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**Armada 35 / Armada 35 LL**  
**Percutaneous Transluminal Angioplasty Catheter**



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## I. DESCRIPTION

The Armada 35 / Armada 35 LL Percutaneous Transluminal Angioplasty (PTA) Catheter is a dual lumen catheter with a balloon located near the distal atraumatic tip. One lumen is used for inflating the balloon and is accessed via the side leg port. The second lumen, starting at the straight entry port, allows access to the distal tip of the catheter for guide wire insertion (max. 0.035"). The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating section of the balloon and help in balloon placement.

The balloon is inflated using the side leg port, at which the balloon expands to a known diameter at a specific pressure. The working pressure range for the balloon is between the nominal size pressure and the rated burst pressure. All balloons distend to sizes above the nominal diameter at pressures greater than the nominal pressure.

The balloon diameter and balloon length are printed on the luer. Refer also to the package label for information about catheter length, guide wire compatibility, nominal and rated burst pressure, balloon compliance and sheath compatibility.

### How the system is supplied

This device is e-beam sterilized. Non-pyrogenic. Do not use if the package is open or damaged. Packaged with every Armada 35 / Armada 35 LL PTA Catheter is a protective tubing that is positioned over the balloon and a balloon compliance card.

### Storage

The Armada 35 / Armada 35 LL PTA Catheter should be stored in a dark, dry and cool place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that the device is used prior to the use by date on the package label.

## II. INDICATIONS

The device is intended for dilatation of lesions in the renal, iliac, femoral, popliteal, tibial, and peroneal, arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

This device is also indicated for stent post-dilatation in the peripheral vasculature.

## III. CONTRAINDICATIONS

- Inability to cross lesion with a guide wire
- Use in the coronary arteries

## IV. WARNINGS / PRECAUTIONS

- This device should only be used by physicians who are experienced and have a thorough understanding of the clinical and technical aspects of PTA.

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- One-time use only – do not resterilize! This single use device cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and/or chemical characteristics introduced under conditions of repeated use, cleaning, and/or resterilization may compromise the integrity of the design and/or materials, leading to contamination due to narrow gaps and/or spaces and diminished safety and/or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to patient and/or user.
  - Do not use if inner package is damaged or opened.
  - Employ aseptic techniques during removal from the package and during use.
  - Any use for procedures other than those indicated in these instructions is not recommended.
  - Use prior to the use by date.
  - Carefully inspect the catheter prior to use to verify that it has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used.
  - Precautions to prevent or reduce blood clotting should be taken when any catheter is used.
  - Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution via the guide wire access port prior to use.
  - Consider the use of systemic heparinization.
  - When the system is introduced into the vascular system, it should be manipulated only under high quality fluoroscopy.
  - The Armada 35 / Armada 35 LL PTA Catheter must always be introduced, moved and or withdrawn over a guide wire (max. 0.035”).
  - Never attempt to move the guide wire when the balloon is inflated.
  - Never use air or any gaseous medium to inflate the balloon.
  - Do not advance the Armada 35 / Armada 35 LL PTA Catheter against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
  - The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the Armada 35 / Armada 35 LL PTA Catheter through a smaller sized sheath introducer than indicated on the label.
  - The size of the inflated balloon should be selected not to exceed the diameter of the artery immediately distal, or proximal, to the stenosis.
  - Inflation in excess of the rated burst pressure may cause the balloon to rupture. Use of a pressure monitoring device is recommended.
  - When post-dilating stents, use a balloon length that is appropriate for the deployed stent length.

## **V. POTENTIAL COMPLICATIONS**

The following complications may occur as a result of PTA, but may not be limited to:

- Abrupt closure
- Access site hematoma
- Aneurysm
- Angina
- Arrhythmias

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- Arteriovenous fistula
  - Bleeding complications which may require transfusion
  - Cerebral ischemia/transient ischemic attack (TIA)
  - Death
  - Embolism (air, tissue, thrombotic, systemic or device component)
  - Fever/pyrogenic reaction
  - Hypersensitivity or allergic reaction to contrast agents and drug reactions
  - Hypertension/hypotension
  - Infection
  - Ischemia, including tissue ischemia, steal syndrome and necrosis
  - Leg edema
  - Myocardial ischemia or infarction
  - Nausea and vomiting
  - Neuropathies or nerve injury
  - Occlusion
  - Organ failure (single, multiple)
  - Pain
  - Palpitations
  - Pseudoaneurysm
  - Renal failure/insufficiency
  - Restenosis
  - Stroke/cerebrovascular accident (CVA)
  - Vascular complications, including entry site, which may require vessel repair
  - Vascular thrombosis
  - Vessel injury, e.g. dissection, perforation
  - Vessel spasm

## **VI. MATERIALS REQUIRED**

- 1000 $\mu$ /500cc Heparinized Normal Saline (HepNS)
- Introducer sheath size based on balloon size (refer to label)
- One inflation device (with pressure monitoring – recommended)
- One 3 way stopcock
- 0.035" guide wire
- 60% contrast diluted 1:1 with normal saline
- Two to three 10-20 cc syringes

## **VII. SELECTION AND PREPARATION OF DEVICE AND COMPATIBILITY WITH ACCESSORIES**

### **Selection of balloon size and compatibility of system to accessories**

The diameter of the expanded balloon should not exceed that of the artery just distal, or proximal, to the stenosis. Verify that the selected accessories accommodate the balloon catheter as labeled.

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## Preparation of PTA catheter

It is very important to check before use that the packaging has not been damaged in a way that might have rendered the catheter unsterile. It is also important at the same time to verify that the chosen catheter is the correct one for the planned procedure. Do not inflate the PTA catheter during prep of the device.

Perform the following steps to remove all air and verify the integrity of the PTA catheter:

- 1) Fill an inflation device/syringe with a mixture of contrast medium and normal saline.
- 2) Remove protective tubing from the balloon.
- 3) Attach the inflation device/syringe to the connector of the balloon lumen. Hold the catheter with the distal tip pointing downwards.
- 4) Open the stopcock to the catheter; pull negative for 30 seconds; release to neutral for contrast fill.
- 5) Close the stopcock to the catheter; purge the inflation device/syringe of all air.
- 6) Repeat steps 4 through 6 until all air is expelled.
- 7) Leave the catheter under negative pressure until the balloon is at the target lesion site.

## VIII. INTRODUCTION AND DILATATION

### Introduction of the system

- 1) The PTA catheter is designed to be introduced percutaneously using the Seldinger technique.
- 2) When the catheter is ready for introducing into the vascular system, the balloon protection tubing should be removed completely from the catheter.
- 3) Place the prepared catheter over a pre-positioned guide wire and advance the tip to the introduction site. It is advantageous to use the balloon catheter with an introducer to facilitate entry.  
**Note:** Perform all further catheter manipulations under fluoroscopy.
- 4) Position the catheter with the center of the balloon in the middle of the stenosis. The radiopaque marker bands indicate the working length of the balloon.

### Inflation of the balloon

- 5) When an acceptable position has been reached, inflate the balloon to achieve the desired dilatation.  
**CAUTION:** Do not exceed the rated burst pressure. Inflating the balloon higher than the rated burst pressure can damage the balloon or catheter or overdilate the selected artery.
- 6) Deflate the balloon by aspirating the inflation syringe or inflation device.
- 7) Maintaining a vacuum in the balloon, withdraw the catheter.  
**Note:** Gentle counterclockwise twisting motion of the balloon may ease withdrawal through the sheath or from the percutaneous entry site. If the balloon cannot be withdrawn through the sheath, withdraw the catheter and sheath as one unit.
- 8) Please note that if multiple balloon-inflations and -deflations have taken place, some resistance can occur upon device withdrawal.
- 9) The results should be checked by angiography.

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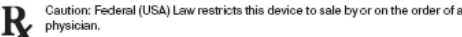

## **IX. PRODUCT INFORMATION DISCLOSURE**

Abbott Vascular has exercised reasonable care in the manufacture of this device. Abbott Vascular excludes all warranties, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device as well as factors relating to the patient, the diagnosis, treatment, surgical procedures, and other matters beyond Abbott Vascular's control directly affect this device and the results obtained from its use. Abbott Vascular shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. Abbott Vascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

## **X. TRADEMARKS**

Armada is a trademark of the Abbott Group of Companies.

## Graphical Symbol for Medical Device Labeling

|   |  |
|---|--|
|  Date of manufacture                                   |  Recommended guide wire   |
|  Manufacturer/Manufactured by                          |  Keep away from sunlight  |
|  Do not use if package is damaged                      |  Nominal balloon length   |
|  Do not re-use   |  Temperature limitation   |
|  Sterilized using irradiation                          |  Recommended Minimum Sheath Introducer  |
|  Use by  |  Over the Wire  |
|  Do not re-sterilize                                   |  Caution, consult accompanying documents  |
|  Keep dry  |  Nominal balloon diameter   |
|  Batch code/LOT number                                 |  Number of units  |
|  Catalogue number                                    |  Do not exceed!   |
|  Nominal pressure                                    |  Usable Catheter Length   |
|  Only sterile and non-pyrogenic in unopened packages |  Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician. |
|  Rated burst pressure                                |  |



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