



SECTION VI

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

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B. Device Name:

Bard® Tru-Trac™ Peripheral Balloon Dilatation Catheter

C. Predicate Device Name:

Medi-Tech® Ultra-Thin™ Balloon Dilatation Catheter

D. Device Description

The Bard Tru-Trac Peripheral Balloon Dilatation Catheter is a multi-lumen catheter with a discrete balloon mounted on its distal tip. The clear lumen, labeled "balloon", is for balloon inflation. The green lumen, labeled "distal", allows the catheter to track over a guidewire and can be used for monitoring of pressure or infusion of medication and/or contrast medium.

The catheter shaft gradually tapers beneath the balloon, nominally one french size. The tip is further tapered to provide a smooth interface with a Bard .035" PTFE-coated guidewire. Two radiopaque markers are placed beneath the "working area" of the balloon.

The balloon is wrapped clockwise (when viewed from the proximal shaft to the distal tip) around the shaft and is protected by a balloon folding tool prior to sterilization. A stylette is inserted in the distal (guidewire) lumen beneath the balloon folding tool.

The Bard Tru-Trac Peripheral Balloon Dilatation Catheter is available in various models incorporating balloon diameters (inflated) of 4mm-10mm; balloon lengths of 2, 3, 4, 8 and 10 cm; shaft lengths ranging from 45 to 125cm (standard lengths of 45, 75, 85 and 125cm); and shaft diameter of 5 Fr. (for balloons with inflated diameters < 10mm) or 5.8 Fr. (for balloons with 10mm inflated diameter).

The device is provided sterile and non-pyrogenic for one time use only and is not intended to be re-used or re-sterilized. Guidewires, guiding catheters or introducers that may be required for a particular procedure are not packaged with the balloon dilatation catheter and must be obtained separately.

E. Intended Use:

As stated in the device package insert (Directions for Use) the Bard Tru-Trac Peripheral Balloon Dilatation Catheters is:

"Recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Any use of this product for procedures other than those indicated is not recommended."

F. Technological Characteristics Summary:

The Bard Tru-Trac Peripheral Balloon Dilatation Catheter is constructed of biocompatible materials. The shaft of the device is constructed of PEBAX (elasticized nylon), the balloon is constructed of PET (polyethyleneterephthalate), the marker bands are tantalum. The catheter is generally inserted through an introducer and over a guidewire, advanced within the vessel to the point of lesion and inflated with fluid to perform dilatation of the vessel.

G. Performance Data:

Each balloon inflates to the stated diameter and length at a specific pressure—typically between 3 and 4 atms. The maximum amount of balloon growth in either diameter or length is less than 15% over the

working pressure range. All balloons are preinflated to full size. The maximum recommended inflation pressure is the pressure at which 99.9% of balloons, at a 95% confidence level, will not burst at or below this pressure upon a single inflation. The maximum inflation pressure is not to exceed 15 atm for inflated balloon diameters <10mm and not to exceed 13 atm for 10mm inflated balloon diameter.