

The SplitWire Percutaneous Transluminal Angioplasty Scoring Device

Instructions for Use

Contents

Contains one (1) SplitWire device.

Sterile. Sterilized with ethylene oxide gas. Radiopaque. For single use only. Do not autoclave.

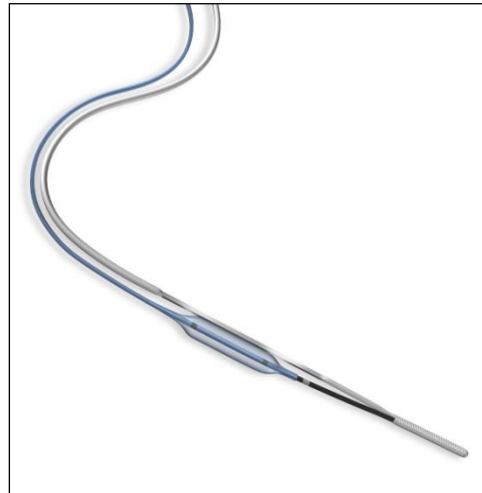
Caution: Federal (USA) law restricts this device to the sale by, or on the order of, a physician.

I. Device Description

SplitWire without PTA Balloon



SplitWire with PTA Balloon



The SplitWire Percutaneous Transluminal Angioplasty Scoring Device is designed to facilitate the dilatation of stenoses.

The SplitWire device is intended to be used with a percutaneous transluminal angioplasty balloon catheter.

The SplitWire device consists of two (2) wires that are joined at the distal end. The larger wire (scoring wire) has a triangular profile near the distal end, that when the balloon is inflated applies pressure to the lesion being treated. The smaller wire (tracking wire) is used to position the PTA balloon catheter in the proper location adjacent to the lesion. There are two (2) radiopaque marker bands on the tracking wire that indicate the location for the PTA balloon catheter placement.

The distal section of the SplitWire is designed to be atraumatic with a radiopaque coil for visibility. The distal section is coated with a soft polymer.

II. Indications for Use

The SplitWire Percutaneous Transluminal Angioplasty Scoring device is indicated for the use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

III. Contraindications

- Where there is the inability to cross the target lesions with a guidewire
- For use in the coronary or neuro vasculature

IV. Warnings

1. Contents supplied sterile using ethylene oxide (EO) process. Do not use if sterile barrier is damaged.
2. For single product and patient use only. Do not re-use, re-process or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Accordingly, the Manufacturer or its Distributors will not be responsible for any direct or consequential damages or expenses resulting from reuse, reprocessing or re-sterilization of the SplitWire device.
3. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.
4. The SplitWire device has not been tested in stents and is not recommended for use in stents. The SplitWire device is not indicated to treat in-stent restenosis. Complications may result from use of the SplitWire device in stents.

V. Precautions

1. Carefully inspect the device prior to use. Do not use if damaged.
2. The device should only be used by a physician trained in the performance of percutaneous transluminal angioplasty.
3. Store in a cool, dark, dry place.
4. Use prior to the 'Use By' date.
5. Fluoroscopic guidance should be used when the SplitWire device is in the vasculature.
6. If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding.

VI. Potential Complications

The complications that may result from a peripheral balloon dilation procedure include:

- Additional intervention
- Allergic reaction to drugs and contrast media
- Aneurysms and Pseudo aneurysms
- Arrhythmias
- Arterial spasm
- Arteriovenous fistula
- Embolization
- Hematoma
- Hemorrhage, including bleeding at puncture site
- Hypotension / Hypertension
- Inflammation
- Occlusion
- Pain or tenderness
- Pneumothorax or hemothorax
- Re-stenosis of the dilated artery
- Sepsis / Infection
- Shock
- Short term hemodynamic deterioration
- Stroke
- Thrombosis
- Vessel dissection, perforation, rupture, or spasm

VII. Recommended Procedure

The SplitWire device is used to augment a PTA balloon catheter during a PTA procedure.

NOTE: The introducer sheath size may need to be increased to accommodate the overall diameter of the PTA balloon catheter and SplitWire device when used together.

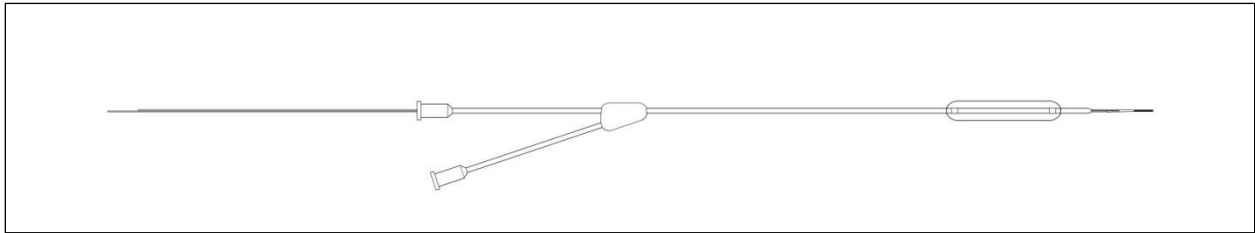
Refer to the PTA balloon catheter instructions for use for information on the use of the PTA balloon catheter.

1. Flush SplitWire device while still contained in packaging hoop.
2. While PTA balloon catheter is still at the treatment / lesion location, advance the entire device (both wires) through the guidewire lumen of the PTA balloon catheter (Figure 1) until the radiopaque tip of the SplitWire is distal to the end of the PTA balloon catheter (Figure 2).

Figure 1. Advance SplitWire Device through guidewire lumen of PTA Balloon Catheter

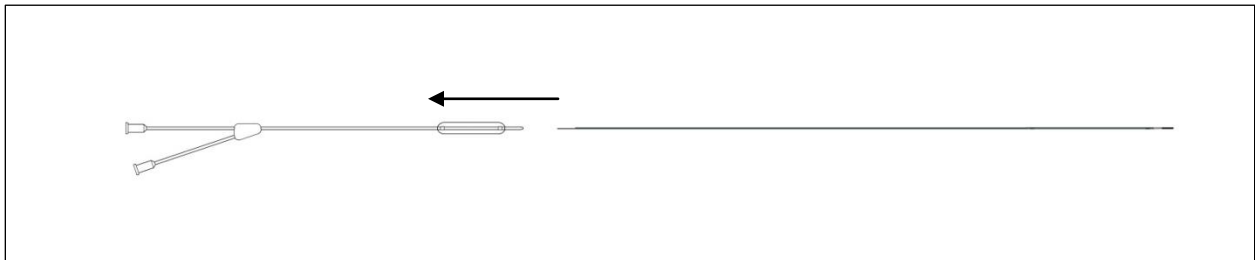


Figure 2. SplitWire and PTA Balloon Catheter at the treatment location



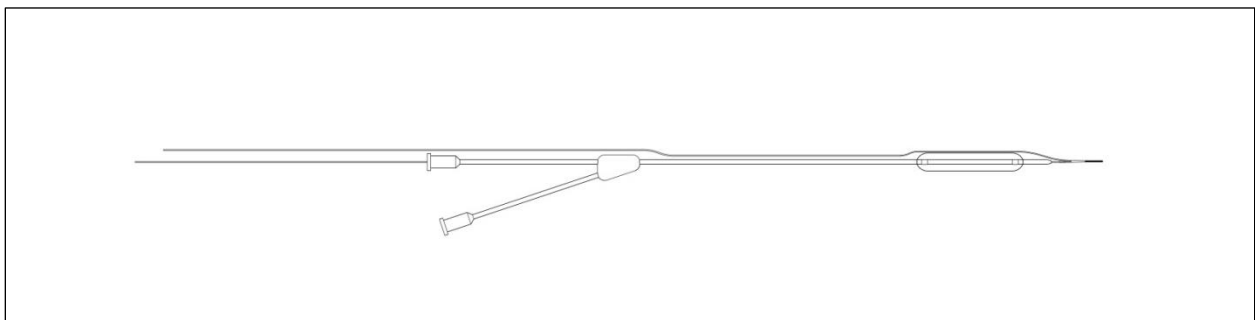
3. If not already done, deflate the PTA balloon catheter according to its instructions for use.
4. Remove the PTA balloon dilation catheter while leaving the SplitWire device in place (Figure 3).

Figure 3. Remove the PTA Balloon Catheter leaving the SplitWire device at treatment location



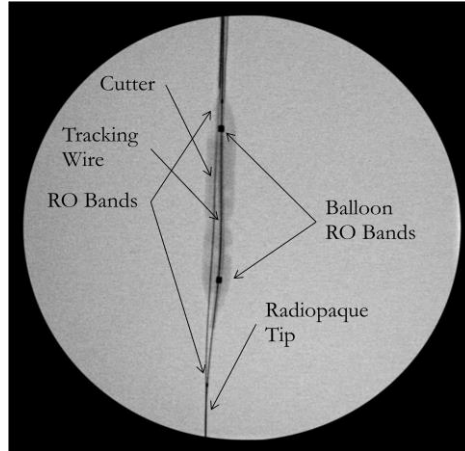
5. Re-advance the PTA balloon catheter over only the tracking wire of the SplitWire device leaving the larger wire external to the outer diameter of the PTA balloon catheter (Figure 4).

Figure 4. Advance the PTA Balloon Catheter over the tracking wire of the SplitWire Device



6. Advance the PTA balloon catheter until resistance is felt and the PTA balloon catheter is fully advanced near the distal RO band of the SplitWire device. Confirm the RO bands of the balloon catheter are inside the RO bands of the SplitWire device (Figure 5).

Figure 5. Proper placement of PTA Balloon Catheter and SplitWire Device prior to treatment



7. Inflate the PTA balloon catheter according to its instructions for use.
8. After treatment deflate balloon and remove both devices from vasculature.

VIII. Disclaimer of Warranty and Limitation of Remedy

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