This is a sterile, single-use product and is not designed for re-sterilisation. Do not reuse, reprocess or re-sterilise.

**Description:**
The Everest Disposable Inflation device is a sterile 20cc inflation device with a locking mechanism that is operated via the Trigger. Normally, the locking mechanism is engaged. Once the Trigger is pulled back, the locking mechanism is released and the piston can be manually manipulated.

The Everest 20 Device is outfitted with a manometer with measuring pressures ranging from vacuum to 20 bars in 0.5 bar increments. The Everest 30 Device is outfitted with a manometer with measuring pressures ranging from vacuum to 30 bars in 1 bar increments. The manometers are accurate to within ±3% of the gauges full scale. A high pressure connecting tube with a male rotating adapter and a disposable 3-way stopcock are also included to aid in preparation of the Device. When purchased as a "survival Kit", the package will include a Y/Tri-Adapter with haemostasis valve, a Guide Wire Insertion Tool and a Steering handle.

**EVEREST 20cc Disposable Inflation Device and Survival Kit**

**Contents of Package:**
Contains one or more of the following: Everest 20 or Everest 30 20cc Disposable Inflation Device, Stopcock, Y/Tri-Adapter with Haemostasis Valve, Guide wire Insertion Tool, and Steering handle.

**Indications:**
The Everest 20cc Inflation Device/Survival kit is to be used to facilitate the use of catheters and guide wires during interventional procedures. The Everest 20cc Inflation Device is designed to be used to inflate/dilate balloon catheters as well as to monitor pressure within the balloon. The Y/Tri-Adapter with Haemostasis Valve is designed to be used on a guiding catheter or dilatation catheter to control back bleeding and to provide a port for introduction of fluids into the interventional system. The Guide Wire Insertion Tool is designed to facilitate placement of a guide wire tip through the Y/Tri-Adapter and into the wire lumen of an interventional catheter. The guide Wire Steering Handle is designed to hold a small diameter guide wire and provide a handle for manipulating the wire.

**Preparation:**
1. Prepare solution of contrast medium and normal saline. Check balloon catheter instructions for recommendations, if any, for specific mixture requirements.
2. Pull the Trigger to release the lock mechanism and manually advance the piston via the knob forward to the 0 (zero) cc position.
3. Submerge the male rotating adapter into the prepared contrast solution. With the Trigger pulled back, aspirate an appropriate volume of contrast solution within the syringe. Release the Trigger.
4. Install the Stopcock onto the male rotating adapter. Adjust the valve so that an open fluid path to the syringe is established.
5. While holding the device upright, purge the air from the syringe and connecting tube by advancing the piston. If necessary, tap the syringe lightly to remove all entrapped air within the system.
6. Once certain that all entrapped air has been removed, adjust the valve of the Stopcock so that the fluid path to the syringe is closed.

Connecting the Inflation Device to the Balloon Dilatation Catheter:
Note: Prior to connecting the Inflation Device, the balloon dilatation catheter should be prepared and tested according to the manufacturer’s instructions.
1. Remove the Stopcock from the male rotating adapter of the Inflation Device.
2. Caution: Failure to remove the stopcock could compromise the integrity of the fluid path allowing air to enter the system and/or contrast solution to leak out. Inflation pressures may not be maintained.
3. Create a fluid to fluid connection between the male rotating adapter of the Inflation Device and the Balloon inflation port and tighten the hubs securely to one another.

Operating Inflation Device:
1. Release the piston by squeezing the trigger below the syringe. In this position the piston can be pushed in freely for inflation or pulled back easily for deflation.
2. To inflate the balloon first squeeze and hold the trigger while slowly pushing the piston knob forward. Next, release the trigger and gradually turn the piston knob clockwise to achieve desired pressure. To decrease pressure, turn the piston knob counterclockwise.
3. To rapidly deflate balloon, squeeze and hold the trigger to release the piston and then pull back on the piston knob. Release the trigger to hold the piston in negative pressure.

Instructions for Use of Accessories:
If the Y/Tri-Adapter is to be used with a guiding catheter:
1. Tread the dilatation catheter through the hole in the cap of the Y/Tri-Adapter. Flush thoroughly to remove air.
2. Advance the dilatation catheter into the guiding catheter.
3. To join the rotating connector of the Y/Tri-Adapter (with the dilatation catheter passing through it) to the guiding catheter, vigorously flush forward through the adapter to remove air while allowing back bleeding through the guiding catheter. This will permit a fluid-fluid interface while the adapter is attached to the guiding catheter.

If the Y/Tri-Adapter is to be used with a dilatation catheter:
1. Attach the rotating connector to the hub of the dilatation catheter.
2. Flush thoroughly to remove any air that may be trapped in the device.
3. Insert the distal tip of the appropriate guide wire into the hub of the guide wire insertion tool. Inset the guide wire insertion tool through the Y/Tri-Adapter and advance the guide wire into the desired device.
4. Remove the guide wire insertion tool, and tighten down the Y/Tri-Adapter haemostasis valve until no back bleeding is evident.

Guide Wire Steering Handle:
1. Advance the appropriate guide wire into the lumen of the dilatation catheter.
2. Slide the steering handle over the proximal end of the guide wire and tighten the handle on the wire.

Warnings:
• Always follow the manufacturer’s directions accompanying the balloon catheter for instructions for use, maximum inflation pressure, precautions and warnings for use.
• Improper tightening of the connection between the Inflation Device and Y/Tri-adapter and accompanying equipment may result in introduction of air into the vascular system. Do not inject any fluid if air bubbles are visible within the fluid path of the Inflation Device or the Y/Tri-Adapter.
• The pressure displayed on the inflation device must not exceed maximum recommended balloon catheter inflation pressure.
• Prolonged exposure to contrast medium may cause components of the device to malfunction and thereby create a safety hazard.
**Storage and Use:**

**Storage:** Store in a cool, dry place away from direct sunlight, preferably in original box.

**Shelf Life:** Refer to the Expiry Date printed on each pack label.

Sterile unless package is opened or damaged. If damage is found call your local Bard Australia Pty Ltd representative.

Pack is a single use device. Dispose of all unused components immediately after pack use.

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**STERILE EO**

Sterilised by Ethylene Oxide

**MANUFACTURER:**

*Bard Australia Pty Ltd*

*ABN 50 001 468 935*

*22 Lambs Road, Artarmon, NSW 2064 Australia*

*Ph +61 2 8875 4000*

*Fax +61 2 8875 4050*

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