INSTRUCTIONS FOR USE

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CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

Manufacturer
Medtronic, Inc., Minneapolis, MN

DESCRIPTION

The AMPHIRION™ DEEP percutaneous transluminal angioplasty (PTA) balloon dilatation catheter is a catheter with a semi-compliant inflatable balloon mounted at the distal tip. Dilatation balloon catheters are used to exert radial force to dilate narrow vessel segments. The AMPHIRION™ DEEP PTA catheter is available in different balloon sizes. Nominal balloon diameter and length are printed on the hub.

BALLOON CONSTRUCTION

Each balloon inflates to its nominal diameter and length at 7ATM. The working pressure range for the balloon is between the nominal pressure and the rated burst pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure. Consult the Compliance Charts included in the catheter packaging for the diameters of the balloons at given pressures.

Note: The rated burst pressure is printed on the package label. In vitro testing has shown that with 95% confidence, 99.9% of the balloons will not burst at or below the rated burst pressure. Balloons should not be inflated in excess of the rated burst pressure. The nominal balloon diameters were measured in vitro and can present a maximum statistical deviation of ±10%.

A single central radiopaque marker or 2 radiopaque markers are available in order to correctly position the balloon under fluoroscopy. The markers are placed on the shaft under the balloon itself, defining its cylindrical area in the double marker version and placed in the middle of the cylindrical area in the single marker version. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate the crossing of tight stenoses.

CATHETER CONSTRUCTION

The AMPHIRION™ DEEP PTA balloon dilatation catheter is a dual lumen device. The lumen marked "WIRE" is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guide wire with a maximum outer diameter of 0.014 in. The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the dilatation balloon with a mixture of contrast medium and saline solution. The catheter tapers beneath the balloon segment to achieve the lowest possible deflated profile.

One or 2 radiopaque marker bands are placed under the balloon segment of the catheter shaft to provide visual reference points for balloon positioning within the vessel. The distal catheter shaft is hydrophilic coated (balloon included).

INDICATIONS FOR USE

The AMPHIRION DEEP PTA balloon dilatation catheter up to 120 mm balloon length is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The AMPHIRION DEEP PTA balloon dilatation catheter in 150 mm and 210 mm balloon length is intended to dilate stenoses in the femoral, popliteal, and infra-popliteal arteries.

CONTRAINDICATIONS

Inability to cross target lesion with a guide wire.

The AMPHIRION DEEP PTA balloon dilation catheter is contraindicated for use in coronary arteries or the neurovasculature.

WARNINGS

- This device is designed and intended for single use only. DO NOT RESTERILIZE

AND/OR REUSE. Reuse or resterilization may create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness, or death. Medtronic will not be responsible for any direct, incidental, or consequential damages resulting from resterilization or reuse.

- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not manipulate the balloon in inflated state. The position of the balloon catheter may only be changed with the guide wire in place.
- If resistance occurs during manipulation, the cause must first be ascertained by fluoroscopy, road mapping or DSA before the balloon is moved backwards or forwards.
- The guide wire may under no circumstances be moved during inflation of the balloon.
- The balloon must be completely deflated before pulling it out of the dilated area.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure-monitoring device is recommended to prevent over pressurization.
- Use only a mixture of contrast medium and saline solution to fill the balloon (1:1). Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the Use Before date specified on the package.

PRECAUTIONS

- Only interventionalists who have sufficient experience should carry out PTA with this balloon catheter. A thorough understanding of the technical principles, clinical applications and risks associated with percutaneous transluminal angioplasty is necessary before using this product.
- AMPHIRION DEEP PTA balloon dilatation catheters should be used with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these lesions.
- Allergic reactions to contrast medium should be identified before PTA.
- The general technical requirements for catheter insertion must be observed at all times. This includes flushing the components with sterile, isotonic saline solution prior to use and the usual prophylactic, systemic heparinization.
- Catheter applications vary and the technique must be selected on the basis of the patient's condition and the experience of the interventionalist.

CAUTION: Larger models of AMPHIRION DEEP PTA balloon dilatation catheters may exhibit slower deflation times particularly on long catheter shafts.

POTENTIAL COMPLICATIONS / ADVERSE EFFECTS

The complications that may result from a balloon dilatation procedure include:
Puncture related:
- Local hematoma
- Local hemorrhage
- Local or distal thromboembolic episodes
- Thrombosis
- Arterio-venous fistula
- Pseudoaneurysm
- Local infections

Dilatation related
- Dissection in the dilated artery wall
- Perforation of the artery wall
- Prolonged spasms
- Acute re-occlusion necessitating surgical intervention
- Restenosis of the dilated artery

Angiography related
- Hypotension
- Pain and tenderness
- Arrhythmias
- Sepsis/infection
- Systemic embolization
- Endocarditis
- Short-term hemodynamic deterioration
- Death
- Drug reactions
- Allergic reaction to contrast medium
- Pyrogenic reaction

PREPARATION TECHNIQUE

Prior to use, carefully examine the unit to verify that the catheter or sterile package has not been damaged in shipment.

As supplied, the balloon and the guide wire lumen of the AMPHIRION DEEP PTA catheter contains air. This air must be displaced to make certain that only liquid fills the balloon while the catheter is in the bloodstream.

CAUTION: Do not use with Lipiodol contrast media, or other such contrast media, which incorporate the components of these agents.

To displace air:

1. Flush out the lumen for the guide wire with heparinized saline solution through the wire lumen, marked "WIRE".
2. Fill a 10 cc syringe with approximately 4 cc of a mixture of contrast medium and normal saline.
3. Attach syringe to the balloon lumen, marked "BALLOON".
4. Pull the syringe plunger to deflate the balloon.
5. To inflate the balloon, point the syringe and balloon tip downward and inject the contrast medium and saline mixture. Repeat this process several times if necessary.
6. Repeat steps 4 and 5 to remove air from the balloon and catheter
7. Deflate the balloon.
8. Looking proximal to distal, manually refold the deflated balloon clockwise around the catheter.
9. Replace the syringe with a manometer controlled dilatation system, which has been partially filled with saline solution.

Continue this procedure until all air has been displaced and the balloon is filled only with contrast mixture.

CAUTION: Do not exceed rated burst pressure during this process.
The AMPHIRION DEEP PTA catheter shaft is coated with a hydrophilic coating. Prior to inserting the catheter, activate the coating by immersing the catheter in normal saline for approximately 30-60 seconds, or wiping down the catheter shaft with a saturated gauze sponge.

CAUTION: Do not wipe down the catheter surface with dry gauze.

CATHETER INSERTION

The AMPHIRION DEEP PTA catheter can be introduced percutaneously, via surgical

cutdown, or through an appropriate sized introducer sheath.

When inserting a catheter through a badly scarred area, use of an introducer sheath is recommended.

CAUTION: Do not advance the guide wire or the balloon dilatation catheter if resistance is met without first determining the cause of resistance and taking remedial action.

NOTE: To avoid kinking, advance the dilatation catheter slowly, in small increments until the proximal end of the guide wire emerges from the catheter.

BALLOON INFLATION

Under fluoroscopic guidance the balloon should be advanced and positioned across the lesion to be dilated. The balloon should be inflated by means of an inflation device. It is recommended that an inflation device with a 10 cc or larger syringe barrel with gauge is used when inflating the AMPHIRION DEEP PTA catheter.

The standard inflation medium is a 1:1 mixture of contrast medium and normal saline.

CAUTION: Do not use air or any gaseous substances as a balloon inflation medium.

BALLON DEFLATION AND REMOVAL

After PTA, the balloon catheter is pulled back over the positioned guide wire. It is important to note that after the balloon has been dilated several times, there may be some resistance as it is pulled back into the introducer.

After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, regional, and national laws and regulations.

HOW SUPPLIED

The AMPHIRION DEEP PTA catheter is supplied sterile and intended for single use only. The AMPHIRION DEEP PTA catheter is sterilized by ethylene oxide gas. It will remain sterile as long as the packaging remains unopened and undamaged. Use product prior to labeled Use Before date.

CAUTION: Do not use if the inner package is open or damaged.

STORAGE

Store at controlled room temperature in dry place. Do not expose to organic solvents (e.g. alcohol), ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used prior to the Use Before date on package label.

WARRANTY DISCLAIMER

Although this product has been manufactured under carefully controlled conditions, Invatec has no control over the conditions under which this product is used. Invatec therefore disclaims all warranties, both express and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Invatec shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Invatec to any representation or warranty with respect to the product.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent

jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular term held to be invalid.

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