

**Bard Urological Division**  
C. R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, GA 30209-2695

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**BAIRD**

**SECTION VI**

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

**A. Submitter Information:**

**Submitter's Name:** C. R. Bard, Inc., Urological Division  
**Submitter's Address:** 8195 Industrial Blvd., Covington, GA 30209  
**Contact Person:** Donna J. Wilson  
**Contact Person's Address:** 8195 Industrial Blvd.,  
Covington, GA 30209  
**Contact Person's Telephone Number:** 770-784-6135  
**Contact Person's FAX Number:** 770-784-6419  
**Date of Preparation:** July 23, 1996

**B. Device Name:**

**Bard® A-Trac™ Urological Balloon Dilation Catheter**

**C. Predicate Device Name:**

**Bard® Tru-Trac™ Peripheral Balloon Dilatation Catheters and  
Microvasive's (Boston Scientific Corporation) Uro Max™ II High  
Pressure Ureteral Balloon Dilatation Catheter and Phantom 5™ Plus  
ST (Short Tip) Ureteral Balloon Dilatation Catheter.**

**D. Device Description:**

**The Bard® A-Trac™ Urological Balloon Dilation 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 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 0.035" 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® A-Trac™ Urological Balloon Dilation 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 for one time use only and is not intended to be re-used or re-sterilized. Guidewires 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 (Information for Use) the Bard® A-Trac™ Urological Balloon Dilation Catheter is:

"Indicated for use in dilation of the ureter or urethra through the working channel of an endoscope."

#### F. Technological Characteristics Summary:

The Bard® A-Trac™ Urological Balloon Dilation Catheter is constructed of biocompatible materials. The shaft of the device is constructed of nylon, the balloon is constructed of PET (polyethylene terephthalate), the marker bands are tantalum. The catheter is generally inserted through the working channel of an endoscope and over a guidewire, advanced within the urethra or ureter to the stone or calculi location or point of stricture and inflated with fluid to perform dilation of the urethra or ureter to allow stone removal or treatment of stricture.

**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.