

0.035" PTA Balloon Dilatation Catheter

INSTRUCTIONS FOR USE

STERILE: Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque.

FOR SINGLE USE ONLY. Do not autoclave. Carefully read all instructions prior to use. Failure to observe all warnings and precautions may result in complications.

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

DEVICE NAME

The device brand name is DYNAMIS ΔV 0.035" PTA (Percutaneous Transluminal Angioplasty) Balloon Dilatation Catheter; the generic device name is 0.035" PTA Balloon Dilatation Catheter.

DEVICE DESCRIPTION

This PTA Balloon Dilatation Catheter is a coaxial Over the Wire (OTW) catheter with a distal inflatable balloon. Two radiopaque markerbands indicate the dilatating section of the balloon and aid in the balloon placement. The proximal portion of the catheter has a bifurcated manifold which includes a balloon lumen marked "BAL" and a guidewire lumen. The catheter is designed so that a specific balloon diameter can be reached depending on the Balloon size and defined pressure. Consult the compliance chart which is included on the product label for the diameter of the balloon at given pressures. Packaged with every product is a balloon protector which is positioned over the balloon for its protection prior to use. A re-wrap tool is also provided on the catheter shaft.

HOW SUPPLIED

STERILE: This device is sterilized with ethylene oxide. Non-pyrogenic.

CONTENTS: One DYNAMIS ΔV 0.035" PTA Balloon Dilatation Catheter.

STORAGE: Store in a dry, dark, cool place. Rotate inventory so that catheters are used prior to the expiration date on the package label.

INDICATIONS

The DYNAMIS ΔV 0.035" PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

CONTRAINDICATIONS

None known for PTA procedure. The DYNAMIS ΔV 0.035" PTA Balloon Dilatation Catheter is contraindicated for use in the coronary arteries, the neurovasculature and for the delivery of stents.

WARNINGS

- This device is intended for single use only; do not reuse. Do not re-sterilize, as this can compromise device performance, and increases the risk of cross contamination due to inappropriate reprocessing.
- 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 in Percutaneous Transluminal Angioplasty (PTA).
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not advance or retract the device unless the balloon is fully deflated under vacuum.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure (RBP). Refer to the product label for device specific information. The RBP is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. To prevent over pressurization, use a pressure monitoring device.
- Inflation at a high rate may damage the balloon.
- Use only clinically recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Do not use with Lipiodol contrast media, or other such contrast media which incorporate the components of this agent.
- Do not use after the "Use by date" specified on the package.
- Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked; this may result in the shaft breaking. Instead prepare a new catheter.

PRECAUTIONS

- A thorough understanding of the principles, clinical applications and risk associated with PTA is necessary before using this product.
- This device is not recommended for applications that may require inflation higher than those recommended for this catheter.
- Do not use if package is open or damaged.
- Prior to use, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- During the procedure, appropriate anti-coagulant therapy must be provided to the patient as needed. Anti-coagulant therapy should be continued for a period of time to be determined by the physician after the procedure.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or similar isotonic solution.
- The minimal acceptable sheath French size is indicated on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath than indicated on the label.

- Not intended for precise arterial blood pressure monitoring.
- Do not advance or withdraw the PTA catheter within the vasculature unless the catheter is pre-loaded onto a guide wire.
- Do not use for procedures other than those indicated in this Instructions for Use.

ADVERSE EVENTS

Potential adverse events include but are not limited to:

- Thrombus
- Vessel dissection, perforation, rupture or spasm
- Death
- Abrupt closure
- Acute myocardial infarction
- Acute or subacute thrombosis
- Additional intervention required (major, moderate)
- Allergic reaction (device, contrast medium and medications)
- Amputation
- Angina
- Air embolization
- Aneurysm
- Arrhythmias (major, minor), including ventricular fibrillation
- Arteriovenous fistula
- Coma
- Embolization, which includes thromboembolization (arterial, pulmonary)
- Hematoma/ Pseudoaneurysm at puncture site
- Hemorrhage, including bleeding at puncture site
- Hypotension/Hypertension
- Inflammation
- Intimal tear
- Ischemia, including tissue ischemia, steal syndrome and necrosis
- Neurological events, including peripheral nerve injury and neuropathies
- Occlusion
- Organ failure (single, multiple)
- Paralysis
- Pyrogenic reaction
- Renal failure
- Seizures
- Sepsis/infection
- Shock
- Stroke
- Transient ischemic attack
- Weakness

MATERIALS REQUIRED

- Introducer sheath(s) in the appropriate size and configuration for the selected vasculature. See product label for specific device compatibility.
- 2-3 syringes (10-20 cc)
- 0.035" (0.89mm) guide wire of appropriate length for the vasculature selected
- Contrast media diluted with saline
- Inflation device
- Guide wire introducer

DILATION CATHETER PREPARATION

- The catheter is packaged in a protective tube and protective pouch; carefully remove the catheter from the package.
- Remove the packaging mandrel (stylet) and the balloon protector (sheath) from the balloon.
- The balloon catheter in deflated position contains tiny air bubbles that should be purged prior to inserting the balloon catheter. To do this, connect a three way stopcock to the inflation port fitting on the dilatation catheter. Flush through the stopcock. Connect a luer-lock syringe, partly filled with sterile normal saline and contrast medium, to the stopcock. Orient the dilatation catheter with the distal tip and the balloon pointing in a downward vertical position. Pull back the plunger and aspirate for 15 seconds until the air is completely evacuated, Release the plunger. Disconnect the syringe and evacuate the collected air. Reconnect the syringe and repeat this operation a couple of times until the balloon is completely free of air bubbles.
- Flush the wire lumen with sterile saline.

INFLATION DEVICE CONNECTION TO CATHETER

- To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium.
- With the stopcock in the closed position, disconnect the syringe used in preparation applying a slight positive pressure. A meniscus of contrast medium will appear in the balloon port when the syringe is removed. Verify that a meniscus of contrast medium is evident in both the dilatation catheter balloon port (hub) and the inflation device connection. Securely couple the inflation device to the balloon port of the balloon dilatation catheter.

USE OF BALLOON ANGIOPLASTY CATHETER

- Insert a guide wire through the hemostatic valve following the manufacturer's instructions or standard practice. Advance the guide wire carefully into the introducer sheath. When complete, withdraw the guide wire introducer, if used.
- Attach a torque device to the wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

c. Back load the distal tip of the dilatation catheter onto the guide wire.

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

d. Advance the catheter through the hemostatic valve slowly, while the balloon is fully deflated. It should be observed that the hemostatic valve is only closed as much to prevent blood return yet permitting easy movements of the dilatation catheter. If resistance is encountered, do not advance the catheter through the adapter.

NOTE: To preserve the folded balloon shape during insertion and catheter manipulation, maintain a vacuum on the inflation lumen.

CAUTION: If strong resistance is met during advancement or withdrawal of the catheter, discontinue movement and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, withdraw the entire system.

e. Under fluoroscopy, use the balloon radiopaque markers to position the balloon within the lesion to be dilated and inflate the balloon to the appropriate pressure (refer to balloon compliance table). Maintain negative pressure on the balloon between inflations.

CAUTION: Do not exceed the rated burst pressure. Higher pressures may damage the balloon or catheter or over distend the selected vessel.

f. Completely deflate the balloon catheter. Withdraw the deflated dilatation catheter and guide wire from the guiding catheter / introducer sheath, through the hemostatic valve.

CAUTION: If the balloon cannot be withdrawn through the sheath, discontinue movement and determine the cause of resistance (with the aid of fluoroscopy) before proceeding. Ensure that you are using the correct sheath size and that the balloon is fully deflated.

BALLOON REINSERTION

Precaution: Do not continue to use the balloon catheter if the shaft has been bent or kinked.

Precaution: Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze, rinsed with sterile normal saline, and refolded with the balloon re-wrap tool. Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire.

1. Load the balloon catheter onto a guidewire and draw and maintain a vacuum on the balloon.

2. Advance the balloon re-wrap tool over the catheter to the proximal end of the balloon.

3. Grasp the catheter shaft just proximal to the balloon with one hand, and with the other hand gently slide the re-wrap tool over the balloon to the catheter tip and then back over the balloon to the catheter.

NOTE: To preserve the folded balloon shape during insertion and catheter manipulation, maintain a vacuum on the inflation lumen.

4. Slide the re-wrap tool to the proximal end of the catheter shaft.

5. Advance the balloon catheter over the prepositioned guidewire to the introduction site and through the introducer sheath. If resistance is encountered, replace the previously used balloon catheter with a new balloon.

6. Continue the procedure according to the “Use of Balloon Angioplasty” herein.

REFERENCES

The physician should consult current literature on current medical practice on balloon dilatation.

WARRANTY

CREAGH MEDICAL Ireland warrants that reasonable care has been used in the design and manufacture of this device. The DYNAMIS ΔV 0.035” PTA Balloon Dilatation Catheters have been manufactured under carefully controlled conditions. As CREAGH MEDICAL Ireland has no control over the conditions under which this product is used, such as, device handling, patient diagnosis; this warranty is limited to the replacement of this instrument. For the avoidance of doubt CREAGH MEDICAL is not liable for any consequential loss arising from the manner in which the product is used. This warranty is exclusive and in lieu of all other warranties either written, oral or implied. No other person may change any of the above or assume any additional liability in relation to this device.

SYMBOL	DESIGNATION
	Contents: One (1) DYNAMIS ΔV 0.035” PTA Balloon Dilatation Catheter.
	Non-pyrogenic
	Caution: Federal (USA) law restricts this device for sale by, or on the order of a Physician.
	Keep Dry
	Keep away from heat
	Do Not Re-sterilize
	For US audiences only.
	For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service.
	Sterilized Using Ethylene Oxide
	Rated Burst Pressure
	Minimum Guide Sheath I.D.
	Do Not Use if Package is Damaged
	Balloon Length
	Balloon Diameter
	Effective length
	Peel here
	Catalog Number
	Nominal Pressure
	Use By: YYYY-MM-DD
	Lot Number
	Inflation Pressure
	Do not exceed rated burst pressure
	Maximum guidewire diameter
	Single Use
	Caution: Consult accompanying documents. Read instructions prior to use.



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