

# $\frac{\text{Sterling}^{\text{m}} \text{ 0.018}^{\text{m}} \text{ balloon catheter}}{\text{DEMAND MORE}}$

from your 0.018" balloon catheter

## The **#1** 0.018" balloon catheter

with the most comprehensive size offering available

## 2-10 mm diameters 10-220 mm lengths

The most comprehensive size offering available

## **10 seconds**\*

Best-in-class deflation time

0.020"\*

Lowest in-class lesion entry profile

The Sterling<sup>™</sup> family<sup>†</sup> offers best-in-class lesion entry profile and deflation times with the most clinically comprehensive size offering and indications available.



Demand Exceptional Crossability

- Exceptionally low 0.020" lesion entry profile on a 0.018" wire
- 7x220 though 5 F

\* Average measurements taken by Boston Scientific (n=3, 5 x 150 mm balloons). Data on file. (TR 90884555). Bench testing may not be representative of clinical performance.

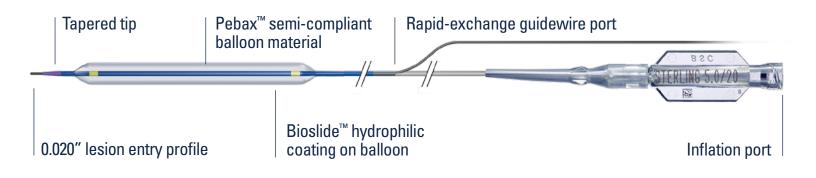
The Sterling family includes Sterling and Sterling SL.
 Monorail only.

US and EU market share data per internal and external analysis.

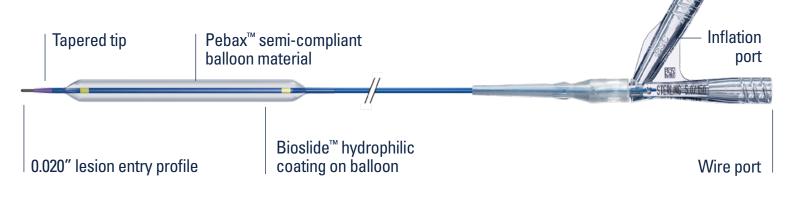
#### Demand the Broadest Size Matrix

- The most comprehensive size offering available in both over-the-wire and Monorail<sup>™</sup> rapid-exchange
- Indicated for wider acute use including carotid<sup>‡</sup> and post stent dilatation

### Sterling<sup>TM</sup> Monorail<sup>TM</sup> Balloon Catheter



## Sterling<sup>TM</sup> Over-the-Wire Balloon Catheter



STERLING™ MONORAIL™ AND STERLING™ OVER-THE-WIRE PTA BALLOON DILATATION CATHETERS STERLING™ SL MONORAIL™ AND STERLING™ SL 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. CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician

INDICATIONS FOR USE: The Sterling OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-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 starts in the peripheral vasculature. **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. INDICATIONS FOR USE: The Sterling SL PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA)

in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

#### CONTRAINDICATIONS: None Known.

STERLING 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 • Hemmorrhage, 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

STERLING SL ADVERSE EVENTS: The complications that may result from a balloon dilatation procedure include, but are not limited to: • Allergic reaction (device, contrast medium and medications) • Arteriovenous fistula • Embolization air, device, plaque, etc. • Hematoma • Hemorrhage, including bleeding at puncture site • Pseudoaneurysm • Sepsis/Infection • Thromboembolic episodes • Vessel injury, e.g. dissection, perforation, rupture • Vessel occlusion • Vessel spasm

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

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 felt during manipulation, determine the cause of the resistance before proceeding. Do not exceed the rated balloon burst pressure. Use only the recommended balloon inflation medium (50% contrast medium/50% sterile saline solution). Never use air or any gaseous medium to inflate the balloon.

Advancing science for life™

#### **Peripheral Interventions**

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