STERLING™ Monorail™ Balloon Catheter

- Tapered tip
- Bioslide™ hydrophilic coating on balloon
- Pebax™ semi-compliant balloon material
- Inflation port
- Rapid-exchange guide wire port
- 0.020” lesion entry profile

STERLING™ Over-the-Wire Balloon Catheter

- Tapered tip
- Bioslide™ hydrophilic coating on balloon
- Pebax™ semi-compliant balloon material
- Inflation port
- Wire port
- 0.020” lesion entry profile

**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 fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

**CONTRAINDICATIONS:**

- None Known.

**STERLING ADVERSE EFFECTS:**

- 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)
- Embolization
- 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

**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.
  - Sepsis/infection
  - 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 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.
The #1 0.018” balloon catheter with the most comprehensive size offering available

10 seconds*  
Best-in-class deflation time

0.020”**  
Lowest in-class lesion entry profile

2-10 mm diameters  
10-220 mm lengths  
The most comprehensive size offering available

The Sterling™ family† 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

Demand the Broadest Size Matrix  
- The most comprehensive size offering available in both over-the-wire and Monorail™ rapid-exchange  
- Indicated for wider acute use including carotid‡ and post stent dilatation

---

* Average measurements taken by Boston Scientific in U.S. by X50 mm balloon. Data on file. (TR 9088455). 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.
STERLING™ MONORAIL™ AND STERLING™ SL OVER-THE-WIRE PTA BALLOON DILATION CATHETERS
STERLING™ MONORAIL™ AND STERLING™ SL OVER-THE-WIRE PTA BALLOON DILATION CATHETERS
STERLING™ OVER-THE-WIRE PTA BALLOON DILATION 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, 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.

INDICATIONS FOR USE: The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, proximal and distal radial, and posterior tibial 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 or subacute thrombosis
• Allergic reaction (device, contrast medium and medications)
• Amputation
• Angina
• Arrhythmias (major, minor), including ventricular fibrillation
• Arteriovenous fistula
• Aneurysm
• Arteritis
• Aspiration
• Atherosclerosis
• Atrioventricular block
• Blood pressure
• Bruising
• Cardiac arrest
• Cardiac catheterization
• Cardiovascular collapse
• Chest discomfort
• Chest pain
• Compartment syndrome
• Compression
• Contrast medium reactions
• Defibrillation
• Dissection
• Driving
• Embolectomy
• Embolization
• Emboli
• Endarterectomy
• Endocarditis
• Endocardial erosion
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditis
• Endocarditi...