

Advanced Inflation Device

Description:

Advanced Inflation Device

Configuration:

See brochure

Intended use:

The Advanced Inflation Device is used with balloon dilation catheter to monitor inflation pressure.

Contraindications:

Those specific to procedures to be performed in conjunction with balloon dilation.

Complications:

Possible complications include, but are not limited to the following:

- Vessel wall perforation
- Infection
- Bleeding
- Edema
- Tissue trauma

Caution:

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

Warning/ Precaution:

- Always follow the manufacturer's directions accompanying the balloon dilation catheter for instruction for use, maximum inflation pressure, precautions and warnings for that device.
- For Single Use Only
- To be used by experienced surgeons
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Store in a cool & dry place.

Instruction for Use:

1. Prepare a solution of contrast medium and normal saline in a small sterile bowl. Check balloon catheter instructions for specific- contrast mixture recommendations.
2. Attach the tubing to the head of the pressure gauge with piston fully depressed.
3. Pulling the syringe plunger with tubing dipped in contrast solution, aspirate enough to fill the syringe.
4. Hold the device upright to purge the air from the syringe and connecting tube. Tap the syringe slightly, to remove all the air bubbles, and fill the connecting tube completely.
5. Inspect the syringe, tubing and stopcock to ensure that the device is completely purged.

6. Attach the Inflation device to the balloon dilatation catheter as manufacturer's direction of use.
7. To inflate the balloon catheter, advance the plunger till possible and then lock the barrel flange. For increasing the pressure, twist the knob slowly till desired inflation pressure is reached.
8. To deflate the balloon, first turn the knob anticlockwise till the pressure is released completely, and then retract the plunger to deflate the balloon completely.

Liability:

Allwin is not liable for defects/ deterioration resulting from abnormal use or modifications made to the product and under these circumstances not covered by the guarantee. Allwin disclaims liability for direct or indirect injuries that may occur as a consequence of the product being modified or wrongly used.

Do not reuse, reprocess & resterilize:

Reuse, Reprocessing & reesterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:

The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages.

The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

Catalogue Number
 Batch Code
 Date of Manufacture
 Use By
 Do not re-use
 Do not Re-Sterilize
 R_x only
 Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Consult Instruction for use
 Do not use if Packing is damaged
 Caution
 Keep out of sunlight
 Keep Dry
 STERILE **EO**
 Sterilized using ethylene oxide

EC REP
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