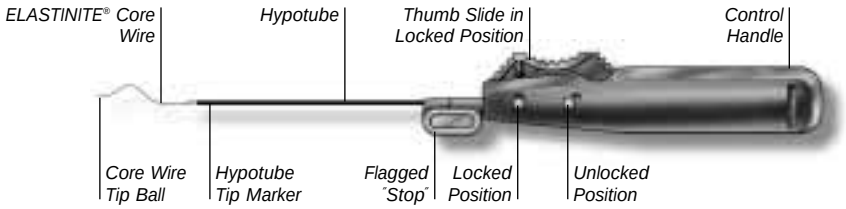
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1001309S	00802526209963	3	Straight	190
1001309JS	00802526209956	3	'J'	190
1001311S	00802526209994	3	Straight	300
1001311JS	00802526209987	3	'J'	300



HI-TORQUE WIGGLE™

Guide Wire

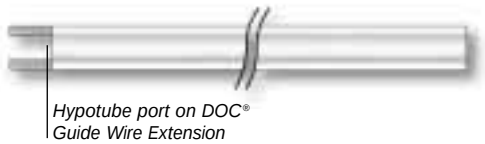
Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Size (in)	Wire Length (cm)
22299MS-W2	00802526210426	2	Straight	.014	190
22299MS-W30	00802526209383	30	Straight	.014	190
22359MS-W2	00802526210419	2	Straight	.014	300
22399MS-W30	00802526211591	30	Straight	.014	300



ANCHOR®

Exchange Device

Stock Number	UPN Number	Description
600116	00802526212697	ANCHOR® Exchange Device



DOC®

Guide Wire Extension

Stock Number	UPN Number	Description	Wire Length (cm)	Compatible Guide Wires (in)
22260	00802526212703	DOC® Guide Wire Extension	145	.014/.018

PRINT PAGE

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Geometric Left


GL 3.5

Stock Number*	Type
1006092	GL3
1006093	SHGL3
1006094	GL3.5
1006095	SHGL3.5
1006098	GL4
1006099	SHGL4
1006100	GL4.5
1006101	SHGL4.5
1006102	GL5
1006103	SHGL5
1006104	GL6
1006105	SHGL6

SH = Side Hole Catheter

*Viking Optima™ UPN numbers on page 67–69

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VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Judkins Left

JL3

JL4

Stock Number*	Type
1006000	JL3
1006001	SHJL3
1006004	JL3.5
1006005	SHJL3.5
1006008	JL4
1006009	SHJL4
1006014	JL4.5
1006015	SHJL4.5
1006018	JL5
1006019	SHJL5
1006022	JL6
1006023	SHJL6

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Judkins Left — Short Tips


JL4S

Stock Number*	Type
1006002	JL3S
1006003	SHJL3S
1006006	JL3.5S
1006007	SHJL3.5S
1006010	JL4S
1006011	SHJL4S
1006016	JL4.5S
1006017	SHJL4.5S
1006020	JL5S
1006021	SHJL5S

SH = Side Hole Catheter

JC Left


JCL 3.5

Stock Number*	Type
1006024	JCL3.5
1006025	SHJCL3.5
1006028	JCL4
1006029	SHJCL4
1006030	JCL4.5
1006031	SHJCL4.5
1006032	JCL5
1006033	SHJCL5

SH = Side Hole Catheter


JCL 4

*VIKING OPTIMA™ UPN numbers on page 67–69

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Amplatz Left


AL2


AL3

Stock Number*	Type
1006111	AL.75
1006112	SHAL.75
1006115	AL1
1006116	SHAL1
1006119	AL1.5
1006120	SHAL1.5
1006123	AL1.75
1006124	SHAL1.75
1006125	AL2
1006126	SHAL2
1006129	AL3
1006130	SHAL3
1006133	AL4
1006134	SHAL4
1006137	ALR1.2
1006138	SHALR1.2

SH = Side Hole Catheter

Amplatz Left - Short Tips


AL5

Stock Number*	Type
1006113	AL.75S
1006114	SHAL.75S
1006117	AL1S
1006118	SHAL1S
1006121	AL1.5S
1006122	SHAL1.5S
1006127	AL2S
1006128	SHAL2S
1006131	AL3S
1006132	SHAL3S
1006135	AL4S
1006136	SHAL4S

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Judkins Right


JR 3.5


JR 4

Stock Number*	Type
1006053	JR3
1006054	SHJR3
1006055	JR3.5
1006056	SHJR3.5
1006059	JR4
1006060	SHJR4
1006067	JR5
1006068	SHJR5
1006071	JR6
1006072	SHJR6

SH = Side Hole Catheter

Judkins Right — Short Tips


JR4S

Stock Number*	Type
1006057	JR3.5S
1006058	SHJR3.5S
1006065	JR4S
1006066	SHJR4S
1006069	JR5S
1006070	SHJR5S

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

JC Right


JCR 4

Stock Number*	Type
1006073	JCR3.5
1006074	SHJCR3.5
1006079	JCR 4
1006080	SHJCR4
1006085	JCR4IF
1006086	SHJCR4IF

SH = Side Hole Catheter

JC Right — Short Tips


JCR4S

Stock Number*	Type
1006077	JCR3.5S
1006078	SHJCR3.5S
1006081	JCR4S
1006082	SHJCR4S

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Amplatz Right

AR1

Stock Number*	Type
1006144	AR1
1006145	SHAR1
1006150	AR2
1006151	SHAR2
1006154	AR3
1006155	SHAR3

SH = Side Hole Catheter

CHMP Curves

CHMP 1.0

CHMP 3.0

Stock Number*	Type
1006206	CHMP.5
1006207	SHCHMP.5
1006208	CHMP1.0
1006209	SHCHMP1.0
1006210	CHMP2.0
1006211	SHCHMP2.0
1006212	CHMP3.0
1006213	SHCHMP3.0

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

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VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Coronary Bypass


BP-L


LIMA

Stock Number*	Type
1006163	LIMA
1006164	SHLIMA
1006167	BP-L
1006168	SHBP-L
1006171	BP-R
1006172	SHBP-R
1006177	JCLGRF
1006178	SHJCLGRF
1006181	JCRGRF
1006182	SHJCRGRF

SH = Side Hole Catheter

90 cm Guides

Stock Number*	Type
1006061	JR4 90 cm
1006062	SHJR4 90 cm
1006165	LIMA 90 cm
1006166	SHLIMA 90 cm
1006169	BP-L 90 cm
1006170	SHBP-L 90 cm
1006173	BP-R 90 cm
1006174	SHBP-R 90 cm
1006200	MP 90 cm
1006201	SHMP 90 cm

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

Hockey Stick

HS

Stock Number*	Type
1006219	HS
1006220	SHHS
1006223	JCHS
1006224	SHJCHS

SH = Side Hole Catheter

Multipurpose

MP

Stock Number*	Type
1006198	MP
1006199	SHMP
1006202	JCMP
1006203	SHJCMP

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

VIKING OPTIMA™
Guiding Catheter

6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .091″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08

Example: 7F JL3 1006000-07

RAD CURVES™ — Transradial Specialty Curves

RAD KEY

RAD-S 4.0

Stock Number*	Type
1006241	RAD KEY †
1006242	RAD-S 3.5 ††
1006243	RAD-S 4.0 ††
1006244	RAD-S 4.5 ††
1006245	RAD-S 5.0 ††
1006251	RAD-MINI KEY †
1006252	RAD-MINI KEY II †

† Available in 6F and 7F sizes only

†† Available in 6F only

Shani Right

SR

Stock Number*	Type
1006237	SR
1006238	SHSR

SH = Side Hole Catheter

*VIKING OPTIMA™ UPN numbers on page 67–69

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VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

Geometric Left


GL3.5

Stock Number*	Type
1001896	GL3
1001897	SHGL3
1001898	GL3.5
1001899	SHGL3.5
1001900	GL4
1001901	SHGL4
1001902	GL4.5
1001903	SHGL4.5
1001904	GL5
1001905	SHGL5
1001906	GL6
1001907	SHGL6

SH = Side Hole Catheter

*VIKING™ UPN numbers on page 70-73

VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

Judkins Left


JL4


JCL4

Stock Number*	Type
1001874	JL3
1001876	SHJL3
1001878	JL3.5
1001880	SHJL3.5
1001882	JL4
1001884	SHJL4
1001886	JL4.5
1001888	SHJL4.5
1001890	JL5
1001892	SHJL5
1001894	JL6
1001895	SHJL6
1001980	JCL3.5
1001981	SHJCL3.5
1002056	JCL4
1001982	SHJCL4
1001983	JCL4.5
1001984	SHJCL4.5
1001985	JCL5
1001986	SHJCL5

Short Tips


JL4S

Stock Number*	Type
1001875	JL3S
1001877	SHJL3S
1001879	JL3.5S
1001881	SHJL3.5S
1001883	JL4S
1001885	SHJL4S
1001887	JL4.5S
1001889	SHJL4.5S
1001891	JL5S
1001893	SHJL5S

SH = Side Hole Catheter

*VIKING™ UPN numbers on page 70-73

VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

Amplatz Left


AL2

Stock Number*	Type
1001908	AL.75
1001909	SHAL.75
1001912	AL1
1001914	SHAL1
1001916	AL1.5
1001917	SHAL1.5
1001920	AL1.75
1001921	SHAL1.75
1001922	AL2
1001924	SHAL2
1001926	AL3
1001928	SHAL3
1001930	AL4
1001931	SHAL4
1001934	ALR1.2
1001935	SHALR1.2

Short Tips


AL2S

Stock Number*	Type
1001910	AL.75S
1001911	SHAL.75S
1001913	AL1S
1001915	SHAL1S
1001918	AL1.5S
1001919	SHAL1.5S
1001923	AL2S
1001925	SHAL2S
1001927	AL3S
1001929	SHAL3S
1001932	AL4S
1001933	SHAL4S

SH = Side Hole Catheter

*VIKING™ UPN numbers on page 70-73

VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09
Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

Judkins Right


JR4


JCR4

Stock Number*	Type
1001936	JR3
1001937	SHJR3
1001938	JR3.5
1001940	SHJR3.5
1001942	JR4
1001944	SHJR4
1001946	JR5
1001948	SHJR5
1001950	JR6
1001951	SHJR6
1001989	JCR3.5
1001990	SHJCR3.5
1001993	JCR4
1001995	SHJCR4
1001997	JCR4IF
1001998	SHJCR4IF


JR4S


SHJCR4S


SHJCR4IF

Short Tips

Stock Number*	Type
1001939	JR3.5S
1001941	SHJR3.5S
1001943	JR4S
1001945	SHJR4S
1001947	JR5S
1001949	SHJR5S
1001991	JCR3.5S
1001992	SHJCR3.5S
1001994	JCR4S
1001996	SHJCR4S

SH = Side Hole Catheter

*VIKING™ UPN numbers on page 70-73

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VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

Shani Right


SR

Stock Number*	Type
1001952	SR
1001953	SHSR

SH = Side Hole Catheter

Amplatz Right


AR2

Stock Number*	Type
1001954	AR1
1001956	SHAR1
1001958	AR2
1001960	SHAR2
1001962	AR3
1001963	SHAR3

Short Tips

Stock Number*	Type
1001955	AR1S
1001957	SHAR1S
1001959	AR2S
1001961	SHAR2S

SH = Side Hole Catheter

*VIKING™ UPN numbers on page 70-73

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VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

Hockey Stick


HS

Stock Number*	Type
1001964	HS
1001965	SHHS
1002001	JCHS
1002002	SHJCHS

SH = Side Hole Catheter

Double Loop


DL75S

Stock Number*	Type
1001974	DL75S
1001977	SHDL75S
1001975	DL90S
1001979	SHDL90S


SHDL75L

Stock Number*	Type
1001976	SHDL75L
1001978	SHDL90L

S = Short Tip Catheter L = Long Tip Catheter
SH = Side Hole Catheter


SHDL90L


SHDL90S

*VIKING™ UPN numbers on page 70-73

VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

Coronary Bypass

LIMA BP-L BP-R

Stock Number*	Type
1001968	LIMA
1001969	SHLIMA
1001970	BP-L
1001971	SHBP-L
1001972	BP-R
1001973	SHBP-R
1001987	JCLGRF
1001988	SHJCLGRF
1001999	JCRGRF
1002000	SHJCRGRF

SH = Side Hole Catheter

Multipurpose

MP

Stock Number*	Type
1001966	MP
1001967	SHMP
1002003	JCMP
1002004	SHJCMP

SH = Side Hole Catheter

*VIKING™ UPN numbers on page 70-73

VIKING™
Guiding Catheter

6F Inner Diameter .066″
Available in 6F only

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06

Example: 6F JL3 1006000-06

RAD CURVES™ — Transradial Specialty Curves

RAD KEY

RAD-S 4.0

Stock Number*	Type
1002040	RAD KEY™
1002041	RAD S™ 3.5
1002042	RAD S™ 4.0
1002043	RAD S™ 4.5
1002044	RAD S™ 5.0

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

CHMP Curves

Stock Number*	Type
1002045	CHMP.5
1002046	CHMP1.0
1002047	CHMP2.0
1002048	CHMP3.0

*VIKING™ UPN numbers on page 70-73

VIKING™
Guiding Catheter

6F Inner Diameter .066″
7F Inner Diameter .075″
8F Inner Diameter .087″
9F Inner Diameter .101″

For ordering purposes, please add the following two digits to stock number for appropriate catheter size:
6F add -06 **7F** add -07 **8F** add -08 **9F** add -09

Example: JL3
6F: 1001874-06 7F: 1001874-07 8F: 1001874-08 9F: 1001874-09

90 cm Guides

Stock Number*	Type
1002017	AR1 90 cm
1002018	AR2 90 cm
1002019	BP-L 90 cm
1002020	BP-R 90 cm
1002021	HS 90 cm
1002022	JR4 90 cm
1002023	LIMA 90 cm
1002024	MP 90 cm
1002025	SHAR1 90 cm
1002026	SHAR2 90 cm
1002027	SHBP-L 90 cm
1002028	SHBP-R 90 cm
1002029	SHHS 90 cm
1002030	SHJCHS 90 cm
1002031	SHJCLGRF 90 cm
1002032	SHJCMP 90 cm
1002033	JCRGRF 90 cm
1002034	SHJCR3.5S 90 cm
1002035	SHJCR4S 90 cm
1002036	SHJCRGRF 90 cm
1002037	SHJR4 90 cm
1002038	SHLIMA 90 cm
1002039	SHMP 90 cm

SH = Side Hole Catheter

*VIKING™ UPN numbers on page 70-73

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TOURGUIDE™ 10F JC SHAPES**

Guiding Catheters

10F Inner Diameter .112″

JC Shapes — Right

SHJCR41F

SHJCR4S

Stock Number (10F)*	UPN Number	Type	Shaft Length (cm)
600898	00802526165962	SHJCR3.5S	100
600706	00802526165702	SHJCR3.5	100
600772	00802526165757	SHJCR4S	100
600708	00802526165719	SHJCR4	100
600773	00802526165764	SHJCR4IF	100
600896	00802526165948	SHJCHS	100
600897	00802526165955	SHJCMP	100
600774	00802526165771	SHJCRGRF	100

JC Shapes — Left

JCL4

Stock Number (10F)*	UPN Number	Type	Shaft Length (cm)
600638	00802526165665	SHJCL3.5	100
600640	00802526165672	SHJCL4	100
600776	00802526165795	SHJCL4.5	100
600777	00802526165801	SHJCL5	100
600775	00802526165788	SHJCLGRF	100

Guiding catheter introducers sold separately.

SH = Side Hole Catheter S=Short Tip Catheter

**All DCA/DVI Shapes start with JC

PRINT PAGE

TOURGUIDE™ 10F
Guiding Catheter

10F Inner Diameter .112″

Judkins Left


JL4


JCL4


JL4S

Stock Number (10F)	UPN Number	Type	Shaft Length (cm)
600628	00802526165634	SHJL3.5	100
600630	00802526165641	SHJL4	100
600634	00802526165658	SHJL5	100
600638	00802526165665	SHJCL3.5	100
600640	00802526165672	SHJCL4	100
600776	00802526165795	SHJCL4.5	100
600777	00802526165801	SHJCL5	100

SH = Side Hole Catheter

PRINT PAGE

TOURGUIDE™ 10F
Guiding Catheter

10F Inner Diameter .112″

Judkins Right

Stock Number (10F)	UPN Number	Type	Shaft Length (cm)
600700	00802526165696	SHJR4	100
600706	00802526165702	SHJCR3.5	100
600708	00802526165719	SHJCR4	100
600712	00802526165726	SHJR4S	100
600772	00802526165757	SHJCR4S	100
600773	00802526165764	SHJCR4IF	100

SH = Side Hole Catheter S = Short Tip Catheter


JR4


JCR4


JR4S


SHJCR4S


SHJCR41F

PRINT PAGE

TOURGUIDE™ 10F
Guiding Catheter

10F Inner Diameter .112″

Hockey Stick

HS

Stock Number (10F)	UPN Number	Type	Shaft Length (cm)
600730	00802526165733	SHHS	100

Multipurpose

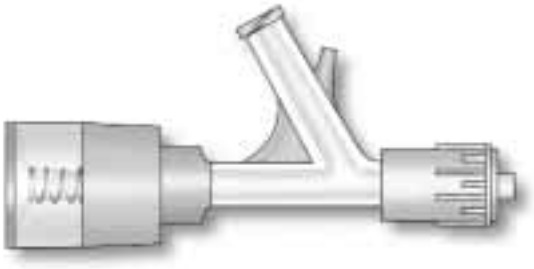
MP

Stock Number (10F)	UPN Number	Type	Shaft Length (cm)
600732	00802526165740	SHMP	100

Judkins Graft

SHJCRGRF

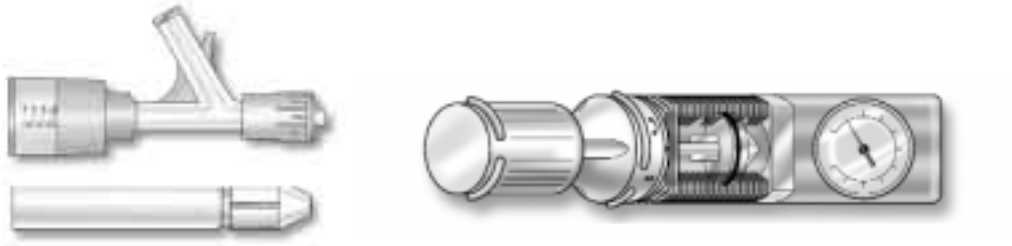
Stock Number (10F)	UPN Number	Type	Shaft Length (cm)
600774	00802526165771	SHJCRGRF	100
600775	00802526165788	SHJCLGRF	100



COPILOT®

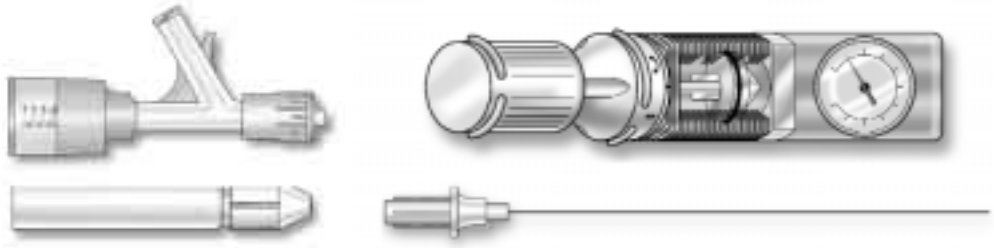
Bleedback Control Valve

Stock Number	UPN Number	Description	Inner Diameter (in/mm)
1003331	00802526258527	COPILOT® Bleedback Control Valve Single Unit	.096″



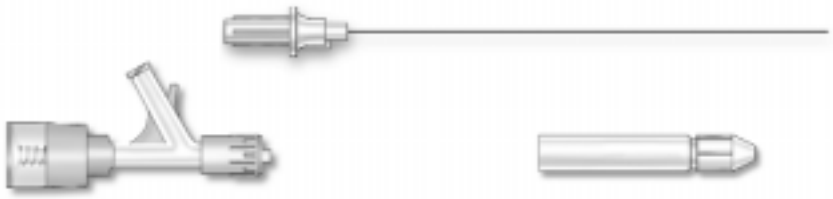
20/20 PRIORITY PACK™ w/ COPILOT®

Stock Number	UPN Number	Description	Syringe (cc)	Gauge (atm)	Inner Diameter (in/mm)	Compatible Guide Wires (in)
1003326	00802526175923	20/20 INDEFLATOR® Inflation Device	20	20		
		COPILOT® Bleedback Control Valve			.096≤	
		Guide Wire Introducer				.010-.018
		Torque Device				.010-.018



20/30 PRIORITY PACK™ w/ COPILOT®

Stock Number	UPN Number	Description	Syringe (cc)	Gauge (atm)	Inner Diameter (in/mm)	Compatible Guide Wires (in)
1003327	00802526175930	20/30 INDEFLATOR® Inflation Device	20	20		
		COPILOT® Bleedback Control Valve			.096≤	
		Guide Wire Introducer				.010-.018
		Torque Device				.010-.018

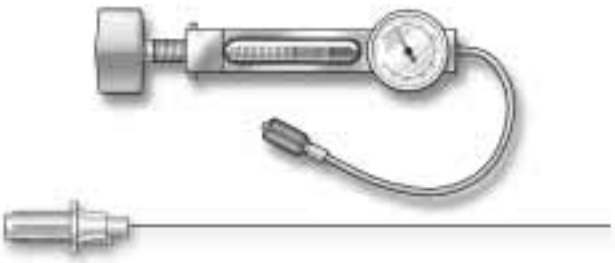


GUIDE WIRE ACCESSORY KIT w/ COPILOT®

Stock Number	UPN Number	Description	Syringe (cc)	Gauge (atm)	Inner Diameter (in/mm)	Compatible Guide Wires (in)
1003330	00802526160097	COPILOT® Bleedback Control Valve			.096≤	
		Guide Wire Introducer				010 - .018
		Torque Device				.010 - .018

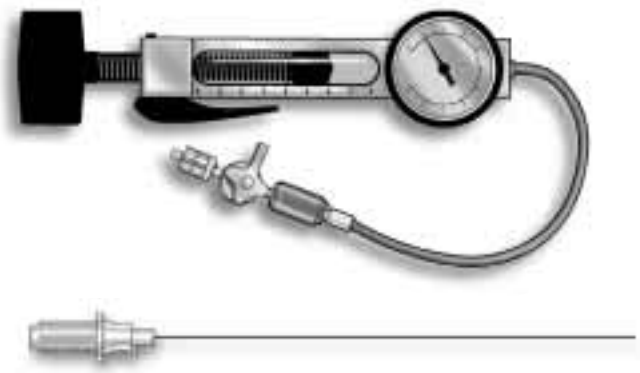
20/20 PRIORITY PACK™ Accessory Kit
20/30 PRIORITY PACK™ Accessory Kit

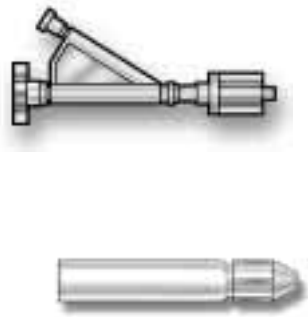
Stock Number	UPN Number	Description	Syringe (cc)	Gauge (atm)	Inner Diameter (in/mm)	Compatible Guide Wires (in)
22297	00802526175787	20/20 INDEFLATOR® Inflation Device	20	20		
		.096″ Rotating Hemostatic Valve			.096/2.44	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018
1000186	00802526175824	20/30 INDEFLATOR® Inflation Device	20	30		
		.096″ Rotating Hemostatic Valve			.096/2.44	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018
22297-115	00802526175794	20/20 INDEFLATOR® Inflation Device	20	20		
		.115″ Rotating Hemostatic Valve			.115/2.92	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018
1000186-115	00802526175831	20/30 INDEFLATOR® Inflation Device	20	30		
		.115″ Rotating Hemostatic Valve			.115/2.92	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018



PTCA PRIORITY PACK™ Accessory Kit

Stock Number	UPN Number	Contents	Syringe (cc)	Gauge (atm)	Inner Diameter (in/mm)	Compatible Guide Wires (in)
22296	00802526175893	INDEFLATOR Plus 20™ Inflation Device	10	20		
		.096″ Rotating Hemostatic Valve			.096/2.44	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018
22296-115	00802526175909	INDEFLATOR Plus 20™ Inflation Device	10	20		
		.115″ Rotating Hemostatic Valve			.115/2.92	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018



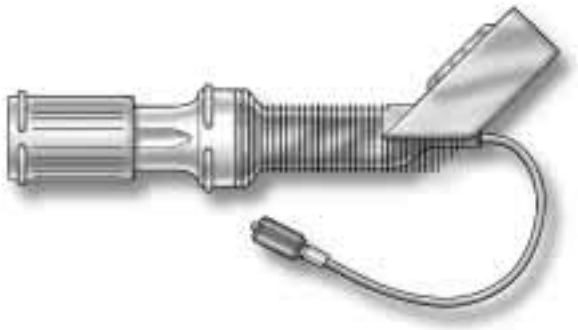


PTCA PRIORITY PACK™ Accessory Kit

Stock Number	UPN Number	Contents	Syringe (cc)	Gauge (atm)	Inner Diameter (in/mm)	Compatible Guide Wires (in)
1000185	00802526175862	INDEFLATOR PLUS 30™ Inflation Device	10	30		
		.096″ Rotating Hemostatic Valve			.096/2.44	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018
1000185-115	00802526175879	INDEFLATOR PLUS 30™ Inflation Device	10	30		
		.115″ Rotating Hemostatic Valve			.115/2.92	
		Guide Wire Introducer				.010 - .018
		Torque Device				.010 - .018

GUIDE WIRE ACCESSORY KIT

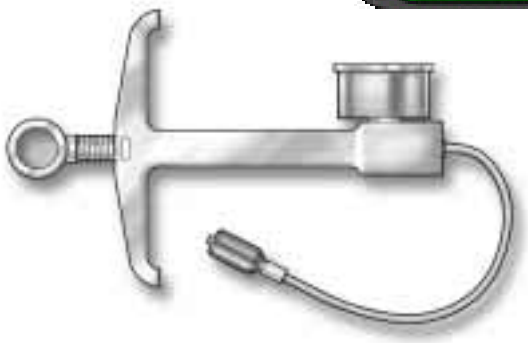
Stock Number	UPN Number	Contents	Inner Diameter (in/mm)	Compatible Guide Wires (in)
22295	00802526160066	Guide Wire Introducer		.010 - .018
		Torque Device		.010 - .018
		.096≤ Rotating Hemostatic Valve	.096/2.44	
22295-115	00802526160073	Guide Wire Introducer		.010 - .018
		Torque Device		.010 - .018
		.115≤ Rotating Hemostatic Valve	.115/2.92	



20/20 INDEFLATOR® Inflation Device

20/30 INDEFLATOR® Inflation Device

Stock Number	UPN Number	Description	Syringe (cc)	Gauge (atm)
24310	00802526175770	20/20 INDEFLATOR® Inflation Device	20	20
1000184	00802526175817	20/30 INDEFLATOR® Inflation Device	20	30



INDEFLATOR PLUS 20™ Inflation Device

Stock Number	UPN Number	Description	Syringe (cc)	Gauge (atm)
24301	00802526175886	INDEFLATOR PLUS 20™ Inflation Device	10	20

INDEFLATOR PLUS 30™ Inflation Device

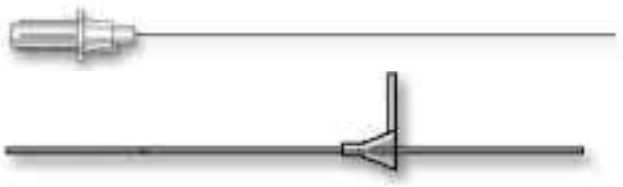
Stock Number	UPN Number	Description	Syringe (cc)	Gauge (atm)
1000183	00802526175855	INDEFLATOR PLUS 30™ Inflation Device	10	30

DUOSTAT®
Rotating Hemostatic Valve

Stock Number	UPN Number	Description	Inner Diameter (in/mm)
23244	00802526160189	DUOSTAT® Rotating Hemostatic Valve	.096/2.44
23246	00802526160202	DUOSTAT® Rotating Hemostatic Valve	.115/2.92

HEMOSTATIC VALVE

Stock Number	UPN Number	Description	Inner Diameter (in/mm)
23242	00802526160172	.096″ Rotating Hemostatic Valve	.096/2.44
23245	00802526160196	.115″ Rotating Hemostatic Valve	.115/2.92



INTRODUCERS

Stock Number	UPN Number	Contents	Compatible Guide Wires (in)
22290	20802526160152	Guide Wire Introducer - Ten Pack	.010 - .018
22231	20802526160145	Funnel Introducer - Ten Pack	.010 - .018

TORQUE DEVICE

Stock Number	UPN Number	Contents	Compatible Guide Wires (in)
22215	20802526160121	Torque Device - Ten Pack	.009 - .018

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STOCK NUMBERS AND UPN NUMBERS FOR VIKING OPTIMA™ GUIDING CATHETERS

Stock Number	UPN Number
1006000-06	00802526217159
1006000-07	00802526213298
1006000-08	00802526217166
1006001-06	00802526213304
1006001-07	00802526213311
1006001-08	00802526213328
1006002-06	00802526213335
1006002-07	00802526213342
1006002-08	00802526213359
1006003-06	00802526213366
1006003-07	00802526213373
1006003-08	00802526213380
1006004-06	00802526217173
1006004-07	00802526217180
1006004-08	00802526217197
1006005-06	00802526217203
1006005-07	00802526217210
1006005-08	00802526217227
1006006-06	00802526213397
1006006-07	00802526213403
1006006-08	00802526213410
1006007-06	00802526213427
1006007-07	00802526213434
1006007-08	00802526213441
1006008-06	00802526217234
1006008-07	00802526217241
1006008-08	00802526217258
1006009-06	00802526217265
1006009-07	00802526217272
1006009-08	00802526217289
1006010-06	00802526217296
1006010-07	00802526217302
1006010-08	00802526217319
1006011-06	00802526213458
1006011-07	00802526213465
1006011-08	00802526213472
1006014-06	00802526217326
1006014-07	00802526217333
1006014-08	00802526217340
1006015-06	00802526217357
1006015-07	00802526213489
1006015-08	00802526217364
1006016-06	00802526217371
1006016-07	00802526213496
1006016-08	00802526213502
1006017-06	00802526213519
1006017-07	00802526213526
1006017-08	00802526213533
1006018-06	00802526217388
1006018-07	00802526217395
1006018-08	00802526217401
1006019-06	00802526217418
1006019-07	00802526217425
1006019-08	00802526217432
1006020-06	00802526213540
1006020-07	00802526213557
1006020-08	00802526213564
1006021-06	00802526213571
1006021-07	00802526213588
1006021-08	00802526213595
1006022-06	00802526217449
1006022-07	00802526213601
1006022-08	00802526217456
1006023-06	00802526213618
1006023-07	00802526213625
1006023-08	00802526213632
1006024-06	00802526217463
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1006025-06	00802526213663
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1006030-08	00802526213779
1006031-06	00802526213786
1006031-07	00802526213793
1006031-08	00802526213809
1006032-06	00802526213816
1006032-07	00802526213823
1006032-08	00802526213830
1006033-06	00802526213847
1006033-07	00802526213854
1006033-08	00802526213861
1006053-06	00802526217760
1006053-07	00802526213878
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1006054-06	00802526213892
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1006055-06	00802526217777
1006055-07	00802526217784
1006055-08	00802526217791
1006056-06	00802526217807
1006056-07	00802526217814
1006056-08	00802526217821
1006057-06	00802526213922
1006057-07	00802526213939
1006057-08	00802526213946
1006058-06	00802526213953
1006058-07	00802526213960
1006058-08	00802526213977
1006059-06	00802526217838
1006059-07	00802526217845
1006059-08	00802526217852
1006060-06	00802526217869
1006060-07	00802526217876
1006060-08	00802526217883
1006061-06	00802526213984
1006061-07	00802526213991
1006061-08	00802526217890
1006062-06	00802526214004
1006062-07	00802526217906
1006062-08	00802526217913
1006065-06	00802526214011
1006065-07	00802526214028
1006065-08	00802526214035
1006066-06	00802526217982
1006066-07	00802526214042
1006066-08	00802526217999
1006067-06	00802526218002
1006067-07	00802526214059
1006067-08	00802526218019
1006068-06	00802526218026
1006068-07	00802526218033
1006068-08	00802526214066
1006069-06	00802526214073
1006069-07	00802526214080
1006069-08	00802526214097
1006070-06	00802526214103
1006070-07	00802526214110
1006070-08	00802526214127
1006071-06	00802526214134
1006071-07	00802526214141
1006071-08	00802526214158
1006072-06	00802526214165
1006072-07	00802526214172
1006072-08	00802526214189

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STOCK NUMBERS AND UPN NUMBERS FOR VIKING OPTIMA™ GUIDING CATHETERS

Stock Number	UPN Number
1006136-06	00802526215209
1006136-07	00802526215216
1006136-08	00802526218507
1006137-06	00802526215223
1006137-07	00802526215230
1006137-08	00802526215247
1006138-06	00802526215254
1006138-07	00802526215261
1006138-08	00802526215278
1006144-06	00802526218514
1006144-07	00802526218521
1006144-08	00802526218538
1006145-06	00802526218545
1006145-07	00802526218552
1006145-08	00802526218569
1006150-06	00802526218576
1006150-07	00802526218583
1006150-08	00802526215285
1006151-06	00802526218590
1006151-07	00802526215292
1006151-08	00802526215308
1006154-06	00802526215315
1006154-07	00802526215322
1006154-08	00802526215339
1006155-06	00802526215346
1006155-07	00802526215353
1006155-08	00802526215360
1006163-06	00802526218729
1006163-07	00802526218736
1006163-08	00802526218743
1006164-06	00802526218750
1006164-07	00802526215377
1006164-08	00802526218767
1006165-06	00802526218774
1006165-07	00802526215384
1006165-08	00802526215391
1006166-06	00802526215407
1006166-07	00802526215414
1006166-08	00802526218781
1006167-06	00802526218798
1006167-07	00802526218804
1006167-08	00802526218811
1006168-06	00802526218828
1006168-07	00802526218835
1006168-08	00802526215421
1006169-06	00802526215438
1006169-07	00802526215445

Stock Number	UPN Number
1006169-08	00802526215452
1006170-06	00802526215469
1006170-07	00802526215476
1006170-08	00802526215483
1006171-06	00802526218842
1006171-07	00802526218859
1006171-08	00802526215490
1006172-06	00802526218866
1006172-07	00802526218873
1006172-08	00802526215506
1006173-06	00802526215513
1006173-07	00802526215520
1006173-08	00802526215537
1006174-06	00802526215544
1006174-07	00802526215551
1006174-08	00802526215568
1006177-06	00802526218910
1006177-07	00802526215605
1006177-08	00802526218927
1006178-06	00802526215612
1006178-07	00802526215629
1006178-08	00802526215636
1006181-06	00802526215674
1006181-07	00802526215681
1006181-08	00802526215698
1006182-06	00802526215704
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1006241-07	00802526216268
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STOCK NUMBERS AND UPN NUMBERS FOR VIKING OPTIMA™ GUIDING CATHETERS

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STOCK NUMBERS AND UPN NUMBERS FOR VIKING™ GUIDING CATHETERS

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STOCK NUMBERS AND UPN NUMBERS FOR VIKING™ GUIDING CATHETERS

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STOCK NUMBERS AND UPN NUMBERS FOR VIKING™ GUIDING CATHETERS

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1001994-08	00802526171154
1001994-09	00802526173202
1001996-06	00802526167256
1001996-07	00802526169106
1001996-08	00802526171178
1001996-09	00802526173226
1001996-10	00802526175084
1001997-06	00802526167263

PRINT PAGE

STOCK NUMBERS AND UPN NUMBERS FOR VIKING™ GUIDING CATHETERS

Stock Number	UPN Number
1001997-07	00802526169113
1001997-08	00802526171185
1001997-09	00802526173233
1001998-06	00802526167270
1001998-07	00802526169120
1001998-08	00802526171192
1001998-09	00802526173240
1001998-10	00802526175107
1001999-06	00802526167287
1001999-07	00802526169137
1001999-08	00802526171208
1001999-09	00802526173257
1002001-06	00802526167300
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1002001-08	00802526171222
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1002003-06	00802526167324
1002003-07	00802526169175
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1002034-09	00802526173608
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1002035-09	00802526173615
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1002037-08	00802526171581
1002037-09	00802526173639
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1002038-08	00802526171598
1002038-09	00802526173646
1002039-06	00802526167683
1002039-07	00802526169533
1002039-08	00802526171604
1002039-09	00802526173653
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1002056-07	00802526169700
1002056-08	00802526171772
1002056-09	00802526173820

RX CROSSSAIL™

Coronary Dilatation Catheter

℞ ONLY

INDICATIONS

The CROSSSAIL™ Coronary Dilatation Catheter is indicated for:

a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction

CONTRAINDICATIONS

The CROSSSAIL™ Coronary Dilatation Catheter is not intended to be used:

- in an unprotected left main coronary artery.
- to treat coronary artery spasm in the absence of a significant stenosis.

WARNINGS

This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent over pressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Use the catheter prior to the “Use By” date specified on the package.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If there is resistance, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

Never apply extreme bending or twisting force to any section of the catheter in order to prevent kinking or damage/separation of the shaft.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60-85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

In the event of catheter damage/separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

This catheter is not intended for use with stents.

PRECAUTIONS

If the surface of the CROSSSAIL™ Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the CROSSSAIL™ Coronary Dilatation Catheter into the coil dispenser after procedural use.

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.

The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty (PTCA).

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

The design and construction of these catheters do not provide the user with distal pressure monitoring capability.

With 4.5 mm and 5.0 mm balloon dilatation catheters, some increased resistance may be noted upon insertion or withdrawal into or out of the guiding catheter. Choosing a larger guiding catheter size may minimize this.

ADVERSE EVENTS

Possible adverse events include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

HIGHSAIL™

Coronary Dilatation Catheter

℞ ONLY

INDICATIONS

The HIGHSAIL™ Coronary Dilatation Catheter is indicated for:

a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction.

c) balloon dilatation of the ACS MULTI-LINK® Stent, ACS MULTI-LINK DUET' Stent, ACS MULTI-LINK TRISTAR™ Stent, ACS MULTI-LINK TETRA™ Stent or ACS MULTI-LINK ULTRA™ Stent after implantation. This indication applies to the following balloon sizes and stent lengths:

Balloon Size	Stent Length
2.5 – 4.0 mm x 8 mm	8 mm
2.5 – 5.0 mm x 13 mm	13 mm
2.5 – 4.0 mm x 15 mm	15 mm
2.5 – 5.0 mm x 18 mm	18 mm
2.5 – 4.0 mm x 23 mm	23 mm
2.5 – 5.0 mm x 28 mm	28 mm
3.0 – 4.0 mm x 33 mm	33 mm
3.0 – 3.5 mm x 33 mm	35 mm
3.0 – 4.0 mm x 33 mm	38 mm

CONTRAINDICATIONS

The HIGHSAIL™ Coronary Dilatation Catheter is not intended to be used:

- in an unprotected left main coronary artery.
- to treat coronary artery spasm in the absence of a significant stenosis.

WARNINGS

This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of in *vitro testing*. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent over pressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Use the catheter prior to the "Use By" date specified on the package.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If there is resistance, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

Never apply extreme bending or twisting force to any section of the catheter in order to prevent kinking or damage/separation of the shaft.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60-85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

In the event of catheter damage/separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

PRECAUTIONS

This device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and/or percutaneous transluminal angioplasty (PTA).

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

If the surface of the HIGHSAIL™ Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the HIGHSAIL™ Coronary Dilatation Catheter into the coil dispenser after procedural use.

With 4.5 mm and 5.0 mm balloon dilatation catheters, some increased resistance may be noted upon insertion or withdrawal into or out of the guiding catheter. Choosing a larger guiding catheter size may minimize this.

ADVERSE EVENTS

Possible adverse events include, but are not limited to, the following:

- acute myocardial infarction
- arrhythmias, including ventricular fibrillation
- arteriovenous fistula
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury
- death
- drug reactions, allergic reaction to contrast medium
- embolism

POWERSAIL™

Coronary Dilatation Catheter

℞ ONLY

INDICATIONS

The POWERSAIL™ Coronary Dilatation Catheter is indicated for:

a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction.

c) balloon dilatation of the ACS MULTI-LINK® Stent, ACS MULTI-LINK DUET™ Stent, ACS MULTI-LINK TRISTAR™ Stent, ACS MULTI-LINK TETRA™ Stent or ACS MULTI-LINK ULTRA™ Stent after implantation. This indication applies to the following balloon sizes and stent lengths:

Balloon Size	Stent Length
2.5 – 4.0 mm x 8 mm	8 mm
2.5 – 5.0 mm x 13 mm	13 mm
2.5 – 4.0 mm x 15 mm	15 mm
2.5 – 5.0 mm x 18 mm	18 mm
2.5 – 4.0 mm x 23 mm	23 mm
2.5 – 5.0 mm x 28 mm	28 mm
3.0 – 4.0 mm x 33 mm	33 mm
3.0 – 3.5 mm x 33 mm	35 mm
3.0 – 4.0 mm x 33 mm	38 mm

CONTRAINDICATIONS

The POWERSAIL™ Coronary Dilatation Catheter is not intended to be used:

- in an unprotected left main coronary artery.
- to treat coronary artery spasm in the absence of a significant stenosis.

WARNINGS

This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent over pressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Use the catheter prior to the “Use By” date specified on the package.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If there is resistance, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

Never apply extreme bending or twisting force to any section of the catheter in order to prevent kinking or damage/separation of the shaft.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60-85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

In the event of catheter damage/separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

PRECAUTIONS

This device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and/or percutaneous transluminal angioplasty (PTA).

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

The design and construction of these catheters do not provide the user with distal pressure monitoring capability.

If the surface of the POWERSAIL™ Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the POWERSAIL™ Coronary Dilatation Catheter into the coil dispenser after procedural use.

With 4.5 mm and 5.0 mm balloon dilatation catheters, some increased resistance may be noted upon insertion or withdrawal into or out of the guiding catheter. Choosing a larger guiding catheter size may minimize this.

ADVERSE EVENTS

Possible adverse events include, but are not limited to, the following:

- acute myocardial infarction
- arrhythmias, including ventricular fibrillation
- arteriovenous fistula
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury
- death
- drug reactions, allergic reaction to contrast medium
- embolism
- hemorrhage or hematoma
- hypo/hypertension
- infection
- restenosis of the dilated vessel
- total occlusion of the coronary artery or bypass graft
- unstable angina

OTW OPENSAIL™

Coronary Dilatation Catheter

℞ ONLY

INDICATIONS

The OPENSAIL™ Coronary Dilatation Catheter is indicated for:

a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction

CONTRAINDICATIONS

The OPENSAIL™ Coronary Dilatation Catheter is not intended to be used:

- in an unprotected left main coronary artery.
- to treat coronary artery spasm in the absence of a significant stenosis.

WARNINGS

This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of in *vitro testing*. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent over pressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Use the catheter prior to the "Use By" date specified on the package.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If there is resistance, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

Never apply extreme bending or twisting force to any section of the catheter in order to prevent kinking or damage/separation of the shaft.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60-85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

In the event of catheter damage/separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

This catheter is not intended for use with stents.

PRECAUTIONS

If the surface of the OPENSAIL™ Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the OPENSAIL™ Coronary Dilatation Catheter into the coil dispenser after procedural use.

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.

The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty (PTCA).

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

With 4.5 mm and 5.0 mm balloon dilatation catheters, some increased resistance may be noted upon insertion or withdrawal into or out of the guiding catheter. Choosing a larger guiding catheter size may minimize this.

ADVERSE EVENTS

Possible adverse events include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

ACS RX ESPRIT™

Coronary Dilatation Catheter (Perfusion)

℞ ONLY

INDICATIONS

The ACS RX ESPRIT™ Coronary Dilatation Catheter is indicated for:

a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction.

CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent over pressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Use the catheter prior to the "Use By" date specified on the package.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If there is resistance, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

Never apply extreme bending or twisting force to any section of the catheter in order to prevent kinking or damage/separation of the shaft.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60-85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.

In the event of catheter damage/separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

This catheter is not intended for use with stents.

PRECAUTIONS

Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

The design and construction of these catheters do not provide the user with distal pressure monitoring capability.

To obtain optimal flow through the dilatation catheter during balloon inflations, it is recommended that the dilatation catheter be flushed with a solution of heparinized normal saline every 5 minutes during inflations exceeding 5 minutes in duration.

Balloon inflation pressures greater than 8 atm, 8 bar or 120 psi for the ACS RX ESPRIT™ Coronary Dilatation Catheter may compromise blood flow through the dilatation catheter during inflation.

ADVERSE EVENTS

Possible adverse events include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

HI-TORQUE®

Guide Wires

℞ ONLY

INDICATIONS

Refer to the device label for any additional product specific indications which may apply.

CONTRAINDICATIONS

ACS HI-TORQUE® Guide Wires are not intended for use in the cerebral vasculature.

Refer to the device label for any additional product specific contraindications which may apply.

WARNINGS

This device is designed and intended for ONE TIME USE ONLY. DO NOT RESTERILIZE AND/OR REUSE.

Observe guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip; otherwise, vessel trauma may occur. In addition, during catheter manipulations, ensure that the distal guide wire tip is visible.

Torquing a guide wire against resistance may cause guide wire damage and/or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw or torque a guide wire which meets resistance. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of the guide wire tip. If guide wire tip prolapse is observed or used for positioning, do not allow the tip to remain in a prolapsed condition; otherwise, damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.

If the guide wire tip becomes entrapped within the vasculature, DO NOT TORQUE THE GUIDE WIRE.

Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform exchanges slowly to prevent air entry and/or trauma.

When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit of the device. Use the radiopaque marker of the interventional device to confirm position.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged guide wires. Using a damaged guide wire may result in vessel damage and/or inaccurate torque response.

Confirm the compatibility of the guide wire diameter with the interventional device before actual use.

Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

Never attach the torque device to the modified portion of the proximal end of the extendable guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC® Guide Wire Extension.

ACS HI-TORQUE® Guide Wires with hydrophilic coating: Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire in a metal cannula or sharp-edged object.

VIKING OPTIMA™

Guiding Catheter

℞ ONLY

INDICATIONS:

The Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced.

CONTRAINDICATIONS:

There are no known contraindications for this device.

WARNINGS:

- This device is distributed STERILE, NON-PYROGENIC and is intended for one-time use only. Do NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate processing.
- The user should not place sideholes in the shaft of the guiding catheter. Use of hospital instruments to puncture the shaft may lead to thrombogenesis or failure of shaft integrity.
- When this guiding catheter is in the body, it should be manipulated while under high-quality fluoroscopic observation.

PRECAUTIONS:

- Prior to use, the guiding catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Guiding catheters should only be used by physicians trained in procedures requiring percutaneous catheter introduction.
- Appropriate anticoagulation of the patient is indicated with the use of this device.

VIKING™

Guiding Catheter

℞ ONLY

INDICATIONS:

The Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced.

CONTRAINDICATIONS:

There are no known contraindications for this device.

WARNINGS:

- This device is distributed STERILE, NON-PYROGENIC and is intended for one-time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and risk of inappropriate sterilization and cross contamination.
- Side holes should not be placed in the shaft of the guiding catheter by the user. Puncturing the shaft of the guiding catheter with hospital instruments may lead to thrombogenesis or failure of shaft integrity.
- When this catheter is in the body, it should be manipulated while under high-quality fluoroscopic observation.

PRECAUTIONS:

- Prior to use, the guiding catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Guiding catheters should only be used by physicians trained in procedures requiring percutaneous catheter introduction.
- Appropriate anticoagulation of the patient is indicated with the use of this device.

TOURGUIDE™

10F Guiding Catheter

℞ ONLY

INDICATIONS

The Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS

This device is distributed STERILE, NON-PYROGENIC and is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and risk of inappropriate sterilization and cross contamination.

Sideholes should not be placed in the shaft of the guiding catheter by the user. Puncturing the shaft of the guiding catheter with hospital instruments may lead to thrombogenesis or failure of shaft integrity.

When this catheter is in the body, it should be manipulated while under high-quality fluoroscopic observation.

PRECAUTIONS

Prior to use, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

Guiding catheters should be used only by physicians trained in procedures requiring percutaneous catheter introduction.

Appropriate anticoagulation of the patient is indicated with the use of this device.

COPILOT®

Bleedback Control Valve

℞ ONLY

INDICATIONS

The COPILOT® Bleedback Control Valve is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter < .096" during interventional procedures.

CONTRAINDICATIONS

The COPILOT® Bleedback Control Valve is not intended for use with pressure injections > 400 psi.

WARNINGS

This device is intended for one time use only. Do NOT resterilize and/or reuse.

Do not inject any fluid if air bubbles are visible within the COPILOT® Bleedback Control Valve.

To prevent damage to a balloon, it must be completely deflated during advancement/withdrawal through the COPILOT® Bleedback Control Valve.

Failure to depress the cap prior to inserting a guide wire introducer could cause seal damage resulting in leakage and/or particulate embolization.

Failure to open the BBC seal and the clamp seal prior to inserting/withdrawing a diagnostic/interventional device could cause damage to the diagnostic/interventional device.

Power injection at pressures greater than 400 psi could result in leakage or detachment of components.

Care should be taken to avoid overtightening the clamp seal, as this may compromise the integrity of the diagnostic/interventional device lumen.

PRECAUTIONS

Prior to use, inspect the COPILOT® Bleedback Control Valve for any damage. Do not use a damaged COPILOT® Bleedback Control Device.

20/20 PRIORITY PACK®

Accessory Kit with COPILOT®

20/30 PRIORITY PACK®

Accessory Kit with COPILOT®

℞ ONLY

INTENDED USE

The intended use for the four disposable devices in the Accessory Kit are as follows:

20/20 INDEFLATOR® Inflation Device / 20/30 INDEFLATOR® Inflation Device — The Inflation Device is recommended for use during vascular procedures in conjunction with interventional devices such as balloon dilatation catheters to create and monitor pressure in the balloon.

COPILOT® Bleedback Control Valve — The COPILOT® Bleedback Control Valve is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter < .096" during interventional procedures.

Guide Wire Introducer — The Guide Wire Introducer is recommended for use during vascular procedures in conjunction with interventional devices and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to assist with the introduction of the guide wire.

Torque Device — The Torque Device is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to facilitate steering the guide wire within the vascular anatomy.

CONTRAINDICATIONS

The COPILOT® Bleedback Control Valve is not intended for use with pressure injections > 400 psi.

WARNINGS

The contents of this kit are designed for one (1) use only. DO NOT RESTERILIZE AND/OR REUSE.

Use only with radiopaque inflation medium recommended by the interventional device manufacturer.

The in vivo interventional device inflation pressure should not exceed the maximum inflation pressure recommended by the manufacturer of the device.

Corrosion and/or contrast medium precipitation may cause components of the device to malfunction and/or cause complications if reused.

Do not inject any fluid if air bubbles are visible within the COPILOT® Bleedback Control Valve.

To prevent damage to a balloon, it must be completely deflated during advancement/withdrawal through the COPILOT® Bleedback Control Valve.

Failure to depress the COPILOT® cap prior to inserting a guide wire introducer could cause seal damage resulting in leakage and/or particulate embolization.

Failure to open the COPILOT® BBC seal and the clamp seal prior to inserting/withdrawing a diagnostic/interventional device could cause damage to the diagnostic/interventional device.

Power injection at pressures greater than 400 psi could result in leakage or detachment of COPILOT® components.

Care should be taken to avoid overtightening the COPILOT® clamp seal, as this may compromise the integrity of the diagnostic/interventional device lumen.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

GUIDE WIRE ACCESSORY KIT

Accessory Kit with COPILOT®

℞ ONLY

INTENDED USE

The intended use for the three disposable devices in the Guide Wire Accessory Kit are as follows:

COPILOT® Bleedback Control Valve — The COPILOT® Bleedback Control Valve is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter < .096" during interventional procedures.

Guide Wire Introducer —The Guide Wire Introducer is recommended for use during vascular procedures in conjunction with interventional devices and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to assist with the introduction of the guide wire.

Torque Device — The Torque Device is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to facilitate steering the guide wire within the vascular anatomy.

CONTRAINDICATIONS

The COPILOT® Bleedback Control Valve is not intended for use with pressure injections > 400 psi.

WARNINGS

The contents of this kit are designed for one (1) use only. DO NOT RESTERILIZE AND/OR REUSE.

Do not inject any fluid if air bubbles are visible within the COPILOT® Bleedback Control Valve.

To prevent damage to a balloon, it must be completely deflated during advancement/withdrawal through the COPILOT® Bleedback Control Valve.

Failure to depress the COPILOT® cap prior to inserting a guide wire introducer could cause seal damage resulting in leakage and/or particulate embolization.

Failure to open the COPILOT® BBC seal and the clamp seal prior to inserting/withdrawing a diagnostic/interventional device could cause damage to the diagnostic/interventional device.

Power injection at pressures greater than 400 psi could result in leakage or detachment of COPILOT® components.

Care should be taken to avoid overtightening the COPILOT® clamp seal, as this may compromise the integrity of the diagnostic/interventional device lumen.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

20/20 PRIORITY PACK™

Accessory Kit

℞ ONLY

INTENDED USE

The 20/20 PRIORITY PACK™ Accessory Kit is recommended for use during cardiovascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices). The 20/20 INDEFLATOR® Indeflation Device is recommended for use in conjunction with balloon catheters.

WARNINGS

Use only the radiopaque inflation medium recommended by the interventional device manufacturer.

The *in vivo* interventional device inflation pressure should not exceed the maximum inflation pressure recommended by the manufacturer of the device.

The contents of this pack are designed for (1) one time use only. DO NOT RESTERILIZE AND/OR REUSE. Corrosion and/or contrast medium precipilation may cause components of the 20/20 INDEFLATOR® Inflation Device to malfunction and/or cause complications if reused.

It is important that the knurled knob on the Rotating Hemostatic Valve be closed tightly to prevent blood leakage around the shaft of the device, yet not so tight as to restrict the flow of fluid (i.e., contrast medium) through the device.

Do not inject any fluid if air bubbles are visible within the Rotating Hemostatic Valve.

During insertion and removal of inflatable devices through the valve, the balloon must be completely deflated to enable it to safely and easily traverse the Rotating Hemostatic Valve.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

20/30 PRIORITY PACK™

Accessory Kit

℞ ONLY

INTENDED USE

The 20/30 PRIORITY PACK™ Accessory Kit is recommended for use during cardiovascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices). The 20/30 INDEFLATOR™ Indeflation Device is recommended for use in conjunction with balloon catheters.

WARNINGS

Use only the radiopaque inflation medium recommended by the interventional device manufacturer.

The *in vivo* interventional device inflation should not exceed the maximum inflation pressure recommended by the manufacturer of the device.

The contents of this pack are designed for one time use only. DO NOT RESTERILIZE AND/OR REUSE. Corrosion and/or contrast medium precipitation may cause components of the 20/30 INDEFLATOR™ Inflation Device to malfunction and/or cause complications if reused.

It is important that the knurled knob on the Rotation Hemostatic Valve be closed tightly to prevent blood leakage around the shaft of the device, yet not so tight as to restrict the flow of fluid (i.e. contrast medium) through the device.

Do not inject any fluid if air bubbles are visible within the Rotating Hemostatic Valve.

During insertion and removal of inflatable devices through the valve, the balloon must be completely deflated to enable it to safely and easily traverse the Rotating Hemostatic Valve.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

GUIDE WIRE ACCESSORY KIT

℞ ONLY

INTENDED USE

The Guide Wire Accessory Kit is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheter, atherectomy devices, stent delivery systems, intravascular ultrasound devices).

WARNINGS

The contents of this kit are designed for one time use only. DO NOT RESTERILIZE AND/OR REUSE.

It is important that the knurled knob on the Rotation Hemostatic Valve be closed tightly to prevent blood leakage around the shaft of the device, yet not so tight as to restrict the flow of fluid (i.e. contrast medium) through the device.

Do not inject any fluid if air bubbles are visible within the Rotating Hemostatic Valve.

During insertion and removal of inflatable devices through the valve, the balloon must be completely deflated to enable it to safely and easily traverse the Rotating Hemostatic Valve.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

20/20 INDEFLATOR®

Inflation Device

℞ ONLY

WARNINGS

Use only with radiopaque inflation medium recommended by the dilatation catheter manufacturer.

This device is intended for one (1) use only. Corrosion and/or contrast medium precipitation may cause components of the device to malfunction and/or cause complications if reused.

The *in vivo* dilatation catheter inflation pressure should not exceed the maximum inflation pressure recommended by the manufacturer of the dilatation catheter.

Refer to the dilatation catheter labeling for intended use, contraindications, and potential complications associated with the use of dilatation catheters in PTCA and/or PTA.

20/30 INDEFLATOR™

Inflation Device

℞ ONLY

INTENDED USE

The 20/30 INDEFLATOR™ Indeflation Device is recommended for use during vascular procedures in conjunction with interventional devices such as balloon dilatation catheter to create and monitor pressure in the balloon.

WARNINGS

Use only with radiopaque inflation medium recommended by the interventional device manufacturer.

The *in vivo* interventional device inflation should not exceed the maximum inflation pressure recommended by the manufacturer of the device.

The 20/30 INDEFLATOR™ Inflation Device is designed for one time use only. DO NOT RESTERILIZE AND/OR REUSE. Corrosion and/or contrast medium precipitation may cause components of the device to malfunction and/or cause complications if reused.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

DUOSTAT®

Rotating Hemostatic Valve

℞ ONLY

INDICATION AND USAGE:

The DUOSTAT, Hemostatic Valve is recommended for maintaining a fluid-tight seal around a dilatation catheter and a guide wire during percutanious transluminal angioplasty.

WARNINGS:

Do not inject any fluid if air bubbles are visible within the valve. First, aspirate the valve to remove the air, then flush the valve with normal saline as described in the "Information for Use" section. During insertion and removal through the valve, the balloon must be completely deflated to enable it to safely and easily traverse the adapter.

GUIDE WIRE INTRODUCER

℞ ONLY

INTENDED USE

The Guide Wire Introducer is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g. balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to assist with the introduction of the guide wire.

WARNINGS

• This device is designed for one time use only. DO NOT RESTERILIZE AND/OR REUSE.

FUNNEL INTRODUCER

℞ ONLY

INDICATION AND USAGE

This device is intended to facilitate the introduction of fixed wire and semimoveable wire dilatation catheters into hemostatic valves or other Tuohy-Borst type hemostatic adaptors.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

TORQUE DEVICE

℞ ONLY

INTENDED USE:

The Torque Device is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to facilitate steering of the guide wire within the vascular anatomy.

PRECAUTIONS

Refer to the appropriate device labeling for intended use, contraindications, and potential complications associated with the use of vascular interventional and/or diagnostic devices.

DIRECTIONAL CORONARY ATHERECTOMY SYSTEMS

PRINT SECTION

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ATHEROCATH-BANTAM®

Coronary Atherectomy Catheter

Part Number	UPN Number	Description	Housing Size (F)	Window Length (mm)
1000464	00802526176265	AtheroCath BANTAM™ Coronary Atherectomy Catheter	5	9
1000465	00802526176272	AtheroCath BANTAM™ Coronary Atherectomy Catheter	6	9
1000466	00802526176296	AtheroCath BANTAM™ Coronary Atherectomy Catheter	7	9

ATHEROCATH GTO®

Coronary Atherectomy Catheter

Part Number	Stock Number	UPN Number	Description	Housing Size (F)	Window Length (mm)
GTO-50-09	20353-01	00802526176388	AtheroCath GTO® Coronary Atherectomy Catheter	5	9
GTO-60-09	20354-01	00802526176395	AtheroCath GTO® Coronary Atherectomy Catheter	6	9
GTO-70-09	20355-01	00802526176418	AtheroCath GTO® Coronary Atherectomy Catheter	7	9

SCA-EX™

Coronary Atherectomy Catheter

Stock Number	Part Number	UPN Number	Description	Housing Size (F)	Window Length (mm)
EX-60-09	20341-01	00802526176746	SCA-EX™ Coronary Atherectomy Catheter	6	9
EX-70-09	20342-01	00802526176760	SCA-EX™ Coronary Atherectomy Catheter	7	9
EX-7GRF-09	20361-01	00802526176661	SCA-EX™ Graft Coronary Atherectomy Catheter	7	9

SCA-EX™ SHORTCUTTER

Coronary Atherectomy Catheter

Stock Number	Part Number	UPN Number	Description	Housing Size (F)	Window Length (mm)
EX-50-05	20343-01	00802526176661	SCA-EX™ ShortCutter Coronary Atherectomy Catheter	5	5
EX-60-05	20344-01	00802526176685	SCA-EX™ ShortCutter Coronary Atherectomy Catheter	6	5
EX-70-05	20345-01	00802526176708	SCA-EX™ ShortCutter Coronary Atherectomy Catheter	7	5

ATHERECTOMY GUIDING CATHETERS

LEFT 10 French

JL 4.0

Stock Number	Part Number	UPN Number	Description	Shaft OD (F)	Usable Length (cm)	Lumen ID (in)
GC-1080-JL3.5SH	20300-01	00802526160356	Judkins Left 3.5	10	100	.104
GC-1080-JL4.0SH	20281-01	00802526160363	Judkins Left 4.0	10	100	.104
GC-1080-JL4.5SH	20282-01	00802526160387	Judkins Left 4.5	10	100	.104
GC-1080-JL5.0SH	20301-01	00802526160394	Judkins Left 5.0	10	100	.104
GC-1080-JLGRFSH	20283-01	00802526160400	Judkins Left Graft	10	100	.104

RIGHT 9.5 French

JR 4.0ST

Stock Number	Part Number	UPN Number	Description	Shaft OD (F)	Usable Length (cm)	Lumen ID (in)
GC-9580-JR4.0STSH	20303-01	00802526160530	Judkins Right 4.0 Short Tip	9.5	100	.104
GC-9580-JR4.0SH	20264-01	00802526160516	Judkins Right 4.0 Standard	9.5	100	.104
GC-9580-JR4.0IFSH	20271-01	00802526160523	Judkins Right 4.0 Inferior	9.5	100	.104
GC-9580-JRGRFSH	20268-01	00802526160554	Judkins Right Graft	9.5	100	.104
GC-9580-HSSH	20305-01	00802526160479	Hockey Stick	9.5	100	.104
GC-9580-MPSH	20304-01	00802526160493	Multipurpose	9.5	100	.104

ATHERECTOMY GUIDING CATHETERS

90 cm LEFT 10 French

JLGRF

Stock Number	Part Number	UPN Number	Description	Shaft OD (F)	Usable Length (cm)	Lumen ID (in)
G-90-10-JLGRF	20335-01	00802526160417	Judkins Left Graft	10	90	.104

90 cm RIGHT 9.5 French

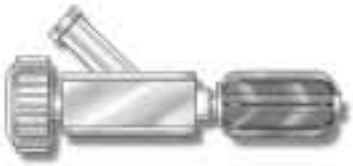
JR 4.0ST

Stock Number	Part Number	UPN Number	Description	Shaft OD (F)	Usable Length (cm)	Lumen ID (in)
G-90-JR4.0ST	20338-01	00802526160547	Judkins Right 4.0 Short Tip	9.5	90	.104
G-90-JRGRF	20339-01	00802526160561	Judkins Right Graft	9.5	90	.104
G-90-HS	20337-01	00802526160486	Hockey stick	9.5	90	.104
G-90-MP	20336-01	00802526160509	Multipurpose	9.5	90	.104

ATHERECTOMY ACCESSORIES

Motor Drive unit

Stock Number	Part Number	UPN Number	Description
CA4100	20164-03	00802526160608	Motor Drive Unit



Rotating Hemostatic Valve

Stock Number	Part Number	UPN Number	Description	Amount per box
CA3100	20165-01	00802526160615	Rotating Hemostatic Valve	2

7 French Guiding Catheter Introducer

Stock Number	Part Number	UPN Number	Description
CA2100	20272-01	00802526160592	7 French Guiding Catheter Introducer

8 French Guiding Catheter Introducer

Stock Number	Part Number	UPN Number	Description
CA2200	20166-01	00802526160585	8 French Guiding Catheter Introducer

LP-90™ Low Pressure Inflation Device

Stock Number	Part Number	UPN Number	Description
CA6000	20328-01	00802526160578	LP-90™ Low Pressure Inflation Device

RGA Pouch Kit

Stock Number	Part Number	Description
RGA1	36088-01	RGA Pouch Kit

ATHEROCATH-BANTAM®

Atherectomy Catheter

℞ ONLY

INDICATIONS

Directional Coronary Atherectomy (DCA) with the ATHEROCATH-BANTAM® Atherectomy Catheter increases the luminal diameter of coronary arteries by mechanically shaving and removing atherosclerotic material from the diseased vessel.

DCA with the ATHEROCATH-BANTAM® Atherectomy Catheter. indicated in patients with coronary artery disease accessible to the ATHEROCATH-BANTAM® Atherectomy Catheter. The ATHEROCATH-BANTAM® Atherectomy Catheter can be used alone or in conjunction with percutaneous transluminal coronary angioplasty (PTCA). Generally, lesions most accessible to DCA are those in the proximal or mid-portion of coronary arteries. Patients selected for DCA should be acceptable candidates for coronary artery bypass graft (CABG) surgery and should be categorized in one of the following groups:

- Patients with single vessel atherosclerotic coronary artery disease with a stenosis that is discrete and subtotal;
- Patients with multiple vessel coronary artery disease that in the physician's judgment does not pose undue risk to the patient;
- Certain patients who have had prior CABG surgery and who have a stenosis or restenosis of the graft;
- Certain patients who have had prior PTCA and who have a restenosis of the native vessel.

CONTRAINDICATIONS

The ATHEROCATH-BANTAM® Atherectomy Catheter is NOT intended to be used with:

- Patients with left main coronary artery disease where an interrupted blood flow would pose undue patient risk.
- Patients with lesions located in or distal to heavily calcified and/or tortuous coronary vessels.
- Patients with calcified aorto-ostial lesions.
- Patients who are not suitable candidates for CABG surgery.
- Patients with totally obstructed coronary arteries where a guidewire cannot be advanced through the occlusion.
- Patients with permanent intracoronary stents within the target lesion vessel.

WARNING:

The.ATHEROCATH-BANTAM® Atherectomy Catheter and ancillary Guidant/Vascular Intervention Atherectomy System components are designed and intended for single patient use only. Single patient is defined as one complete procedure on one patient. Do not resterilize and/or reuse these products. Reuse will result in product malfunction, transmission of blood-transmitted diseases and/or other serious complications.

The ATHEROCATH-BANTAM® Atherectomy Catheter should be used only with a Guidant/Vascular Intervention Low Pressure Inflation Device or other manufacturer's inflation device with pressure monitoring capability. Failure to do so may result in balloon rupture due to over-pressurization and, if so, will consequently injure the vessel.

The ATHEROCATH-BANTAM® Atherectomy Catheter should be performed only at hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. A cardiac surgery team should be on alert while atherectomy is being performed.

Appropriate anticoagulant and coronary vasodilator therapy must be used during this procedure.

PRECAUTIONS

Guidant/Vascular Intervention requires that at least one physician from each hospital desiring to use Simpson Coronary AtheroCath (SCA) catheters receive training through the Guidant/Vascular Intervention Sponsored Directional Coronary Atherectomy (DCA) Training Course.

Guidant/Vascular Intervention recommends that other physicians desiring to use DCA catheters receive training through at least one of the following:

- Guidant/Vascular Intervention sponsored DCA training course,
- attendance at other professional symposia providing training in DCA techniques,
- working with another physician experienced in DCA.

Use only the recommended balloon inflation medium (60% contrast medium full strength, or 76% contrast medium diluted 50:50 with sterile physiologic saline). Never use air or any gaseous medium to inflate the balloon when it is inside the patient. Use of higher concentrations of contrast medium will result in prolonged balloon inflation and deflation times, and prolonged interruption of blood flow.

When the ATHEROCATH-BANTAM® Atherectomy Catheter is inside the patient, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images. Use of this system with inadequate fluoroscopic guidance could result in vessel injury.

Careful inspection prior to use should verify that the ATHEROCATH-BANTAM® Atherectomy Catheter has not been damaged in shipment and that its size, shape and condition are suitable for the specific procedure for which it is to be used. Use of an Inappropriately sized or damaged catheter could cause vessel injury.

Note the product "Use By" date.

POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) may be associated with the use of a coronary atherectomy device in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of lesion segment
- Spasm
- Stroke/cerebrovascular accident
- Total Occlusion of coronary artery

ATHEROCATH-GTO®

Atherectomy Catheter

℞ ONLY

INDICATIONS FOR USE

Directional Coronary Atherectomy (DCA) with the ATHEROCATH-GTO® catheter increases the luminal diameter of coronary arteries by mechanically shaving and removing atherosclerotic material from the diseased vessel.

DCA with the ATHEROCATH-GTO® catheter is indicated in patients with coronary artery disease accessible to the ATHEROCATH-GTO® catheter. The ATHEROCATH-GTO® catheter can be used alone or in conjunction with percutaneous transluminal coronary angioplasty (PTCA). Generally, lesions most accessible to atherectomy are those in the proximal or mid-portion of coronary vessels. Patients selected for coronary atherectomy should be acceptable candidates for coronary artery bypass graft (CABG) surgery and should be categorized in one of the following groups:

- Patients with single vessel atherosclerotic coronary artery disease with a stenosis that is discrete and subtotal;
- Patients with multiple vessel coronary artery disease that in the physician's judgment does not pose undue risk to the patient;
- Certain patients who have had prior coronary artery bypass graft surgery and who have had a stenosis or restenosis of the graft;
- Certain patients who have had prior PTCA and who have a restenosis of the native vessel.

CONTRAINDICATIONS

The ATHEROCATH-GTO Atherectomy Catheter is NOT intended to be used with:

- Patients with left main coronary artery disease where an interruption of blood flow would pose undue patient risk;
- Patients with lesions located in or distal to heavily calcified and/or tortuous coronary vessels;
- Patients with calcified aorto-ostial lesions;
- Patients who are not suitable candidates for coronary artery bypass graft surgery;
- Patients with totally obstructed coronary arteries where a guide wire cannot be advanced through the occlusion.

WARNINGS

The ATHEROCATH-GTO® Catheter and ancillary Guidant/Vascular Intervention Atherectomy System components are designed and intended for single patient use only. Single patient is defined as one complete procedure on one patient. Do not resterilize and/or reuse these products. Reuse will result in product malfunction, transmission of blood-transmitted diseases and/or serious complications.

The ATHEROCATH-GTO® catheter should be used only with a Guidant/Vascular Intervention Low Pressure Inflation Device or other manufacturer's inflation device with pressure monitoring capability. Failure to do so may result in balloon rupture due to overpressurization and, if so, will consequently injure the vessel.

DCA with the ATHEROCATH-GTO® catheter should be performed only at hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. A cardiac surgery team should be on alert while atherectomy is being performed.

Appropriate anticoagulant and coronary vasodilator therapy must be used during this procedure.

PRECAUTIONS

The AtheroCath-GTO® catheter should be used only by physicians experienced in coronary angioplasty.

Guidant/Vascular Intervention requires that at least one physician from each hospital desiring to use DCA devices receive training through the Guidant/Vascular Intervention-sponsored Directional Coronary Atherectomy (DCA) Training Course.

Guidant/Vascular Intervention recommends that other physicians desiring to use DCA devices receive training through at least one of the following:

- Guidant/Vascular Intervention sponsored DCA training course,
- attendance at other professional symposia providing training in DCA techniques,
- working with another physician experienced in DCA.

Use only the recommended balloon inflation medium (60% contrast medium full strength, or 76% contrast medium diluted 50:50 with sterile physiologic saline). Never use air or any gaseous medium to inflate the balloon when it is inside the patient. Use of higher concentrations of contrast medium will result in prolonged balloon inflation and deflation times, and prolonged interruption of blood flow.

When the ATHEROCATH-GTO® catheter is inside the patient, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images. Use of this system with inadequate fluoroscopic guidance could result in vessel injury.

Careful inspection prior to use should verify that the ATHEROCATH-GTO® catheter has not been damaged in shipment and that its size, shape and condition are suitable for the specific procedure for which it is to be used. Use of an inappropriately sized or damaged catheter could cause vessel injury.

Potential Adverse Events

Adverse events (in alphabetical order) may be associated with the use of a coronary atherectomy device in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of lesion segment
- Spasm
- Stroke/cerebrovascular accident
- Total Occlusion of coronary artery

SIMPSON CORONARY ATHEROCATH® SCA-EX™ SCA-EX SHORTCUTTER™ CATHETERS

℞ ONLY

INDICATIONS FOR USE

Directional Coronary Atherectomy (DCA) with the SCA-EX/SHORTCUTTER™ catheter increases the luminal diameter of coronary arteries by mechanically shaving and removing atherosclerotic material from the diseased vessel.

DCA with the SCA-EX/SHORTCUTTER™ catheter is indicated in patients with coronary artery disease accessible to the SCA-EX/SHORTCUTTER™ catheter. The SCA-EX/SHORTCUTTER™ catheter can be used alone or in conjunction with percutaneous transluminal coronary angioplasty (PTCA). Generally, lesions most accessible to atherectomy are those in the proximal or mid-portion of coronary vessels. Patients selected for coronary atherectomy should be acceptable candidates for coronary artery bypass graft (CABG) surgery and should be categorized in one of the following groups:

- Patients with single vessel atherosclerotic coronary artery disease with a stenosis that is discrete and subtotal;
- Patients with multiple vessel coronary artery disease that in the physician's judgement does not pose undue risk to the patient;
- Certain patients who have had prior coronary artery bypass graft surgery and who have had a stenosis or restenosis of the graft;
- Certain patients who have had prior PTCA and who have a restenosis of the native vessel.

CONTRAINDICATIONS

The SCA-EX/SHORTCUTTER™ Catheter is NOT intended to be used with:

- Patients with left main coronary artery disease where an interruption of blood flow would pose undue patient risk;
- Patients with lesions located in or distal to heavily calcified and/or tortuous coronary vessels;
- Patients with calcified aorto-ostial lesions;
- Patients who are not suitable candidates for coronary artery bypass graft surgery;
- Patients with totally obstructed coronary arteries where a guide wire cannot be advanced through the occlusion.

WARNINGS

The SCA-EX/SHORTCUTTER™ Catheter and ancillary Guidant/Vascular Intervention Atherectomy System components are designed and intended for single patient use only. Single patient is defined as one complete procedure on one patient. Do not resterilize and/or reuse these products. Reuse will result in product malfunction, transmission of blood-transmitted diseases and/or serious complications.

The SCA-EX/SHORTCUTTER™ catheter should be used only with a Guidant/Vascular Intervention Low Pressure Inflation device or other manufacturer's inflation device with pressure monitoring capability. Failure to do so may result in balloon rupture due to overpressurization and, if so, will consequently injure the vessel.

DCA with the SCA-EX/SHORTCUTTER™ catheter should be performed only at hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. A cardiac surgery team should be on alert while atherectomy is being performed.

Appropriate anticoagulant and coronary vasodilator therapy must be used during this procedure.

PRECAUTIONS

The SCA-EX/SHORTCUTTER™ catheter should be used only by physicians experienced in therapeutic cardiovascular catheter techniques.

The SIMPSON CORONARY ATHEROCATH® SCA-EX™ and SCA-EX SHORTCUTTER™ Atherectomy catheters should be used only by physicians experienced in coronary angioplasty.

Guidant/Vascular Intervention requires that at least one physician from each hospital desiring to use SIMPSON CORONARY ATHEROCATH® SCA-EX™ catheters receive training through the Guidant/Vascular Intervention-sponsored Directional Coronary Atherectomy (DCA) Training Course.

Guidant/Vascular Intervention recommends that other physicians desiring to use DCA devices receive training through at least one of the following:

- Guidant/Vascular Intervention sponsored DCA training course
- Attendance at other professional symposia providing training in DCA techniques
- Working with another physician experienced in DCA

Use only the recommended balloon inflation medium (60% contrast medium full strength, or 76% contrast medium diluted 50:50 with sterile physiologic saline). Never use air or any gaseous medium to inflate the balloon when it is inside the patient. Use of higher concentrations of contrast medium will result in prolonged balloon inflation and deflation times, and prolonged interruption of blood flow.

When the SCA-EX/SHORTCUTTER™ catheter is inside the patient, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images. Use of this system with inadequate fluoroscopic guidance could result in vessel injury.

Careful inspection prior to use should verify that the SCA-EX/SHORTCUTTER™ catheter has not been damaged in shipment and that its size, shape and condition are suitable for the specific procedure for which it is to be used. Use of an inappropriately sized or damaged catheter could cause vessel injury.

POTENTIAL ADVERSE EFFECTS

Adverse events (in alphabetical order) may be associated with the use of a coronary atherectomy device in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of lesion segment
- Spasm
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

GUIDE WIRE INTRODUCER

℞ ONLY

INTENDED USE

The Guide Wire Introducer is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g. balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices) to assist with the introduction of the guide wire.

WARNINGS

- This device is designed for one time use only. DO NOT RESTERILIZE AND/OR REUSE.

ROTATING HEMOSTATIC VALVE

℞ ONLY

INDICATION AND USAGE

The Hemostatic Valve is recommended for maintaining a fluid-tight seal around a dilatation catheter during percutaneous transluminal angioplasty.

WARNINGS

The inside diameter of the smallest portion of the valve is 0.096" (2.44 mm).

Do not inject any fluid if air bubbles are visible within the valve. First, aspirate the valve to remove the air, then flush the valve with normal saline as described in the "Information for Use" section.

During insertion and removal through the valve, the balloon must be completely deflated to enable it to safely and easily traverse the adapter.

PERIPHERAL PRODUCTS

PRINT SECTION

PERIPHERAL GUIDE WIRES

HI-TORQUE SPARTACORE™ 14 Guide Wire 97

HI-TORQUE MEMCORE FIRM™ 14 Guide Wire 97

HI-TORQUE STEELCORE™ 18 LT Guide Wire 98

HI-TORQUE STEELCORE™ 18 Guide Wire 98

HI-TORQUE SUPRA CORE 35™ Guide Wire 98

PERIPHERAL GUIDING CATHETERS

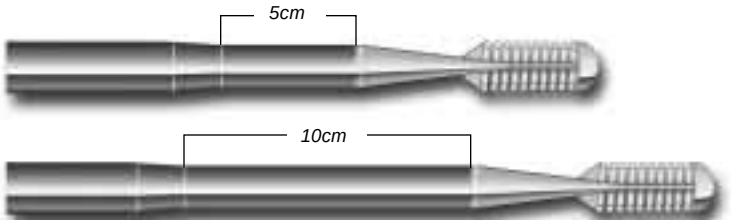
VERIPATH™ Peripheral Guiding Catheter:

- Hockey Stick 99
- Multipurpose 99
- Renal Double Curve 1 99
- Renal Double Curve 99
- LIMA 99

PERIPHERAL CATHETERS

RX VIATRAC™ 14 Peripheral Dilatation Catheter 100–101

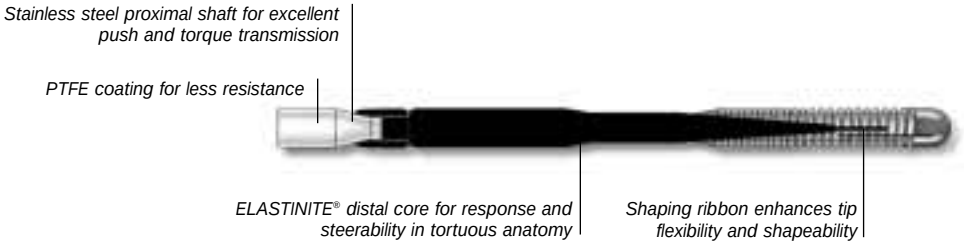
OTW VIATRAC™ 18 Peripheral Dilatation Catheter 102



Available in 5 & 10 cm transition lengths

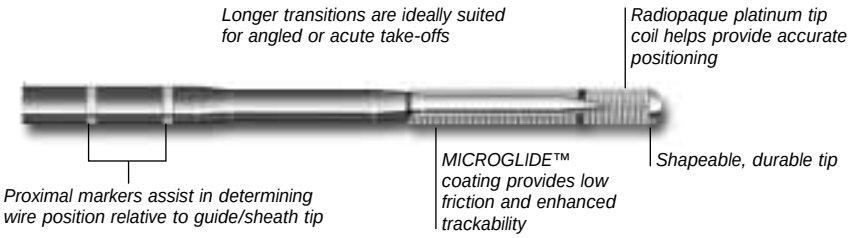
HI-TORQUE SPARTACORE™ 14
Guide Wire

Stock Number	UPN Number	Intermediate Segment Length (cm)	Tip Shape	Wire Length (cm)
1005201	00802526199110	5	Straight	130
1005202	00802526199097	5	Straight	190
1005203	00802526199073	5	Straight	300
1005204	00802526199134	10	Straight	130
1005205	00802526199103	10	Straight	190
1005206	00802526199080	10	Straight	300



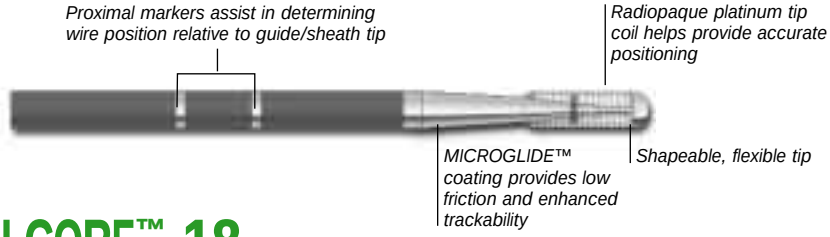
HI-TORQUE MEMCORE FIRM™ 14
Guide Wire

Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1003299-HC	00802526199059	4.5	Straight	130
1003299J-HC	00802526199066	4.5	'J'	130



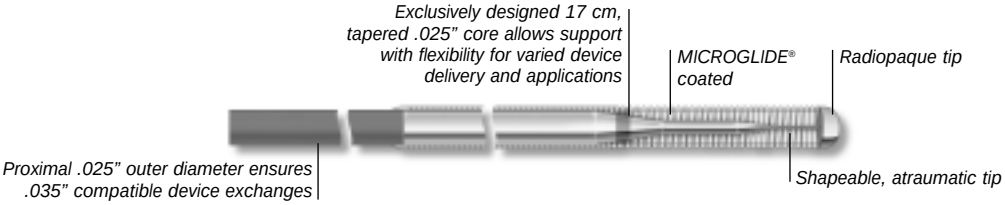
HI-TORQUE STEELCORE™ 18 LT
Guide Wire

Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1007709	00802526221170	5	Straight	190
1007709-J	00802526221200	5	'J'	190
1007710	00802526221187	5	Straight	300
1007710-J	00802526221217	5	'J'	300



HI-TORQUE STEELCORE™ 18
Guide Wire

Stock Number	UPN Number	Tip Radiopacity (cm)	Tip Shape	Wire Length (cm)
1003281	00802526199158	5	Straight	190
1003282	00802526199141	5	Straight	300



HI-TORQUE SUPRA CORE™ 35
Guide Wire

Stock Number	UPN Number	Tip Shape	Wire Length (cm)($)
1002703	00802526199219	Straight	145
1002703-01	00802526199172	Straight	190
1002703-02	00802526199196	Straight	300

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6F Inner Diameter .068″
7F Inner Diameter .078″
8F Inner Diameter .088″

VERIPATH™
Peripheral Guiding Catheter

Hockey Stick

Stock Number	UPN Number	Catheter Shape	Catheter Length (cm)
1005604-06	00802526196898	HS	50
1005604-07	00802526196942	HS	50
1005604-08	00802526196997	HS	50

Multipurpose

Stock Number	UPN Number	Catheter Shape	Catheter Length (cm)
1005591-06	00802526196850	MP	50
1005591-07	00802526196904	MP	50
1005591-08	00802526196959	MP	50

Renal Double Curve 1

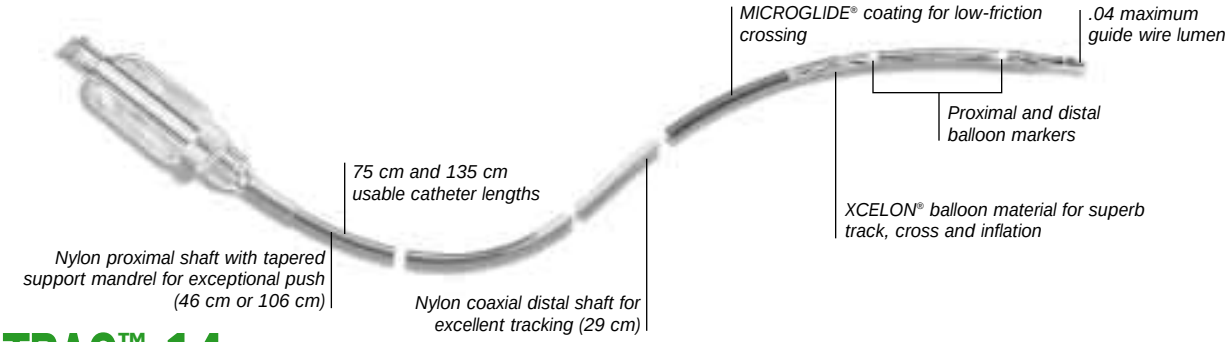
Stock Number	UPN Number	Catheter Shape	Catheter Length (cm)
1005592-06	00802526196867	RDC1	50
1005592-07	00802526196911	RDC1	50
1005592-08	00802526196966	RDC1	50

Renal Double Curve

Stock Number	UPN Number	Catheter Shape	Catheter Length (cm)
1005594-06	00802526196874	RDC	50
1005594-07	00802526196928	RDC	50
1005594-08	00802526196973	RDC	50

LIMA

Stock Number	UPN Number	Catheter Shape	Catheter Length (cm)
1005597-06	00802526196881	LIMA	50
1005597-07	00802526196935	LIMA	50
1005597-08	00802526196980	LIMA	50



RX VIATRAC™ 14

Peripheral Dilatation Catheter (additional part numbers on next page)

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Rated Burst Pressure (atm)	Proximal/Distal Shaft Diameter (F)	Catheter Length (cm)
15 mm						
1002989-15	00802526195501	4.00	0.033	15	3.3/3.3-2.9	75
1002990-15	00802526195518	4.50	0.033	15	3.3/3.3-2.9	75
1002991-15	00802526195525	5.00	0.035	15	3.3/3.3-2.9	75
1002992-15	00802526195532	5.50	0.039	15	3.3/3.3	75
1002993-15	00802526195549	6.00	0.039	15	3.3/3.3	75
1002994-15	00802526195556	6.50	0.040	15	3.3/3.5	75
1002995-15	00802526195563	7.00	0.044	14	3.3/3.5	75
1003006-15	00802526195570	4.00	0.033	15	3.3/3.3-2.9	135
1003007-15	00802526195587	4.50	0.033	15	3.3/3.3-2.9	135
1003008-15	00802526195594	5.00	0.035	15	3.3/3.3-2.9	135
1003009-15	00802526195600	5.50	0.039	15	3.3/3.3	135
1003010-15	00802526195617	6.00	0.039	15	3.3/3.3	135
1003011-15	00802526195624	6.50	0.040	15	3.3/3.5	135
1003012-15	00802526195631	7.00	0.044	14	3.3/3.5	135
20 mm						
1002989-20	00802526195655	4.00	0.033	15	3.3/3.3-2.9	75
1002990-20	00802526195662	4.50	0.033	15	3.3/3.3-2.9	75
1002991-20	00802526195679	5.00	0.035	15	3.3/3.3-2.9	75
1002992-20	00802526195686	5.50	0.039	15	3.3/3.3	75
1002993-20	00802526195693	6.00	0.039	15	3.3/3.3	75
1002994-20	00802526195709	6.50	0.040	15	3.3/3.5	75
1002995-20	00802526195716	7.00	0.044	14	3.3/3.5	75
1003006-20	00802526195822	4.00	0.033	15	3.3/3.3-2.9	135
1003007-20	00802526195839	4.50	0.033	15	3.3/3.3-2.9	135
1003008-20	00802526195846	5.00	0.035	15	3.3/3.3-2.9	135
1003009-20	00802526195853	5.50	0.039	15	3.3/3.3	135
1003010-20	00802526195860	6.00	0.039	15	3.3/3.3	135
1003011-20	00802526195877	6.50	0.040	15	3.3/3.5	135
1003012-20	00802526195884	7.00	0.044	14	3.3/3.5	135

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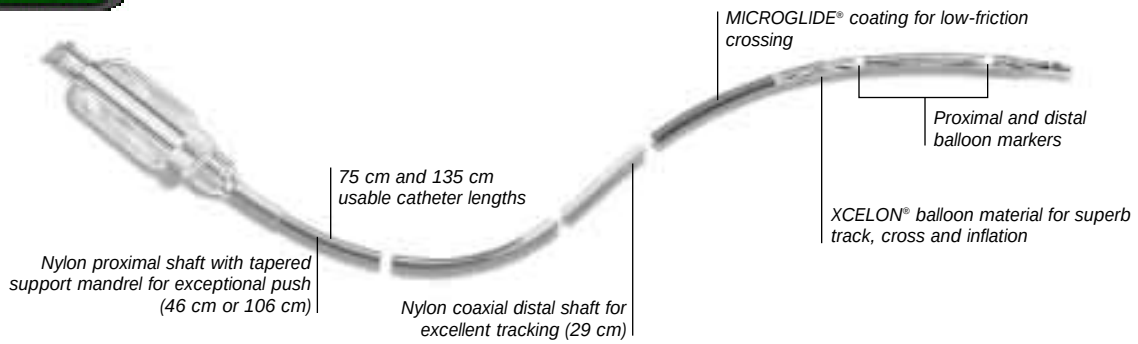

RX VIATRAC™ 14 (continued)

Peripheral Dilatation Catheter

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Rated Burst Pressure (atm)	Proximal/Distal Shaft Diameter (F)	Catheter Length (cm)
30 mm						
1002989-30	00802526195983	4.00	0.033	15	3.3/3.3-2.9	75
1002990-30	00802526195990	4.50	0.033	15	3.3/3.3-2.9	75
1002991-30	00802526196003	5.00	0.035	15	3.3/3.3-2.9	75
1002992-30	00802526196010	5.50	0.039	15	3.6/3.3	75
1002993-30	00802526196027	6.00	0.039	15	3.6/3.3	75
1002994-30	00802526196034	6.50	0.040	15	3.6/3.5	75
1002995-30	00802526196041	7.00	0.044	14	3.6/3.5	75
1003006-30	00802526196058	4.00	0.033	15	3.3/3.3-2.9	135
1003007-30	00802526196065	4.50	0.033	15	3.3/3.3-2.9	135
1003008-30	00802526196072	5.00	0.035	15	3.3/3.3-2.9	135
1003009-30	00802526196089	5.50	0.039	15	3.6/3.3	135
1003010-30	00802526196096	6.00	0.039	15	3.6/3.3	135
1003011-30	00802526196102	6.50	0.040	15	3.6/3.5	135
1003012-30	00802526196119	7.00	0.044	14	3.6/3.5	135
40 mm						
1002989-40	00802526196126	4.00	0.033	15	3.3/3.3-2.9	75
1002990-40	00802526196133	4.50	0.033	15	3.3/3.3-2.9	75
1002991-40	00802526196140	5.00	0.035	15	3.3/3.3-2.9	75
1002992-40	00802526196157	5.50	0.039	15	3.6/3.3	75
1002993-40	00802526196164	6.00	0.039	15	3.6/3.3	75
1002994-40	00802526196171	6.50	0.040	15	3.6/3.5	75
1002995-40	00802526196188	7.00	0.044	14	3.6/3.5	75
1003006-40	00802526196195	4.00	0.033	15	3.3/3.3-2.9	135
1003007-40	00802526196201	4.50	0.033	15	3.3/3.3-2.9	135
1003008-40	00802526196218	5.00	0.035	15	3.3/3.3-2.9	135
1003009-40	00802526196225	5.50	0.039	15	3.6/3.3	135
1003010-40	00802526196232	6.00	0.039	15	3.6/3.3	135
1003011-40	00802526196249	6.50	0.040	15	3.6/3.5	135
1003012-40	00802526196256	7.00	0.044	14	3.6/3.5	135

Maximum Guide Wire = .014″

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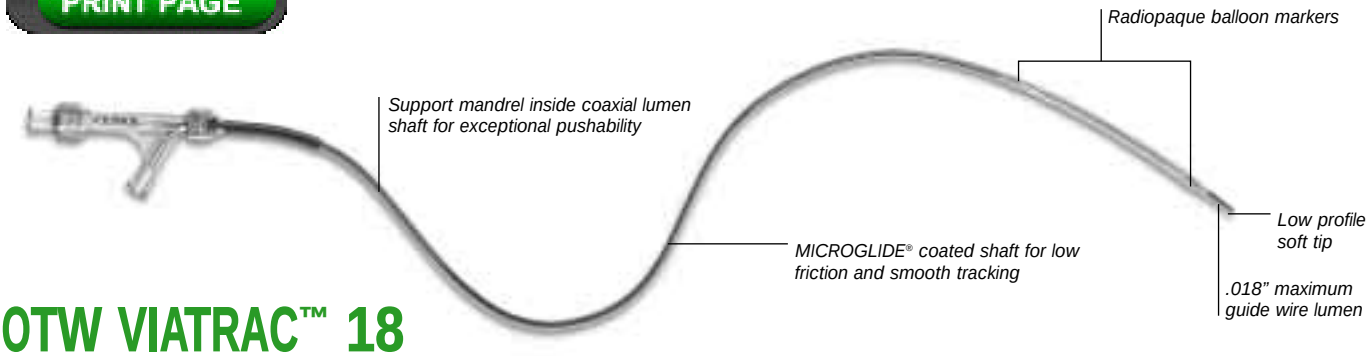


OTW VIATRAC™ 18

Peripheral Dilatation Catheter

Stock Number	UPN Number	Inflated Balloon Diameter (mm)	Crossing Profile (in)	Rated Burst Pressure (atm)	Proximal/Distal Shaft Diameter (F)	Catheter Length (cm)
20 mm						
1005045-20	00802526194900	6.00	0.042	15	4.2/3.5	75
1005047-20	00802526194917	7.00	0.045	14	4.6/4.1	75
1005049-20	00802526194924	8.00	0.049	14	4.6/4.1	75
1005050-20	00802526194931	9.00	0.053	12	4.6/4.2	75
1005051-20	00802526194948	10.00	0.058	12	4.6/4.2	75
1005062-20	00802526194955	6.00	0.042	15	4.2/3.5	135
1005064-20	00802526194962	7.00	0.045	14	4.6/4.1	135
1005066-20	00802526194979	8.00	0.049	14	4.6/4.1	135
1005067-20	00802526194986	9.00	0.053	12	4.6/4.2	135
1005068-20	00802526194993	10.00	0.058	12	4.6/4.2	135
30 mm						
1005045-30	00802526195006	6.00	0.042	15	4.2/3.5	75
1005047-30	00802526195013	7.00	0.045	14	4.6/4.1	75
1005049-30	00802526195020	8.00	0.049	14	4.6/4.1	75
1005050-30	00802526195037	9.00	0.053	12	4.6/4.2	75
1005051-30	00802526195044	10.00	0.058	12	4.6/4.2	75
1005062-30	00802526195051	6.00	0.042	15	4.2/3.5	135
1005064-30	00802526195068	7.00	0.045	14	4.6/4.1	135
1005066-30	00802526195075	8.00	0.049	14	4.6/4.1	135
1005067-30	00802526195082	9.00	0.053	12	4.6/4.2	135
1005068-30	00802526195099	10.00	0.058	12	4.6/4.2	135
40 mm						
1005045-40	00802526195105	6.00	0.042	15	4.2/3.5	75
1005047-40	00802526195112	7.00	0.045	14	4.6/4.1	75
1005049-40	00802526195129	8.00	0.049	14	4.6/4.1	75
1005050-40	00802526195136	9.00	0.053	12	4.6/4.2	75
1005051-40	00802526195143	10.00	0.058	12	4.6/4.2	75
1005062-40	00802526195150	6.00	0.042	15	4.2/3.5	135
1005064-40	00802526195167	7.00	0.045	14	4.6/4.1	135
1005066-40	00802526195174	8.00	0.049	14	4.6/4.1	135
1005067-40	00802526195181	9.00	0.053	12	4.6/4.2	135
1005068-40	00802526195198	10.00	0.058	12	4.6/4.2	135

Maximum Guide Wire = .018″

HI-TORQUE®

Guide Wires

℞ ONLY

INDICATIONS

Refer to the device label for any additional product specific indications which may apply.

CONTRAINDICATIONS

HI-TORQUE® Guide Wires are not intended for use in the cerebral vasculature.

Refer to the device label for any additional product specific contraindications which may apply.

WARNINGS

This device is designed and intended for ONE TIME USE ONLY. DO NOT RESTERILIZE AND/OR REUSE.

Observe guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip; otherwise, vessel trauma may occur. In addition, during catheter manipulations, ensure that the distal guide wire tip is visible.

Torquing a guide wire against resistance may cause guide wire damage and/or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw or torque a guide wire which meets resistance. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of the guide wire tip. If guide wire tip prolapse is observed or used for positioning, do not allow the tip to remain in a prolapsed condition; otherwise, damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.

If the guide wire tip becomes entrapped within the vasculature, DO NOT TORQUE THE GUIDE WIRE.

Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform exchanges slowly to prevent air entry and/or trauma.

When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit of the device. Use the radiopaque marker of the interventional device to confirm position.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged guide wires. Using a damaged guide wire may result in vessel damage and/or inaccurate torque response.

Confirm the compatibility of the guide wire diameter with the interventional device before actual use.

Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

Never attach the torque device to the modified portion of the proximal end of the extendable guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC™ Guide Wire Extension.

HI-TORQUE® Guide Wires with hydrophilic coating: Avoid abrasion of the hydrophilic coating.

Do not withdraw or manipulate the hydrophilic-coated wire in a metal cannula or sharp-edged object.

PERIPHERAL GUIDING CATHETER

℞ ONLY

INTENDED USE

The peripheral guiding catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced into the peripheral vasculature.

The inner catheter is intended to provide support during the introduction and withdrawal of a guiding catheter.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS

This device is distributed STERILE, NON-PYROGENIC and is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and risk of inappropriate sterilization and cross contamination.

When this guiding catheter (and inner catheter, if used) is in the body, it should be manipulated while under high-quality fluoroscopic observation.

The user should not place sideholes in the shaft of the guiding catheter. Puncturing the shaft of the guiding catheter with hospital instruments may lead to thrombogenesis or failure of shaft integrity.

PRECAUTIONS

Prior to use, the device should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

Guiding catheters should be used only by physicians trained in procedures requiring percutaneous catheter introduction.

Appropriate anticoagulation of the patient is indicated with the use of this device.

RX VIATRAC™ 14

Peripheral Dilatation Catheters

℞ ONLY

INDICATIONS

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is intended:

a) To dilate stenosis in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries) or for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

b) For post-stent dilatation of the PALMAZ™ P204 stent with the 20 mm balloon length only, implanted in vessels ranging from 4.0 mm to 7.0 mm in diameter.

CONTRAINDICATIONS

None known for Percutaneous Transluminal Angioplasty (PTA).

WARNINGS

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is not intended for use in the coronary arteries.

This device is intended for one-time use only. Do NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device specific information. The rated burst pressure (RBP) is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure (RBP). Use of a pressure monitoring device is recommended to prevent over pressurization.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Use the catheter prior to the "Use By" date specified on the package.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked as this may result in the shaft breaking. Instead, prepare a new catheter.

PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with Percutaneous Transluminal Angioplasty (PTA) is necessary before using this product.

Any use for procedures other than those indicated in these instructions is not recommended.

This device is not recommended for use in lesions which may require inflation higher than those recommended for this catheter.

Do not use if package is open or damaged.

Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the catheter.

It is important that the hemostatic valve (if used) be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tightly that it restricts the flow of contrast into and out of the balloon or restricts guide wire movement.

COMPLICATIONS

Potential complications include but are not limited to:

- air embolization
- aneurysm
- hematoma at puncture site
- vessel perforation or dissection
- arteriovenous fistula
- thrombus

OTW VIATRAC™ 18

Peripheral Dilatation Catheter

℞ ONLY

INDICATIONS

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is intended:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries)
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post deployment optimization of the 28 and 38 mm MEGALINK™ Biliary Stent (6.0 to 10.0 mm diameters), and 18 mm MEGALINK™ Biliary Stent (6.0 to 8.0 mm diameters).

CONTRAINDICATIONS

None known for Percutaneous Transluminal Angioplasty (PTA).

WARNINGS

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is not intended for use in the coronary arteries.

This device is intended for one-time use only. Do NOT resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device specific information. The rated burst pressure (RBP) is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure (RBP). Use of a pressure monitoring device is recommended to prevent over pressurization.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Use the catheter prior to the "Use By" date specified on the package.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked as this may result in the shaft breaking. Instead, prepare a new catheter.

PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with Percutaneous Transluminal Angioplasty (PTA) is necessary before using this product.

Any use for procedures other than those indicated in these instructions is not recommended.

This device is not recommended for use in lesions which may require inflation higher than those recommended for this catheter.

Do not use if package is open or damaged.

Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

COMPLICATIONS

Potential complications (in alphabetical order) include but are not limited to:

- air embolization
- aneurysm
- arteriovenous fistula
- hematoma at puncture site
- thrombus
- vessel perforation or dissection

BILIARY STENT SYSTEMS

PRINT SECTION

BILIARY STENT SYSTEMS

DYNALINK™ Biliary Self-Expanding Stent System 107

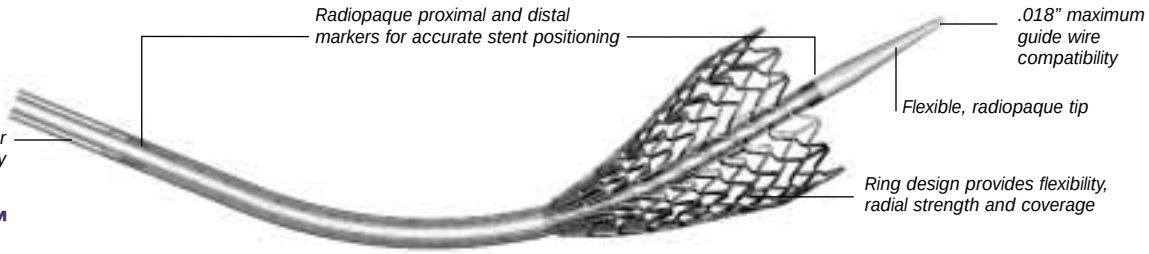
DYNALINK™ .035 Biliary Self-Expanding Stent System 108

RX HERCULINK™ PLUS Biliary Stent System 109

OMNILINK™ .018 Biliary Stent System 110-111

OMNILINK™ .035 Biliary Stent System 112-113

MEGALINK™ Biliary Stent 114



DYNALINK™

Biliary Self-Expanding Stent System

Stock Number	UPN Number	Unconstrained Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1007548-28	00802526251467	5.00	28	80
1007549-28	00802526251474	6.00	28	80
1007550-28	00802526251481	7.00	28	80
1007551-28	00802526251498	8.00	28	80
1007552-28	00802526251504	9.00	28	80
1007545-28	00802526251511	10.00	28	80
1007548-38	00802526251528	5.00	38	80
1007549-38	00802526251535	6.00	38	80
1007550-38	00802526251542	7.00	38	80
1007551-38	00802526251559	8.00	38	80
1007552-38	00802526251566	9.00	38	80
1007545-38	00802526251573	10.00	38	80
1007548-56	00802526251580	5.00	56	80
1007549-56	00802526251597	6.00	56	80
1007550-56	00802526251603	7.00	56	80
1007551-56	00802526251610	8.00	56	80
1007552-56	00802526251627	9.00	56	80
1007545-56	00802526251634	10.00	56	80
1006516-28	00802526251641	5.00	28	120
1006517-28	00802526251658	6.00	28	120
1006518-28	00802526251665	7.00	28	120
1006519-28	00802526251672	8.00	28	120
1006520-28	00802526251689	9.00	28	120
1006521-28	00802526251696	10.00	28	120
1006516-38	00802526251702	5.00	38	120
1006517-38	00802526251719	6.00	38	120
1006518-38	00802526251726	7.00	38	120
1006519-38	00802526251733	8.00	38	120
1006520-38	00802526251740	9.00	38	120
1006521-38	00802526251757	10.00	38	120
1006516-56	00802526251764	5.00	56	120
1006517-56	00802526251771	6.00	56	120
1006518-56	00802526251788	7.00	56	120
1006519-56	00802526251795	8.00	56	120
1006520-56	00802526251801	9.00	56	120
1006521-56	00802526251818	10.00	56	120

Maximum Guide Wire = .018″.

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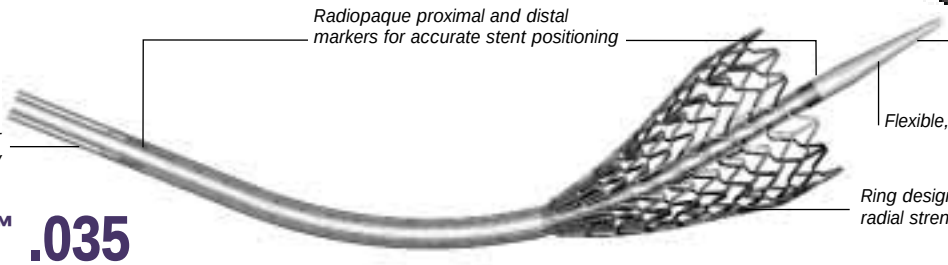
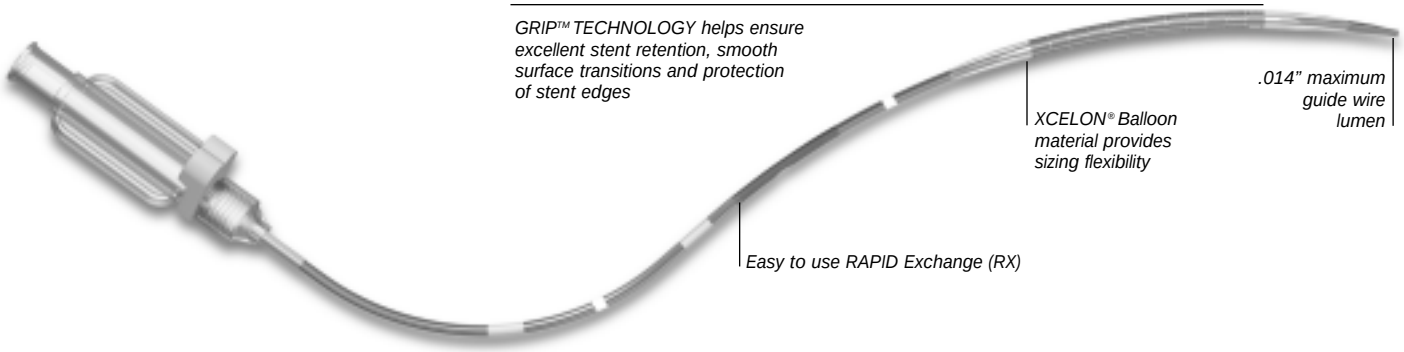


DYNALINK™ .035

Biliary Self-Expanding Stent System

Stock Number	UPN Number	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1008279-28	00802526262494	5.00	28	80
1008280-28	00802526262524	6.00	28	80
1008281-28	00802526262555	7.00	28	80
1008282-28	00802526262586	8.00	28	80
1008283-28	00802526262616	9.00	28	80
1008284-28	00802526262647	10.00	28	80
1008279-38	00802526262500	5.00	38	80
1008280-38	00802526262531	6.00	38	80
1008281-38	00802526262562	7.00	38	80
1008282-38	00802526262593	8.00	38	80
1008283-38	00802526262623	9.00	38	80
1008284-38	00802526262654	10.00	38	80
1008279-56	00802526262517	5.00	56	80
1008280-56	00802526262548	6.00	56	80
1008281-56	00802526262579	7.00	56	80
1008282-56	00802526262609	8.00	56	80
1008283-56	00802526262630	9.00	56	80
1008284-56	00802526262661	10.00	56	80
1008285-28	00802526262678	5.00	28	120
1008286-28	00802526262708	6.00	28	120
1008287-28	00802526262739	7.00	28	120
1008288-28	00802526262760	8.00	28	120
1008289-28	00802526250118	9.00	28	120
1008290-28	00802526250149	10.00	28	120
1008285-38	00802526262685	5.00	38	120
1008286-38	00802526262715	6.00	38	120
1008287-38	00802526262746	7.00	38	120
1008288-38	00802526262777	8.00	38	120
1008289-38	00802526250125	9.00	38	120
1008290-38	00802526250156	10.00	38	120
1008285-56	00802526262692	5.00	56	120
1008286-56	00802526262722	6.00	56	120
1008287-56	00802526262753	7.00	56	120
1008288-56	00802526262784	8.00	56	120
1008289-56	00802526250132	9.00	56	120
1008290-56	00802526250163	10.00	56	120

Maximum Guide Wire = .035″.



RX HERCULINK™ PLUS

Biliary Stent System

Stock Number	UPN Number	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1008012-12	00802526255229	4.00	12	80
1008014-12	00802526255267	4.50	12	80
1008016-12	00802526255304	5.00	12	80
1008018-12	00802526255342	5.50	12	80
1008020-12	00802526255380	6.00	12	80
1008022-12	00802526255427	6.50	12	80
1008012-18	00802526255236	4.00	18	80
1008014-18	00802526255274	4.50	18	80
1008016-18	00802526255311	5.00	18	80
1008018-18	00802526255359	5.50	18	80
1008020-18	00802526255397	6.00	18	80
1008022-18	00802526255434	6.50	18	80
1008024-18	00802526255465	7.00	18	80
1008013-12	00802526255243	4.00	12	135
1008015-12	00802526255281	4.50	12	135
1008017-12	00802526255328	5.00	12	135
1008019-12	00802526255366	5.50	12	135
1008021-12	00802526255403	6.00	12	135
1008023-12	00802526255441	6.00	12	135
1008013-18	00802526255250	4.00	18	135
1008015-18	00802526255298	4.50	18	135
1008017-18	00802526255335	5.00	18	135
1008019-18	00802526255373	5.50	18	135
1008021-18	00802526255410	6.00	18	135
1008023-18	00802526255458	6.50	18	135
1008025-18	00802526255472	7.00	18	135

Maximum Guide Wire = .014″.

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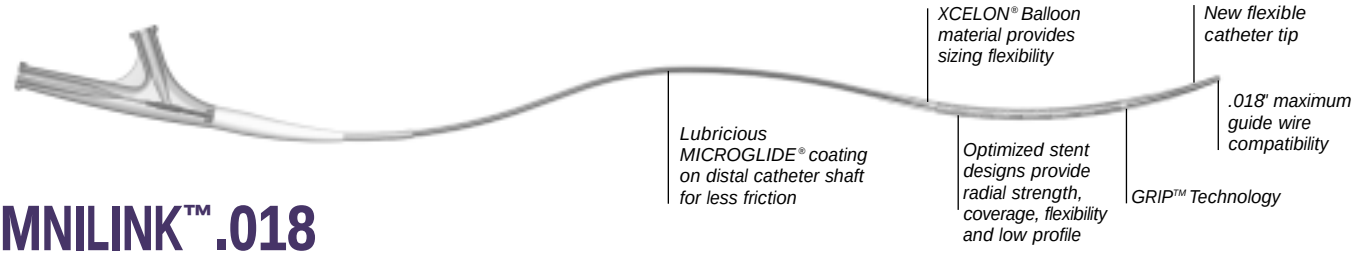
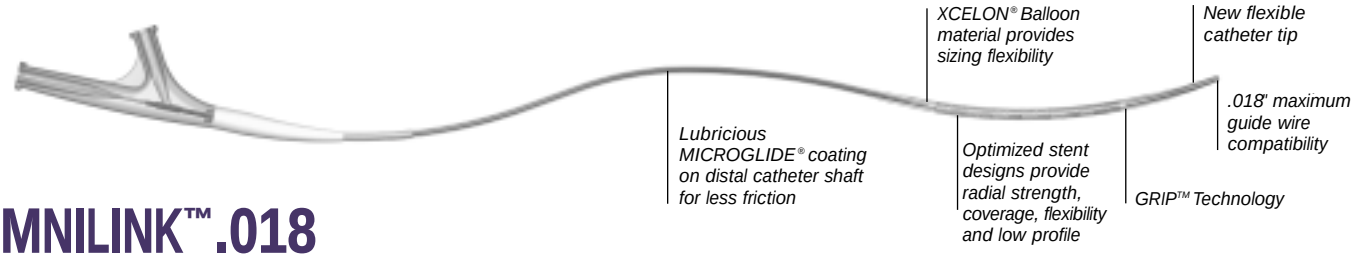


OMNILINK™.018

Biliary Stent System (additional part numbers on next page)

Stock Number	UPN Number	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1007980-18	00802526261404	5.00	18	80
1007982-18	00802526261442	6.00	18	80
1007984-18	00802526261480	7.00	18	80
1007986-18	00802526261527	8.00	18	80
1007987-18	00802526261565	9.00	18	80
1007980-28	00802526261411	5.00	28	80
1007982-28	00802526261459	6.00	28	80
1007984-28	00802526261497	7.00	28	80
1007986-28	00802526261534	8.00	28	80
1007987-28	00802526261572	9.00	28	80
1007988-28	00802526261619	10.00	28	80
1007980-38	00802526261428	5.00	38	80
1007982-38	00802526261466	6.00	38	80
1007984-38	00802526261503	7.00	38	80
1007986-38	00802526261541	8.00	38	80
1007987-38	00802526261589	9.00	38	80
1007988-38	00802526261626	10.00	38	80
1007980-58	00802526261435	5.00	58	80
1007982-58	00802526261473	6.00	58	80
1007984-58	00802526261510	7.00	58	80
1007986-58	00802526261558	8.00	58	80
1007987-58	00802526261596	9.00	58	80
1007988-58	00802526261633	10.00	58	80
1007942-18	00802526261169	5.00	18	135
1007944-18	00802526261206	6.00	18	135
1007946-18	00802526261244	7.00	18	135
1007948-18	00802526261282	8.00	18	135
1007949-18	00802526261329	9.00	18	135
1007950-18	00802526261367	10.00	18	135
1007988-18	00802526261602	10.00	18	135
1007942-28	00802526261176	5.00	28	135
1007944-28	00802526261213	6.00	28	135
1007946-28	00802526261251	7.00	28	135
1007948-28	00802526261299	8.00	28	135
1007949-28	00802526261336	9.00	28	135
1007950-28	00802526261374	10.00	28	135



OMNILINK™.018

Biliary Stent System (continued)

Stock Number	UPN Number	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1007942-38	00802526261183	5.00	38	135
1007944-38	00802526261220	6.00	38	135
1007946-38	00802526261268	7.00	38	135
1007948-38	00802526261305	8.00	38	135
1007949-38	00802526261343	9.00	38	135
1007950-38	00802526261381	10.00	38	135
1007942-58	00802526261190	5.00	58	135
1007944-58	00802526261237	6.00	58	135
1007946-58	00802526261275	7.00	58	135
1007948-58	00802526261312	8.00	58	135
1007949-58	00802526261350	9.00	58	135
1007950-58	00802526261398	10.00	58	135

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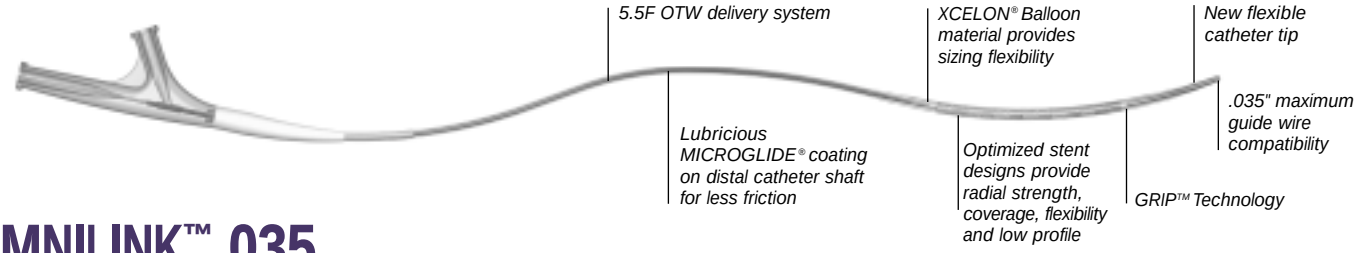

OMNILINK™.035

Biliary Stent System (additional part numbers on next page)

Stock Number	UPN Number	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1008176-18	00802526259142	5.00	18	80
1008178-18	00802526259180	6.00	18	80
1008180-18	00802526259227	7.00	18	80
1008182-18	00802526259265	8.00	18	80
1008183-18	00802526259302	9.00	18	80
1008184-18	00802526259340	10.00	18	80
1008176-28	00802526259159	5.00	28	80
1008178-28	00802526259197	6.00	28	80
1008180-28	00802526259234	7.00	28	80
1008182-28	00802526259272	8.00	28	80
1008183-28	00802526259319	9.00	28	80
1008184-28	00802526259357	10.00	28	80
1008176-38	00802526259166	5.00	38	80
1008178-38	00802526259203	6.00	38	80
1008180-38	00802526259241	7.00	38	80
1008182-38	00802526259289	8.00	38	80
1008183-38	00802526259326	9.00	38	80
1008184-38	00802526259364	10.00	38	80
1008176-58	00802526259173	5.00	58	80
1008178-58	00802526259210	6.00	58	80
1008180-58	00802526259258	7.00	58	80
1008182-58	00802526259296	8.00	58	80
1008183-58	00802526259333	9.00	58	80
1008184-58	00802526259371	10.00	58	80
1008161-18	00802526259012	5.00	18	135
1008163-18	00802526259050	6.00	18	135
1008165-18	00802526259098	7.00	18	135
1008167-18	00802526259135	8.00	18	135
1008168-18	00802526259890	9.00	18	135
1008169-18	00802526259937	10.00	18	135
1008161-28	00802526259029	5.00	28	135
1008163-28	00802526259067	6.00	28	135
1008165-28	00802526259104	7.00	28	135
1008167-28	00802526259869	8.00	28	135
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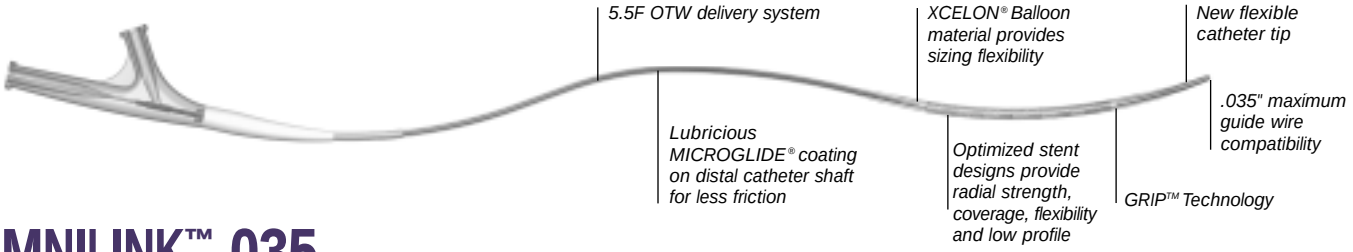
1008169-28	00802526259944	10.00	28	135



OMNILINK™.035

Biliary Stent System (continued)

Stock Number	UPN Number	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1008161-38	00802526259036	5.00	38	135
1008163-38	00802526259074	6.00	38	135
1008165-38	00802526259111	7.00	38	135
1008167-38	00802526259876	8.00	38	135
1008168-38	00802526259913	9.00	38	135
1008169-38	00802526259951	10.00	38	135
1008161-58	00802526259043	5.00	58	135
1008163-58	00802526259081	6.00	58	135
1008165-58	00802526259128	7.00	58	135
1008167-58	00802526259883	8.00	58	135
1008168-58	00802526259920	9.00	58	135
1008169-58	00802526259968	10.00	58	135

MEGALINK™
Biliary Stent

Stock Number	UPN Number	Stent Length (mm)	Stent Diameter (mm)
1002949-18	00802526197895	18	6-8*
1002949-28	00802526197901	28	6-10**
1002949-38	00802526197918	38	6-10**
1002949-58	00802526197925	58	6-10**

*Maximum post-dilatation diameter 9 mm

**Maximum post-dilatation diameter 11 mm

DYNALINK™

Biliary Self-Expanding Stent System

℞ ONLY

INDICATIONS

The DYNALINK™ Biliary Self-Expanding Stent System is intended for palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS

- Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis
- Patients with bleeding disorders
- Severe ascites

WARNINGS

DO NOT USE IF TEMPERATURE INDICATOR IS BLACK.

The safety and effectiveness of this device for use in the vascular system have not been established.

The long term safety and effectiveness of this device in the biliary system have not been established.

Should **unusual resistance** be felt **at any time** during stricture access or Delivery System removal, the introducer sheath/guiding catheter and stent system **should be removed as a single unit.** Applying excessive force to the stent Delivery System can potentially result in loss or damage to the stent and Delivery System components. (See Stent/System Removal - Precautions.)

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

The stent is not designed for repositioning or recapturing.

Persons allergic to nickel titanium may suffer an allergic reaction to this implant.

Only physicians familiar with the complications, side effects and hazards commonly associated with biliary stent placement should use this device.

The DYNALINK™ Biliary Self-Expanding Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the DYNALINK™ Biliary Self-Expanding Stent System be used in conjunction with other stents.

Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the DYNALINK™ Biliary Self-Expanding Stent System, for their intended uses, contraindications, and potential complications.

When multiple stents are required, stent materials should be of similar composition.

PRECAUTIONS

Carefully inspect the DYNALINK™ Biliary Self-Expanding Stent System to verify that the device has not been damaged in shipment. Take care to avoid unnecessary handling, which may kink or damage the delivery system.

Stent Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note the product "Use By" date.
- **Do not remove the stent from its Delivery System.**
- Special care must be taken not to handle or in any way disrupt the stent on the Delivery System. This is most important during delivery system removal from packaging, mandrel removal, placement over guide wire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.

Stent Placement - Precautions

- **Ensure that ALL SLACK IS REMOVED from the Delivery System to enable precise stent placement.**
- Do not expand the stent if it is not properly positioned in the bile duct. (See Stent/System Removal - Precautions.)
- **Do not attempt to pull a partially expanded stent back through the sheath or guiding catheter; dislodgment of the stent from the Delivery System may occur.**

Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma or perforation to the bile duct.

Stent/System Removal - Precautions

Should unusual resistance be felt at any time during either stricture access or removal of the Delivery System post stent implantation, the entire system should be **removed as single unit.**

When removing the Delivery System as a single unit:

- Do not retract the Delivery System into the guiding catheter or sheath.
- Ensure that the handle is re-advanced to the locked position and the lock is re-engaged.
- Tighten the RHV (if applicable) to secure the Delivery System to the guiding catheter; then remove the guiding catheter or sheath and delivery system as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent biliary access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

- Great care must be exercised when **crossing a newly deployed stent** with a guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

POTENTIAL ADVERSE EFFECTS

Potential complications associated with the use of a biliary endoprosthesis may include, but are not limited to, the following:

- Sepsis
- Bile duct occlusion / obstruction
- Tumor overgrowth at the stent ends
- Bile duct perforation potentially leading to infection or death
- Abscess
- Cholangitis
- Peritonitis
- Parenchymal hemorrhage
- Pancreatitis
- Stent migration

DYNALINK™ .035

Biliary Self-Expanding Stent System

℞ ONLY

INDICATIONS:

The DYNALINKTM .035 Biliary Self-Expanding Stent System is intended for palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS:

- Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis
- Patients with bleeding disorders
- Severe ascites

WARNINGS:

DO NOT USE IF TEMPERATURE INDICATOR IS BLACK.

The safety and effectiveness of this device for use in the vascular system have not been established.

The long term safety and effectiveness of this device in the biliary system have not been established.

Should unusual resistance be felt at any time during stricture access or Delivery System removal, the introducer sheath/guiding catheter and stent system should be removed as a single unit. Applying excessive force to the stent Delivery System can potentially result in loss or damage to the stent and Delivery System components. (See Stent/System Removal – Precautions.)

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

The stent is not designed for repositioning or recapturing.

Persons allergic to nickel titanium may suffer an allergic reaction to this implant.

Only physicians familiar with the complications, side effects and hazards commonly associated with biliary stent placement should use this device.

The DYNALINK™ .035 Biliary Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the DYNALINK™ .035 Biliary Stent System be used in conjunction with other stents.

Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the DYNALINK™ .035 Biliary Self-Expanding Stent System, for their intended uses, contraindications, and potential complications.

When multiple stents are required, stent materials should be of similar composition.

PRECAUTIONS:

Carefully inspect the DYNALINK™ .035 Biliary Self-Expanding Stent System to verify that the device has not been damaged in shipment. Take care to avoid unnecessary handling, which may kink or damage the delivery system.

Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note the product "Use By" date.
- Do not remove the stent from its Delivery System.
- Special care must be taken not to handle or in any way disrupt the stent on the Delivery System. This is most important during delivery system removal from packaging, mandrel removal, placement over guide wire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.

Stent Placement - Precautions

- Ensure that ALL SLACK IS REMOVED from the Delivery System to enable precise stent placement.
- Do not expand the stent if it is not properly positioned in the bile duct. (See Stent/System Removal – Precautions.)
- Do not attempt to pull a partially expanded stent back through the sheath or guiding catheter; dislodgment of the stent from the Delivery System may occur.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma or perforation to the bile duct.

Stent / System Removal – Precautions

Should unusual resistance be felt at any time during either stricture access or removal of the Delivery System post stent implantation, the entire system should be removed as single unit.

When removing the Delivery System as a single unit:

- Do not retract the Delivery System into the guiding catheter or sheath.
- Ensure that the handle is re-advanced to the locked position and the lock is re-engaged.
- Tighten the RHV (if applicable) to secure the Delivery System to the guiding catheter; then remove the guiding catheter or sheath and delivery system as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent biliary access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

- Great care must be exercised when crossing a newly deployed stent with a guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

POTENTIAL ADVERSE EFFECTS

Potential complications associated with the use of a biliary endoprosthesis may include, but are not limited to, the following:

- Sepsis
- Bile duct occlusion / obstruction
- Tumor overgrowth at the stent ends
- Bile duct perforation potentially leading to infection or death
- Abscess
- Cholangitis
- Peritonitis
- Parenchymal hemorrhage
- Pancreatitis
- Stent migration

RX HERCULINK™ PLUS

Biliary Stent System

℞ ONLY

INDICATIONS

The RX HERCULINK™ PLUS Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS

The RX HERCULINK™ PLUS Biliary Stent System is contraindicated for use in:

- Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis
- Patients with bleeding disorders
- Severe ascites

WARNINGS

The safety and effectiveness of this device for use in the vascular system have not been established.

The long-term safety and effectiveness of this device in the biliary system have not been established.

Should unusual resistance be felt at any time during stricture access or Delivery System removal, the introducer sheath/guiding catheter and stent system should be removed as a single unit. Applying excessive force to the Stent Delivery System can potentially result in loss or damage to the Stent and Delivery System components. (See Stent/System Removal — Precautions.)

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

Once fully deployed the stent can not be repositioned.

Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.

Only physicians familiar with the complications, side effects and hazards commonly associated with biliary stent placement should use this device.

The RX HERCULINK™ PLUS Biliary Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the RX HERCULINK™ PLUS Biliary Stent System be used in conjunction with other stents.

PRECAUTIONS

Stent Handling — Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its delivery balloon.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from packaging, placement over guide wire and advancement through rotating hemostatic valve adapter, guiding catheter hub or introducer sheath hemostatic valve.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement — Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in the 'Clinician Use Manual' section.
- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the bile duct. Oversizing of the stent can result in a ruptured bile duct. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure
- Do not expand the stent if it is not properly positioned in the bile duct. (See Stent/System Removal — Precautions.)
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated
  on product label. Use of pressures higher than specified on product label may result in a ruptured balloon with possible bile duct damage or perforation.
- Do not attempt to pull an unexpanded stent back through the introducer sheath/guiding catheter; dislodgment of the stent from the balloon may occur.

Stent/System Removal — Precautions

Should unusual resistance be felt at any time during either stricture access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the introducer sheath/guiding catheter.
- Position the proximal balloon marker just distal to the tip of the introducer sheath/guiding catheter.
- Advance the guide wire in the anatomy as far distally as safely possible.
- Secure the Delivery System to the introducer sheath/guiding catheter; then remove the introducer sheath/guiding catheter, guide wire and Delivery System as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent biliary access, leave the guide wire in place and remove all other system components.

Post Implant — Precautions

Great care must be exercised when crossing a newly deployed stent with a guide wire or balloon catheter to avoid disrupting the stent geometry.

The stent may cause artifacts with MRI scans due to distortion of the magnetic field. The artifacts caused by the stainless steel stent should not be greater than those caused by metal surgical clips.

POTENTIAL adverse effects

Potential complications associated with the use of a biliary endoprosthesis may include, but are not limited to, the following:

- Sepsis
- Bile duct occlusion / obstruction
- Tumor overgrowth at the stent ends
- Bile duct perforation potentially leading to infection or death
- Abscess
- Cholangitis
- Peritonitis
- Parenchymal hemorrhage
- Pancreatitis
- Stent migration

OMNILINK™.018

Biliary Stent System

℞ ONLY

The OMNILINK™ .018" Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS:

The OMNILINK™ .018" Biliary Stent System is contraindicated for use in:

- Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis
- Patients with bleeding disorders
- Severe ascites

WARNINGS:

The safety and effectiveness of this device for use in the vascular system have not been established.

The long term safety and effectiveness of this device in the biliary system have not been established.

Should unusual resistance be felt at any time during stricture access or Delivery System removal, the guiding catheter/introducer sheath and stent system should be removed as a single unit. Applying excessive force to the stent Delivery System can potentially result in loss or damage to the stent and Delivery System components. (See Stent/System Removal – Precautions.)

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

Once fully deployed the stent can not be repositioned.

Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.

Only physicians familiar with the complications, side effects and hazards commonly associated with biliary stent placement should use this device.

The OMNILINK™ .018" Biliary Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the OMNILINK™ .018" Biliary Stent System be used in conjunction with other stents.

PRECAUTIONS:

Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its delivery balloon.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from packaging, placement over guide wire and advancement through guiding catheter/introducer sheath hemostatic valve.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in the Clinician Use Manual.
- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the bile duct. Oversizing of the stent can result in a ruptured bile duct. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure
- Do not expand the stent if it is not properly positioned in the bile duct. (See Stent/System Removal – Precautions.)
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on product label. Use of pressures higher than specified on product label may result in a ruptured balloon with possible bile duct damage or perforation.
- Do not attempt to pull an unexpanded stent back through the guiding catheter/introducer sheath; dislodgment of the stent from the balloon may occur.

Stent/System Removal - Precautions

Should unusual resistance be felt at any time during either stricture access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter/introducer sheath.
- Position the proximal balloon marker just distal to the tip of the guiding catheter/introducer sheath.
- Advance the guide wire in the anatomy as far distally as safely possible.
- Secure the Delivery System to the guiding catheter/introducer sheath; then remove the guiding catheter/introducer sheath, guide wire and Delivery System as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent biliary access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

Great care must be exercised when crossing a newly deployed stent with a guide wire or balloon catheter to avoid disrupting the stent geometry.

The stent may cause artifacts in MRI scans due to distortion of the magnetic field. The artifacts caused by the stainless steel stent should not be greater than those caused by metal surgical clips.

COMPLICATIONS:

Potential complications associated with the use of a biliary endoprosthesis may include, but are not limited to, the following:

- Abscess
- Bile duct occlusion / obstruction
- Bile duct perforation potentially leading to infection or death
- Cholangitis
- Pancreatitis
- Parenchymal hemorrhage
- Peritonitis
- Sepsis
- Stent migration
- Tumor overgrowth at the stent ends

OMNILINK™.035

Biliary Stent System

Rx ONLY

INDICATIONS

The OMNILINK™ .035 Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS:

The OMNILINK™ .035 Biliary Stent System is contraindicated for use in:

- Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis
- Patients with bleeding disorders
- Severe ascites

WARNINGS:

Should unusual resistance be felt at any time during stricture access or Delivery System removal, the guiding catheter/introducer sheath and stent system should be removed as a single unit. Applying excessive force to the Stent Delivery System can potentially result in loss or damage to the stent and Delivery System components. (See Stent/System Removal – Precautions.)

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

Once fully deployed, the stent cannot be repositioned.

Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.

Only physicians familiar with the complications, side effects and hazards commonly associated with biliary stent placement should use this device.

The OMNILINK™ .035 Biliary Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the OMNILINK™ .035 Biliary Stent System be used in conjunction with other stents.

PRECAUTIONS:

- The long term safety and effectiveness of this device in the biliary system have not been established.
- The safety and effectiveness of this device for use in the vascular system have not been established.

Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its delivery balloon.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from packaging, placement over guide wire and advancement through guiding catheter/introducer sheath hemostatic valve.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging

  technique described in the Clinician Use Manual.
- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the bile duct. Oversizing of the stent can result in a ruptured bile duct. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure.
- Do not expand the stent if it is not properly positioned in the bile duct. (See Stent/System Removal – Precautions.)
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on product label. Use of pressures higher than specified on product label may result in a ruptured balloon with possible bile duct damage or perforation.
- Do not attempt to pull an unexpanded stent back through the guiding catheter/introducer sheath; dislodgment of the stent from the balloon may occur.

Stent/System Removal - Precautions

Should unusual resistance be felt at any time during either stricture access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter/introducer sheath.
- Position the proximal balloon marker just distal to the tip of the guiding catheter/introducer sheath.
- Advance the guide wire in the anatomy as far distally as safely possible.
- Secure the Delivery System to the guiding catheter/introducer sheath; then remove the guiding catheter/introducer sheath, guide wire and Delivery System as a single unit.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent biliary access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

Great care must be exercised when crossing a newly deployed stent with a guide wire or balloon catheter to avoid disrupting the stent geometry.

The stent may cause artifacts in MRI scans due to distortion of the magnetic field. The artifacts caused by the stainless steel stent should not be greater than those caused by metal surgical clips.

POTENTIAL COMPLICATIONS:

Potential complications associated with the use of a biliary endoprosthesis may include, but are not limited to, the following:

- Abscess
- Bile duct occlusion / obstruction
- Bile duct perforation potentially leading to infection or death
- Cholangitis
- Pancreatitis
- Parenchymal hemorrhage
- Peritonitis
- Sepsis
- Stent migration
- Tumor overgrowth at the stent ends

MEGALINK™

Biliary Stent

Rx ONLY

INDICATIONS

The MEGALINK™ Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS

Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis.

WARNINGS

The safety and effectiveness of this device for use in the vascular system have not been established.

This device is designed and intended for ONE TIME USE ONLY. DO NOT RESTERILIZE AND/OR REUSE.

Use the stent prior to the "use by" date specified on the package.

Only physicians familiar with the complications, side effects and hazards commonly associated with biliary stent placement should use this device.

The maximum balloon inflation pressure used to deploy the stent must not exceed the rated burst pressure specified in the balloon manufacturer's instructions. Use of a pressure-monitoring device is recommended to prevent overpressurization.

Should unusual resistance be felt at any time during either stricture access, or removal of an undeployed stent, the balloon catheter, stent, and wire should be removed as a single unit.

Stenting across a major bifurcation may hinder or prevent future endoscopic access or procedures.

Do not perform a magnetic resonance imaging (MRI) scan on patients post-stent implantation until the stent has completely healed (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

PRECAUTIONS

Carefully inspect the MEGALINK™ Biliary Stent prior to use to verify that the stent has not been damaged in shipment and that the device dimensions are suitable for the specific procedure. Take care to avoid unnecessary handling.

The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the bile duct. Oversizing of the stent can result in a ruptured bile duct. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure.

Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the MEGALINK™ Biliary Stent, for their intended uses, contraindications, and potential complications.