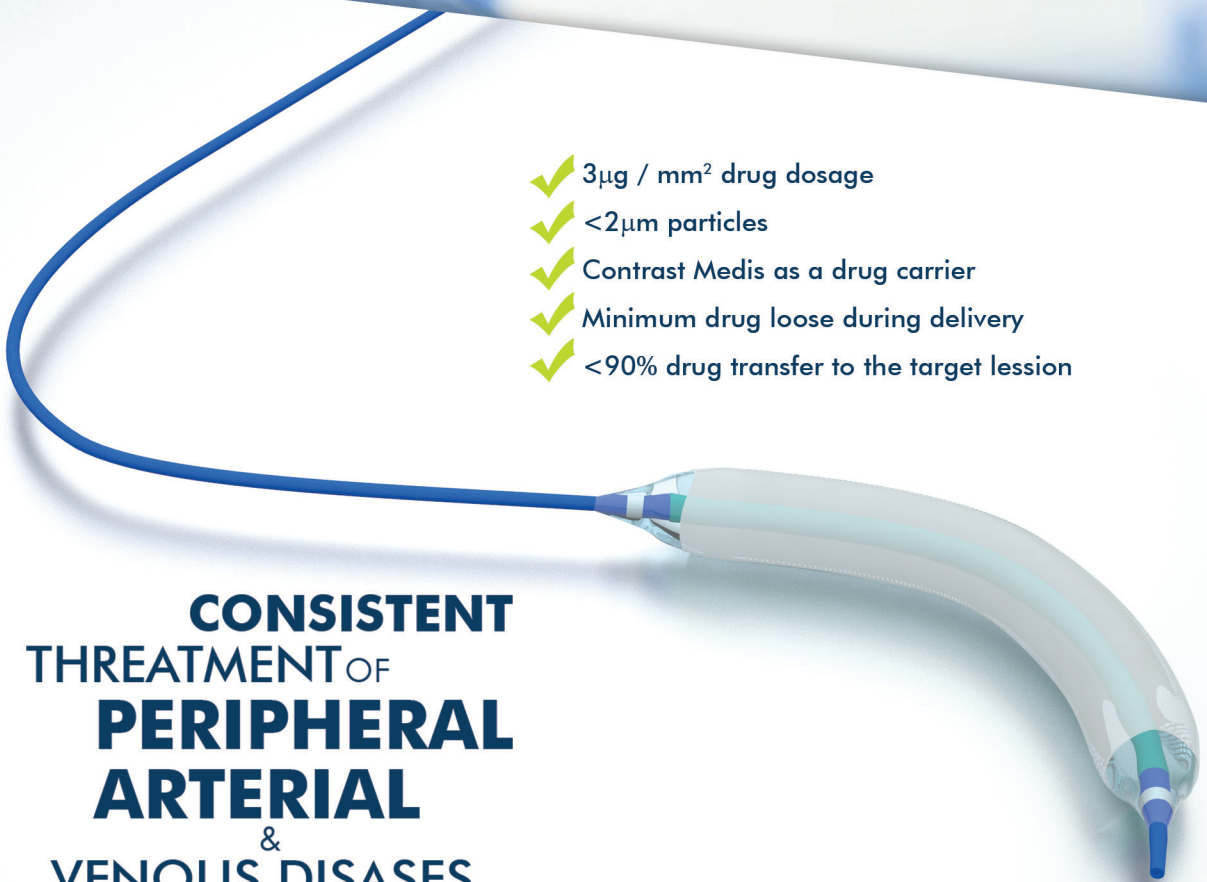
Extender©

PACLITAXEL - COATED PTA BALLOON CATHETER

INSTRUCTION FOR USE | ENGLISH

ALL INSTRUCTIONS MUST BE READ BEFORE USE

- 3µg / mm² drug dosage
- <2µm particles
- Contrast Medis as a drug carrier
- Minimum drug loose during delivery
- <90% drug transfer to the target lession



CONSISTENT THREATMENT OF PERIPHERAL ARTERIAL & VENOUS DISASES

INVAMED
RD GLOBAL Research & Development
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TD03.3.8.14

Extender©

Drug Eluting
PTA Balloon Catheter

INSTRUCTIONS FOR USE

1. PRODUCT NAME

Product name EXTENDER Drug Eluting Balloon

2. DEVICE DESRIPTION

Drug Eluting PTA Balloon Catheter is used for the treatment of coronary and peripheral vessels with balloon structure that performs drug release at the tip. In the interventional treatment of fem-pop coronary and peripheral artery disease, treats by providing rapid and effective drug eluting.
Drug Eluting PTA Balloon Catheter is a Class III Medical-Surgical product (which can be used in body during surgery) in accordance with the requirements of the "EU Directive" 93/42 / EEC.
Drug Eluting PTA Balloon Catheter is a distally inflatable catheter with two lumens. One of them is used to inflate a lumen balloon with contrast material; the other lumen is used in conjunction with a guide wire to advance the balloon into the stenosis. Two radioopaque markers Show the dilatation part of the balloon and helps positioning. It also shows the length of the balloon. The tip of the PTA Balloon is designed for easy access and to advance through the calcified lesion easily.

The balloon lumen with the sign "BAL" on it is used to inflate and lower the balloon. The nominal balloon pressure is indicated on the manifold. The guidewire lumen is used to track the catheter on a pre-positioned guidewire.The drug-eluting PTA Balloon Catheter is coated with 3μg of PAKLITAXEL active agent per mm2 in a degradable release matrix at the balloon surface. With inflation of the balloon, this drug-coated surface is contacted to the vessel wall and the transfer to the vessel's vascular surface is ensured. Performs treatment with release. The pressure applied should be controlled when the balloon is inflated according to the case and according to the vessel morphology.
Drug Eluting PTA Balloon Catheter can be used in the treatment of atherosclerosis in peripheral lesions, in stent restenoses, in lesions up to 200 mm in length with vessel diameters between 2.00 and 10.00. It can be used for peripheral stent implantations, for pre-dilatation and post-dilatation purposes to increase the luminal diameter.

Table.1 Product Content

EXTENDER DRUG ELUTING PTA BALLOON CATHETER OTW	
Balloon Lengths	20-120 cm
Balloon Diameters	2.00-12.00 mm
Medicine	Paclitaxel
Drug Dosage	3 μg/ mm2
Balloon Material	Pebax, Nylon (Vestamid L2101F)
Catheter Design	OTW
Guide Wire Compatibility	0.014"/0,018"/0,035" According to balloon diameter
Shaft Diameter	5F According to balloon diameter
Introducer Sheath Compliance	5F- 7F
Coating in the oscillation system	Hydrophilic Coating

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MATRIX of PRODUCT MODELS

	BALLOON DIAMETER	Catheter Shaft Length 80 / 135 cm								
		20mm	30mm	40mm	60mm	80mm	100mm	120mm	150mm	RBP
RAPID EXCHANGE	2,0mm	✓	✓	✓	✓	✓	✓	✓	✓	27 Atm
	2,5mm	✓	✓	✓	✓	✓	✓	✓	✓	
	3,0mm	✓	✓	✓	✓	✓	✓	✓	✓	
	3,5mm	✓	✓	✓	✓	✓	✓	✓	✓	
	4,0mm	✓	✓	✓	✓	✓	✓	✓	✓	
OTW	4,5mm	✓	✓	✓	✓	✓	✓	✓		
	5,0mm	✓	✓	✓	✓	✓	✓	✓		
	5,5mm	✓	✓	✓	✓	✓	✓	✓		25 Atm
	6,0mm	✓	✓	✓	✓	✓	✓	✓		
	6,5mm	✓	✓	✓	✓	✓	✓	✓		
	7,0mm	✓	✓	✓	✓	✓	✓	✓		
	8,0mm	✓	✓	✓	✓	✓	✓	✓		24 Atm
	9,0mm	✓	✓	✓	✓	✓	✓	✓		20 Atm
	10,0mm	✓	✓	✓	✓	✓	✓	✓		
	12,0mm	✓								18 Atm

3. DEFINITIONS OF DRUG CONTENT

Paclitaxel is a proven drug with anti-proliferative properties. The product has cell anti-proliferation and cell anti-migration properties. The extender has a homogeneous distribution and contains paclitaxel at the safe dose interval to perform the treatment. The high lipophilic nature of paclitaxel has proved its anti-proliferative effect in coronary and peripheral artery diseases. With the unique mechanism of action, long-term results are obtained with one application.

4. MANNER OF INTRODUCTION

Sterile: EXTENDER Drug Eluting Balloon sterilized with ethylene oxide. It is non pyrogenic
Ingredients: EXTENDER Drug Eluting Balloon
Storage: Store in dry and at controlled room temperature. Do not expose to organic solvents, ionization radiation or ultraviolet light.

5. INDICATIONS

Treatment of atherosclerotic vessel occlusions in renal, iliac, femoral, iliofemoral, popliteal and infrapopliteal arteries.

6. CONTRAINDICATIONS

- General impairment (if Glasgow Coma Scale is 3)
- Multiple doses for a single lesion (Over dose)
- Sensitivity to Paclitaxel or Oscillation matrix (Iopromide)
- Allergic reaction to paclitaxel or swing matrix (iopromide)
- Contrast media or allergy
- Pregnancy or breastfeeding
- Occlusion completed / treated vessel
- Cardiogenic shock
- Hemorrhagic diarrhea or gastrointestinal ulceration or cerebral circulation irregularity
- Bypass specification
- Risk of heart attack due to poor blood flow or thrombus
- Patients whose vessel diameter is smaller than 2.25
- EF <30%
- Coronary artery spasms in cases without stenosis

7. WARNINGS

The product is disposable. Don't reuse or re-sterilize Reuse or re-sterilization processes may cause structural changes on the device and chemical residues, failure of the device or harm to the patient as a result of failure of the device. Reuse or re-sterilization processes may result in infection, permanent disease , disability or death.

Don't use after the "date of expiry" on the package.

8. PRECAUTIONS

- Extender Drug Eluting PTA Balloon Catheter should only be applied by doctors who are expert in the use of the product. The cardiac surgical team should be found throughout the use process.
- The manufacturer shall not be liable for damage caused by use other than those specified in these operating instructions.
- Extender Drug Eluting PTA Balloon Catheter is a disposable product and ready to use.
- Doctors who are trained in percutaneous, intravascular techniques and procedures should use the system.
- Pay attention to the catheter being loaded on the proximal end of the guidewire to prevent transport and wire or catheter bending.
- Do not advance the Extender Drug Eluting PTA Balloon Catheter without a guide wire in place.
- Perform the manipulation procedure under high quality fluoroscopic observation when exposed to the catheter vascular system.
- If you feel resistance during manipulation with torque, determine the cause of resistance before continuing.
- Do not have direct contact with the drug loaded part.
- Keep in dark and dry places.
- Do not expose the appliance to autoclave or organic solvents. Before use, make sure that the diameter and length of the guide wire to be used during use are compatible with the catheter.
- Pay attention to the expiration date stated on the package.
- Do not use expired products.
- Check the package and material in order before use.
- Do not use any product that shows any problems.
- The catheter should only be used under fluoroscopy.
- Use a guide catheter or guiding sheath of appropriate size.
- If you are having problems with advancing the catheter, do not force. Identify the reason for the progress.

9. ADVERS EFFECTS

- Hematoma in vascular intervention
- Pseudoaneurysm or aneurysm
- Acute myocardial infarction
- Allergic reaction to contrast agent
- Arrhythmia
- Chest anjini
- Arterial perforation
- Peripheral or coronary artery spasm
- Cerebral circulatory disorders
- Anticaogulant or antiplatetlets result bleeding
- Death
- Dissection
- Bleeding
- Drug side effects
- Thrombosis
- Arterial rupture
- Hypotension
- Fire
- Ischemia
- Ventricular fibrillation
- Local or systemic infection
- Arterio-venous fistula
- Device, air, plaque, thrombus, tissue, artery and so on. implanted emboli
- Coronary artery occlusion
- Arrhythmia with ventricular fibrillation
-

Pharmaceutical Effects

The confusion of low amounts of paclitaxel with blood plasma has been supported by the literature that paclitaxel may not show any adverse effects that are present in routine systemic therapy.

Paclitaxel Concentration: 3 µg / mm ²

10. CONTRAINDICATIONS

The product is contraindicated in patients who are hypersensitive to paclitaxel or any substance in the formulation, especially polyoxyethyl castor oil.
Taksen is contraindicated during pregnancy and lactation and should not be used in patients with a neutrophil count of <1,500 / mm3.

- Allergic or immunological reaction to drug or matrix on balloon surface
- Hair loss
- Anemia
- Gastrointestinal system impairment
- Hematologic disorder
- Liver enzyme disorder
- Changes in vascular structure, inflammation, cell damage or necrosis
- Disorders in the heart system
- Muscle aches
- Peripheral neuropathy

11. REQUIRED MATERIALS

- Extender Drug Eluting PTA Balloon Catheter
- Guide wire of suitable size with system
- Introducer Set / guiding catheter
- 60% contrast medium diluted with 1: 1 saline
- Inflating syringe

11. PREPARATION

Extender Drug Eluting PTA Balloon Prior to application of catheter, all equipment to be used for treatment should be carefully observed against defects. Check the package to ensure that it is not damaged during shipping, and make sure the balloon is not damaged if the sterile barrier is intact.

To prepare the catheter for use, follow these steps:

1. Wash and fill the guidewire lumen of the dilatation catheter with normal saline.

2. Prepare an inflatable device with contrast material. (Standard inflator is a mixture of 1: 1 contrast medium and normal saline).

3. To release the air in the balloon section:

    a. Fill a 20 cc syringe or inflator with about 4 cc of contrast agent.
    b. After you have inserted the syringe or inflation device into the balloon inflation lumen, guide the catheter in a position to look down on the distal tip and the balloon vertically.
    c. Apply negative pressure and aspirate for 15 seconds. Slowly evacuate the pressure until the air does not return to the device.
    d. Remove the syringe or inflation device from the inflation port of the dilatation catheter.
    e. Evacuate all air from the syringe or from the inflator. Reattach the syringe or inflation device to the inflation port of the dilatation catheter. Continue applying negative pressure until the air no longer returns to the device.
    f. Slowly turn the device pressure to neutral.

4. Remove the syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without allowing air into the system.
5. Remove the package arm and remove the protective sleeve.

NOTE: Before placing the balloon in the body, all air should be drained and replaced with blowing agent (repeat steps 3a to 3f if necessary); otherwise complications may occur.

12. APPLICATION

1. Place the prepared catheter on a pre-positioned guidewire and advance the tip into the entry area.

NOTE: When placing and moving the catheter, apply vacuum to the inflation lumen to prevent collapse of the balloon.

CAUTION: When the balloon catheter is being moved or retracted, apply the negative pressure with the inflation system to fully lower the balloon. Do not advance or retract the balloon catheter in the vein when there is no guide wire in front of the catheter.

2. Carefully guide the catheter through the sheath.

NOTE: Perform all other catheter movements under fluoroscopy.

3. Carefully advance the catheter towards selected stenosis.

CAUTION: If resistance is encountered during catheter advancement or withdrawal, stop the procedure and determine the cause of the catheter before continuing. If the cause of resistance can not be determined, withdraw the entire system.

4. Using the fluoroscopic and radiopaque marker strips, place the catheter in the appropriate position.

5. Once the acceptable position is achieved, inflate the balloon to provide the desired dilatation. Recommended balloon inflation time is 60 seconds fot two times inflation.

CAUTION: Do not exceed the specified burst pressure. Higher pressures may damage the balloon or catheter, or cause the selected artery to over-dilate.

WARNING: Inflation at high speed may damage the ball.

NOTE: Balloon inflation should be performed by extending the guidewire forward from the catheter tip. It is strongly recommended that the guide wire, balloon catheter, or both remain on the lesion until the procedure is complete and the dilatation system is removed.

6. Lower the balloon by pulling the vacuum on the inflating syringe or inflator. Wait for a sufficient period of time before the balloon is completely collapsed before you go out.

7. Continue vacuuming (do not apply pressure) when withdrawing the catheter.

CAUTION: If the balloon can not retract through the sheath, stop motion and identify the cause of resistance (using fluoroscopy) before proceeding. Make sure that you are using the correct sheath size and that the balloon is completely collapsed.

13. SHELF LIFE

The product has a shelf life of 3 years after the date of manufacture when protected under specified conditions . Not used after expiration date.

14. DISPOISON

Dispose the product according to the standard institutional processes for medical waste, including disposable devices contacting with blood.

15. WARRANTY DISCLAIMER AND SETTLEMENT LIMITATION

For the Invamed product/products described in this issue, there is no express or implied warranty including the intended warranty without having any limitation from the point of view of marketability or fit for specific purpose. Under no circumstances, Invamed shall not be responsible for and direct, casual or consequential damage other than those clearly indicated in the specific law. Nobody has authority for representing or guarantying the Invamed other than those specifically specified in this document. With this issue, the definitions or specifications in the Invamed printed material have only the purpose of generally defining the product on the production date and they do not mean any open guarantee. Invamed shall not be responsible for any direct, incidental or consequential damage originated from re-use of the product.

DESCRIPTION OF LABEL / MARKING

Sterilized by ethylene oxide.

Pay attention to label warnings.

Read instructions before use

Fragile

Single use only. Cannot be u: second time.

Caution: Federal Law restricts this device to sale by or on the order of a physician

Dispose according to the medical

Keep away from sunlight

Keep at the temperature of 5 - 24C°

May create potential biological waste after use

Do not use if the product is damaged or package is already

Keep in dry place

Cannot be re-sterilized.

Non-pyrogen

Expiration date

Production date

Lot Number

Catalogue Number

Manufacturer

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