

# Sterling<sup>®</sup>

Balloon Dilatation Catheter

Breakthrough 4F Profile

Boston  
Scientific

*Delivering what's next.™*

# Sterling®

Balloon Dilatation Catheter

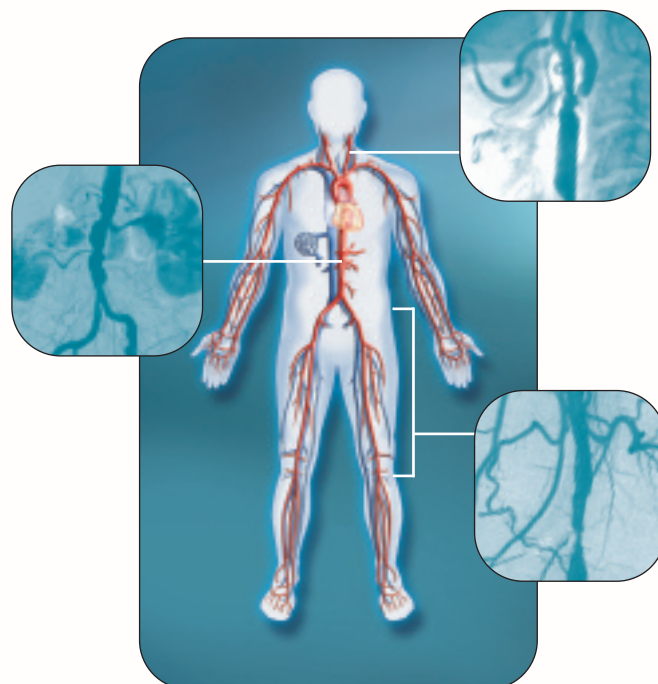


## A new measure for *deliverability and trackability*

The Sterling Balloon Dilatation Catheter is designed to meet the challenges of carotid (Monorail® indication only), renal and lower extremity anatomy with a powerful combination of deliverability and trackability – resulting in clinical versatility. Excellent trackability in both Over-the-Wire and rapid-exchange platforms, plus a broad size offering, provide multiple solutions for all of your peripheral intervention needs.

### Clinical Versatility

- Over-the-Wire and rapid-exchange platforms for use in the peripheral vasculature
- Extensive size matrix
  - Balloon diameters of 3mm-10mm
  - Balloon lengths of 10mm-100mm
  - Three shaft lengths of 40cm, 80cm and 135cm
- Specifically designed for use in carotid (Monorail indication only), renal and lower extremity arteries and dialysis fistulae

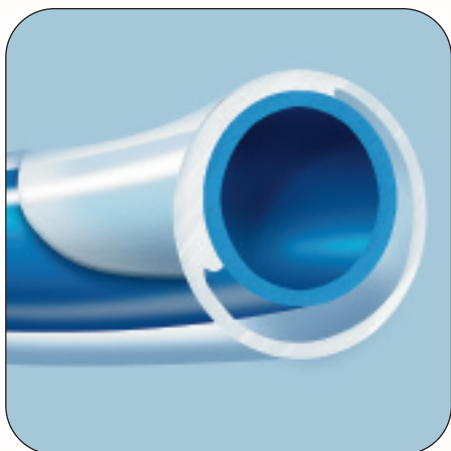


## Breakthrough Deliverability

- Ultra-low balloon profile is 4F introducer sheath compatible up through 8mm x 40mm
- Seamless, laser-bonded, tapered tip designed to promote crossability through tight stenoses and near occlusions
- Semi-compliant Pebax® Balloon Material with hydrophilic coating designed to facilitate advancement through complex lesions

## Assured Trackability

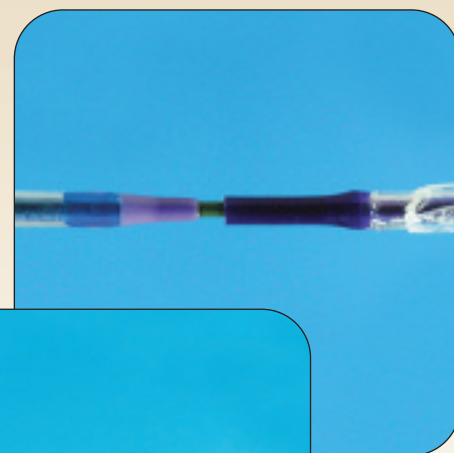
- Lubricious inner shaft engineered to enhance trackability
- Flexible tip and shaft designed to facilitate navigation through tortuous vasculature



Cross section of tack weld

Illustration provided by Boston Scientific Corporation.  
Illustration not necessarily to scale.

Sterling® Balloon Dilatation Catheter  
and Abbott Agiltrac™ 0.018" Peripheral  
Dilatation Catheter (6mm x 20mm)

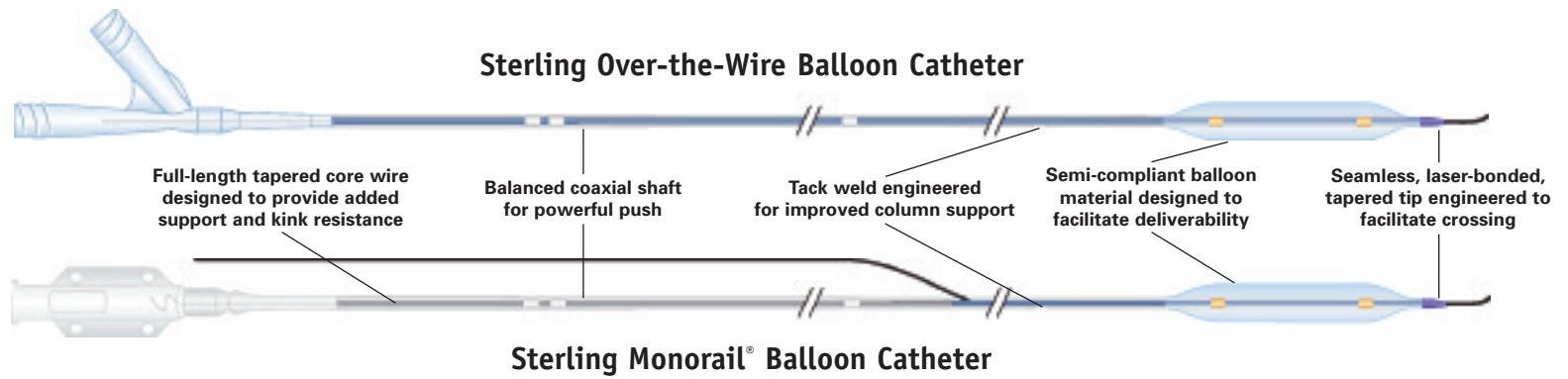


Sterling Balloon Dilatation Catheter  
and Cordis Slalom® PTA Balloon  
Dilatation Catheter (6mm x 20mm)

Photographs taken by Boston Scientific Corporation.

## Responsive Pushability

- Balanced coaxial shaft design features flexibility for tracking combined with powerful pushability
- Tack weld of distal inner to outer shaft engineered to provide excellent column support to enable advancement through challenging anatomy
- Full-length tapered core wire designed to provide added support and kink resistance in the Monorail platform



**Typical Sterling Balloon Dilatation Catheter Compliance**

Monorail Balloon Diameter (mm)										
Pressure (ATM)	3mm	3.5mm	4mm	4.5mm	5mm	5.5mm	6mm	6.5mm	7mm	8mm
6	2.99*	3.53*	3.99*	4.52*	5.01*	5.51*	5.97*	6.40*	6.97*	7.99*
7	3.05	3.60	4.07	4.61	5.10	5.61	6.06	6.50	7.07	8.10
8	3.10	3.66	4.13	4.68	5.17	5.70	6.14	6.58	7.17	8.19
9	3.14	3.70	4.19	4.73	5.23	5.77	6.20	6.65	7.24	8.26
10	3.18	3.75	4.24	4.79	5.29	5.83	6.26	6.71	7.31	8.32
11	3.22	3.79	4.27	4.84	5.34	5.88	6.31	6.76	7.37	8.38
12	3.25	3.82	4.31	4.87	5.38	5.93	6.35	6.81	7.42	8.44**
13	3.28	3.85	4.35	4.91	5.43	5.98	6.40	6.85	7.47	--
14	3.31**	3.88**	4.38**	4.95**	5.47**	6.02**	6.44**	6.90**	7.53**	--

\*Nominal pressure = 6 ATM.  
\*\*Rated burst pressure = 14 ATM (3mm-7mm) and 12 ATM (8mm). DO NOT EXCEED.

Over-the-Wire Balloon Diameter (mm)										
Pressure (ATM)	4mm	5mm	6mm 20mm-60mm	6mm 80mm-100mm	7mm 20mm-40mm	7mm 60mm-100mm	8mm 20mm-40mm	8mm 60mm-80mm	9mm	10mm
6	3.99*	5.01*	5.97*	6.10*	6.97*	7.11*	7.99*	8.03*	8.93*	9.92*
7	4.07	5.10	6.06	6.19	7.07	7.22	8.10	8.13	9.05	10.05
8	4.13	5.17	6.14	6.28	7.17	7.31	8.19	8.21	9.15	10.17
9	4.19	5.23	6.20	6.34	7.24	7.39	8.26	8.28	9.24	10.28
10	4.24	5.29	6.26	6.40	7.31	7.46	8.32	8.34	9.34**	10.38**
11	4.27	5.34	6.31	6.46	7.37	7.53	8.38	8.40	--	--
12	4.31	5.38	6.35	6.50	7.42	7.59	8.44**	8.46**	--	--
13	4.35	5.43	6.40	6.55	7.47	7.65	--	--	--	--
14	4.38**	5.47**	6.44**	6.60**	7.53**	7.71**	--	--	--	--

\*Nominal pressure = 6 ATM.  
\*\*Rated burst pressure = 14 ATM (4mm-7mm), 12 ATM (8mm) and 10 ATM (9mm-10mm). DO NOT EXCEED.

**STERLING® MONORAIL® AND STERLING® OVER-THE-WIRE PTA BALLOON DILATATION CATHETERS**

Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

**INDICATIONS FOR USE:** The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

The Sterling Over-the-Wire PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

**CONTRAINDICATIONS:** None Known.

**WARNINGS:** To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length 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. To avoid balloon rupture, do not exceed the rated

balloon burst pressure. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. This product contains no detectable latex.

**ADVERSE EFFECTS:**The complications that may result from a balloon dilatation procedure include: • Abrupt closure • Acute myocardial infarction • Acute or subacute thrombosis • Additional intervention required (major, moderate) • Allergic reaction (device, contrast medium and medications) • Amputation • Aneurysm • Angina • Arrhythmias (major, minor), including ventricular fibrillation • Arteriovenous fistula • Coma • Death • Embolization, which includes thromboembolization (arterial, pulmonary) • Hematoma • Hemorrhage, including bleeding at puncture site • Hypotension/Hypertension • Inflammation • Intimal tear • Ischemia, including tissue ischemia, steal syndrome and necrosis • Neurological events, including peripheral nerve injury and neuropathies • Occlusion • Organ failure (single, multiple) • Paralysis • Pseudoaneurysm • Pyrogenic reaction • Renal failure • Restenosis • Seizures • Sepsis/infection • Shock • Stroke • Transient ischemic attack • Vessel dissection, perforation, rupture or spasm • Weakness

**PRECAUTIONS:** The Sterling Monorail PTA Balloon Dilatation Catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty.

**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

Pebax is a registered trademark of Arkema Corporation. Agiltrac is a trademark of Abbott Cardiovascular Systems, Inc. Slalom is a trademark of Johnson & Johnson.



*Delivering what's next.™*

Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760-1537  
www.bostonscientific.com

*To order product or for more information, contact customer service at 1.888.272.1001.*

© 2009 Boston Scientific Corporation or its affiliates. All rights reserved.

90560336 DEC09