**BARD® Bi-Directional and Kelly-Wick Tunnelers**

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

**INSTRUCTIONS FOR USE**

**Indication**

The BARD® Bi-Directional and Kelly-Wick Tunnelers are intended to aid in creating subcutaneous tunnels for the placement of vascular prostheses (grafts) or autogenous grafts for arteriovenous access, peripheral vascular, and extra-anatomic bypass procedures.

**Description**

The Kelly-Wick tunneler consists of two components: a shaft with integral handle and a tip. The BARD® Bi-Directional tunneler consists of three components: a shaft, a separate handle and a tip. When the components are assembled they create a single unit device.

The Tunnelers are reusable medical devices, and are made of medical grade stainless steel.

**Precautions**

1. Care should be exercised to protect the BARD® Bi-Directional and Kelly-Wick Tunnelers from mechanical damage. Rough handling may mar the surface of the tunnelers. The BARD® Bi-Directional and Kelly-Wick Tunnelers are fabricated from stainless steel. These devices will stand up to repeated use if proper care is exercised.

2. Do not soak instruments in saline or bleach solutions, which may damage the surface of the instruments.

3. The BARD® Bi-Directional and Kelly-Wick Tunnelers are supplied non-sterile and require complete disassembly prior to cleaning.

4. The BARD® Bi-Directional and Kelly-Wick Tunnelers must be thoroughly cleaned, inspected and sterilized prior to each use.

5. Do not soak instruments in saline or bleach solutions which may damage the surface of the instruments.

6. Bard Peripheral Vascular does not recommend sterilizing the BARD® Bi-Directional or Kelly-Wick Tunnelers with ethylene oxide or flash sterilization.

**Cleaning Prior to Sterilization**

Decontamination and sterilization prior to use are the responsibility of the hospital facility as the Tunnelers are sold non-sterile.

Personnel should wear appropriate protective attire when handling the BARD® Bi-Directional and Kelly-Wick Tunnelers. If the hospital is not equipped with a combination instrument washer-sterilizer, the following procedure should be followed:

1. Immediately after use, completely disassemble the Tunnelers and rinse the components in warm water to assist in the removal of visible debris.

2. If the final wash is to be delayed, the tunneler should be immersed in warm water containing an effective neutral pH (pH = 7) blood solvent or detergent. Reference PRECAUTION #5.

3. It is important to inspect all components of the BARD® Bi-Directional and Kelly-Wick Tunnelers, even those not used in the surgical procedure, to ensure that the entire set is washed and clean prior to sterilization.

4. Use a neutral pH, low sudsing detergent during the wash. It is important to remove all particles of adhering tissue and dried blood from the crevices of the device, particularly on the threaded portions of the shafts and bullet tips and the knurling on the handle. Use only specially recommended stainless steel wire brushes or stiff plastic brushes for cleaning. Avoid using ordinary soap which may leave insoluble alkali films and abrasives, which may roughen the metallic surfaces.

5. Immediately after washing, the Tunnelers should be rinsed with hot water for a brief period and then dried thoroughly.

6. It is important to inspect all Tunnelers components and the Tunneler Sterilization Cassette to insure that they are clean and free of damage prior to sterilization. Damage that could prevent proper function of the Tunnelers includes scratches, cross-threading, etching, pitting, burrs, nicks, dents or cracks. Reference PRECAUTIONS #1 and #4.

After cleaning and decontamination, all components should be placed in an appropriate sterilization cassette that must be enclosed in an appropriate commercially available sterilization wrap, used in accordance with the wrap manufacturer’s instructions.
NOTE: Bullet tips are small. The holes in the cassette should not allow any of the parts to fall out.

Maintenance Procedures:
Proper maintenance of the Tunnelers requires careful handling of the devices to avoid damaging the threaded portions. If these areas are damaged through improper handling (i.e., dropping, cross-threading, brushing with abrasives), the parts may not fit together properly or be interchangeable on the shafts. If such damage occurs, contact Bard Peripheral Vascular for appropriate replacement parts and ordering information.

If the instrument will not be completely cleaned manually as previously described, it should be rinsed and pre-cleaned of all debris prior to placing it in a combination washer/sterilizer. Follow your washer/sterilizer equipment manufacturer’s instructions for minimum exposure requirements for surgical instruments.

Recommendations for Steam Sterilization
The BARD® Bi-Directional and Kelly-Wick Tunnelers and all associated accessories are made of stainless steel and, after appropriate cleaning and decontamination, may be repeatedly exposed to methods of sterilization utilizing steam without compromising the physical properties of the device. This device is not considered a terminally sterilized medical device, but rather, a reusable medical device.

After cleaning and decontamination, the BARD® Bi-Directional and Kelly-Wick Tunnelers may be sterilized following your saturated steam sterilizer equipment manufacturer’s instructions for minimum exposure requirements for surgical instruments or by using the following cycle parameters. Reference PRECAUTION #6.

Temperature: 250° F (121° C)
Pressure: 15 psi (1.034 BAR)
Time: 30 minutes

Prior to opening the sterilization wrap, inspect the wrap for tears, pinholes, or other damage that might compromise sterility. The Cassette must be enclosed in an appropriate commercially available sterilization wrap in order to preserve sterility after processing. The following standards/guidelines may be referenced for further information on the safe handling and biological cleaning and sterilization of medical devices:

AAMI/ANSI/ISO 11134 “Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization.”
ANSI/AAMI ST35-1996 “Good Hospital Practice: handling and biological decontamination of safe medical devices in health care facilities and in non-clinical settings.”

Selection of Tips
The Tunneler bullet tips are interchangeable. They are available in a variety of sizes. To create the appropriately sized tunnel for a chosen specific graft configuration, use the following guidelines for bullet tip selection:

For natural vessels, unsupported ePTFE or polyester vascular grafts and similar products, select a bullet tip of the same size as the internal diameter (ID) of the graft being implanted.

For bypass grafts with external spiral support such as Flex Small beading, IMPRA FLEX™ grafts, CENTERFLEX™ grafts, BARD® polyester grafts or similar products with external support, select a bullet tip one or two millimeters larger than the internal diameter of the graft being implanted. For example, when implanting a 6 mm ID graft, use the 7 mm or 8 mm bullet tip to create the tunnel. Switch to a tip of the same size as the internal diameter (ID) of the graft prior to pulling the graft through the tunnel.

The hollow 4 mm vein tip may be used with the luer lock adapter for injection of heparin and contrast fluid, instillation of vasolytic agents, and placement of small veins.

Selection of Tunneler Shafts
The shafts measure 6 mm in diameter and are available in several lengths and configurations (straight and curved). All BARD® Bi-Directional Tunneler shafts are designed such that the detachable handle and bullet tips will fit on either end of the shaft. Select a shaft of appropriate length and configuration that creates the proper subcutaneous tunnel for graft placement.
Directions for use:

1. Select the appropriate bullet tip and shaft. If using the BARD® Bi-Directional Tunneler attach the handle to one end of the shaft. Screw the bullet tip securely onto the other end of the tunneler by hand.

2. Follow standard surgical practice to create entrance and exit incisions for the Tunneler.

3. Use the sterile assembled Tunneler to create a tissue tunnel connecting the entrance and exit incisions.

4. When the tunneler passes through the incision exit site and a satisfactory tunnel has been created, place the graft over a bullet tip that matches the internal diameter of the graft. Secure the graft on the bullet tip by tying a suture at the waist of the bullet tip, or use the suture hole at the base of the tip to aid in securing the graft. The BARD® Bi-Directional Tunneler provides for the option of pulling the graft through the tunnel in the same direction the tunnel was created. To use this option, observe the following:

   a. When the tunneler passes through the incision exit site and a satisfactory tunnel has been created, remove the handle and bullet tip from the shaft.

   b. Secure the handle on the end of the shaft where the bullet tip was just removed. Ensure the shaft mates to the handle (i.e., the shaft cannot rotate) prior to tightening the handle base.

   c. Select a bullet tip that matches the internal diameter of the graft and attach it to the other end of the shaft. Secure the graft on the bullet tip by tying a suture at the waist of the bullet tip, or use the suture hole at the base of the tip to aid in securing the graft.

5. Pull the graft through the tunnel using the handle.

6. When the graft has been pulled into position in the tunnel, remove the graft from the Tunneler by cutting the suture or graft.

7. Proceed with making the vascular anastomoses.

Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.
Bi-Directional Bullet Tip

Bi-Directional Vein Tip

Bi-Directional Luer Adapter

Bi-Directional Tunneler 25cm Curved Shaft

Bi-Directional Tunneler 24cm Straight Shaft

Bi-Directional Tunneler 55cm Curved Shaft

Bi-Directional Cassette

Bi-Directional Tip Plate