INSTRUCTIONS FOR USE

INDICATIONS:
Recommended for use in catheterization for angiography of cardiovascular vessels and / or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel.

CATHETER CHARACTERISTICS:
The MULTI-TRACK™ angiographic catheter is a single lumen catheter with side holes at the tip and a 1cm section at the distal tip for catheter tracking. The tubing of the catheter is radiopaque for proper visualization under fluoroscopy.

HOW SUPPLIED:
Supplied sterilized by ethylene oxide gas. Sterile and non-pyrogenic if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

WARNING:
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross contamination.
- Do not advance the MULTI-TRACK™ angiographic independent from the guidewire.
- Do not advance the guidewire or any other component if resistance is met, without first determining the cause and taking remedial action.
- The rated burst pressure for this device is 1000 psi. Do not exceed 1000 psi.

PRECAUTIONS:
- The MULTI-TRACK™ angiographic catheter procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage.
- Careful attention must be paid to the maintenance of tight catheter connections and aspiration before proceeding to avoid air introduction into the system.
- Under no circumstances should any portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.
- Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.
- Do not use excessive force on the catheter. During an angiographic procedure, excessive force is determined to be the force required to bend a standard 0.035" guidewire.
- The flow rates have been calculated as follows at 1000 psi:

Catheter Size (Fr)	Catheter Length (cm)	Flow Rate (ml/sec)
3	80	5.5
3	100	4
4	80	13
4	100	11
5	80	22
5	100	20
6	100	25

POTENTIAL COMPLICATIONS:
Potential complications related to the introduction of the catheter into the body include, but are not limited to, the following:
1) Infection,
2) Air embolism, and
3) Hematoma formation.

PREPARATORY MEASURES:
1. Remove the catheter from its packaging and carefully examine for bends or kinks. Carefully flush the MULTI-TRACK™ angiographic catheter with saline.

INSTRUCTIONS:
1. Enter the vessel percutaneously using the standard seldinger technique over the appropriate guidewire for the size catheter being used.
2. Position an appropriate guidewire for the catheter being used into the desired site. Connect the distal portion of the MULTI-TRACK™ angiographic catheter to the guidewire and advance the catheter to the entrance into the body. Flush the catheter in order to remove all air bubbles from its lumen.
3. Hold the guidewire and gently advance the MULTI-TRACK™ angiographic catheter into the skin. If resistance is encountered, put an appropriate guidewire into the lumen of the MULTI-TRACK™ angiographic catheter in order to stiffen the shaft while pushing.
4. Once the catheter is in the vessel, flush again according to standard practice.
5. Advance the catheter into the desired position either by simply pushing on its shaft or with the aid of a guidewire in its lumen.
6. Perform pressure measurements and/or angiographies according to the standard practice or hospital protocols.
7. After terminating the use of the MULTI-TRACK™ angiographic catheters, they are sequentially removed and another procedure can be performed on the guidewire which was positioned in the beginning.
8. After removal of all devices from the vascular access apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

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WARNING:

These catheters are placed in the extremely hostile environment of the human body. Catheters may fail to function for a variety of causes including, but not limited to, medical complications or failure of catheters by breakage. In addition, despite the exercise of all due care in design, component selection, manufacture and testing prior to sale, catheters may be easily damaged before, during, or after insertion by improper handling or other intervening acts. Consequently, no representation or warranty is made that failure or cessation of function of catheters will not occur or that the body will not react adversely to the placement of catheters or that medical complications will not follow the use of catheters. B. Braun Interventional Systems Inc. cannot warrant or guarantee B. Braun Interventional Systems Inc. accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.

WARRANTY AND LIMITATIONS:

Catheters and accessories are sold in an 'as is' condition. The entire risk as to the quality and performance of the catheter is with the buyer. B. Braun Interventional Systems Inc. disclaims all warranties, expressed or implied, with respect to catheters and accessories, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. B. Braun Interventional Systems Inc. shall not be liable to any person for any medical expenses or any direct or Consequential damages resulting from the use of any catheter or accessory or caused by any defect, failure, or malfunction of any catheter or accessory, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind B. Braun Interventional Systems Inc. to any representation or warranty with respect to catheters and accessories.

MULTI-TRACK™

ANGIOGRAPHIC CATHETER

Instructions for Use

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