Peripheral DCB PTA Catheter

A Product name

The product name of this device is GENOSS™ Peripheral DCB PTA catheter.

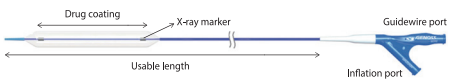
B Device description

GENOSS™ Peripheral DCB PTA Catheter is an Over-the-Wire (OTW) Percutaneous Transluminal Angioplasty (PTA) catheter with a semi-compliant balloon coated with a formulation of paclitaxel (drug) and two excipients. The GENOSS™ Peripheral Drug-Coated Balloon (DCB) catheter is designed to provide mechanical dilatation and inhibit restenosis by delivering drug to diseased arterial tissue.
The GENOSS™ Peripheral DCB catheter has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.035 in (0.89 mm) to facilitate advancement of the catheter. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter includes a tapered tip to facilitate advancement to and through the stenosis.The GENOSS™ Peripheral DCB catheter has two 1.0 mm radiopaque marker bands (one proximal and one distal) which, in conjunction with fluoroscopy, aid in the placement of the balloon. The proximal shaft marks define the length to the distal end of the catheter. The working lengths of the GENOSS™ Peripheral DCB catheter are 50 cm, 80 cm, and 130 cm. The proximal portion of the GENOSS™ Peripheral DCB catheter includes one female Luer-lock port connected to the inflation lumen, and one female Luer-lock port for the guidewire lumen. The GENOSS™ Peripheral DCB catheter has a hydrophilic coating on its outer surface. The GENOSS™ Peripheral DCB catheter is compatible with introducer sheath sizes according to the recommendations on the label.

1. Device component description

The OTW balloon catheter consists of a proximal hub, dual-lumen shaft, and a distal dilatation balloon. The central lumen extends to the distal tip and is used to pass the catheter over a guidewire with a diameter of 0.035 in (0.89 mm). The balloon inflation lumen is used to inflate and deflate the balloon with a mixture of contrast medium and saline solution. Two radiopaque platinum-iridium markers indicate the working length of the balloon to position the balloon across the target lesion during fluoroscopy. See image of the device, GENOSS™ peripheral DCB PTA catheter (Figure 1).

Figure 1: GENOSS™ Peripheral DCB PTA catheter



2. Drug component description

The GENOSS™ Peripheral DCB has a drug coating formulation consisting of paclitaxel (the active pharmaceutical ingredient) and two excipients (Shellac and Vitamin E-TPGS).

1) Paclitaxel
The active pharmaceutical ingredient in the balloon coating is paclitaxel (PTx). The dose density of paclitaxel is 3.5 μ g per mm2 of the balloon surface. The principal mechanism by which PTx inhibits neointimal growth is through the stabilization of microtubules by preventing depolymerization during the final G2/M phase of cell division. PTx is a semi-synthetic paclitaxel synthesized from precursor compounds, isolated from a spectrum of Taxus species and hybrids. Paclitaxel is a diterpenoid with a characteristic taxane skeleton of 20 carbon atoms, a molecular weight of 854 g/mol and a molecular formula of C47H51NO14. It is highly lipophilic, insoluble in water, but freely soluble in methanol, ethanol, chloroform, ethyl acetate and dimethyl sulfoxide.

Table 1: Paclitaxel Dose per Balloon

		Balloon Length (mm)						
		20	40	60	80	100	120	150
Balloon Diameter (mm)	4	880 μg	1760 μg	2639 μg	3519 μg	4398 μg	5278 μg	6597 μg
	5	1099 μg	2199 μg	3298 μg	4398 μg	5497 μg	6597 μg	8246 μg
	6	1319 μg	2638 μg	3958 μg	5277 μg	6597 μg	7916 μg	9896 μg
	7	1539 μg	3078 μg	4618 μg	6157 μg	7696 μg	9236 μg	

2) Shellac
The coating utilizes the inactive ingredients, Shellac as an excipient to facilitate the release and transfer of paclitaxel into the arterial wall. Shellac is a natural polymer, which is used as enteric coating material in pharmaceutical applications.

3) Vitamin E-TPGS
The coating utilizes the inactive ingredients, Vitamin E-TPGS as an excipient to facilitate the release and transfer of paclitaxel into the arterial wall. Vitamin E TPGS has been approved by FDA as a safe adjuvant and widely used in drug delivery systems.

3. User Information

The GENOSS™ Peripheral DCB PTA Catheter is non-pyrogenic.
Only physicians who are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with native superficial femoral or popliteal artery interventional procedures should use this device.

C Indication for Use

GENOSS™ Peripheral DCB PTA catheter is indicated for percutaneous transluminal angioplasty (PTA) of de novo or restenotic lesions located in native superficial femoral and proximal popliteal arteries (SFA/PPA) with reference vessel diameters of 4 – 7 mm.

D Contraindications

Use of the GENOSS™ Peripheral DCB PTA catheter is contraindicated in:
- Lesion is unable to be crossed with a guidewire.
- Patients with severe allergic reactions to contrast media.
- Patients who are sensitive or allergic to paclitaxel and/or excipients (Shellac, Vitamin E-TPGS).
- Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy.
- Women who are breastfeeding, pregnant.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries.

E Warnings

- Never use air or any gaseous medium to inflate the balloon (a 50:50 mixture of contrast medium and sterile saline is recommended).
- When the balloon catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- If unusual resistance is felt during manipulation, determine the cause of the resistance before proceeding. If the source of resistance cannot be determined, it is recommended to extract the entire system with the guiding sheath.
- If difficulty is experienced during balloon inflation, do not continue. Deflate the balloon and remove the catheter.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel segment to be treated. The inflated length of the balloon (shoulder to shoulder) may exceed the length of the lesion/stenosis by approximately 10 mm on either side within the targeted artery.
- Do not exceed the balloon rated burst pressure. Use of an inflation device is recommended to prevent over-pressurization.
- The safety of using multiple GENOSS™ Peripheral DCBs with a total drug dosage exceeding 28,586 μ g of Paclitaxel in a patient has not been studied.
- Using a drug-eluting stent in conjunction with GENOSS™ Peripheral DCB at the same treatment site has not been studied.
- Do not move the guidewire during inflation of the GENOSS™ Peripheral DCB PTA catheter.

F Precautions

- The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal angioplasty.
- Use the balloon catheter prior to the "Use By" date specified on the package.
- The balloon catheter should be used with caution for procedures involving calcified lesions due to the abrasive nature of these lesions.
- The balloon catheter is not intended for injection of contrast medium.
- Full arterial wall apposition of the GENOSS™ Peripheral DCB is necessary for proper drug transfer to the vessel.
- Carefully inspect the balloon 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.
- If unusual resistance is felt during catheter advancement through the valve, do not use the balloon catheter. Replace with a new GENOSS™ Peripheral DCB.
- Do not touch, wipe, bend, or squeeze the balloon. Do not allow it to contact any liquids including organic solvents such as alcohol or detergents prior to insertion. Damage to the balloon coating or premature release of the drug may occur.
- To minimize the possible introduction of air into the system, it is imperative that prior to proceeding, careful attention is paid to the maintenance of tight catheter connections and thorough aspiration and flushing of the system.
- If using a Tuohy-Borst type adapter, take care not to over-tighten the hemostasis valve around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon or damaging the drug coating.
- Never advance the balloon catheter without the guidewire extending from the distal tip.
- This product should not be used in patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy.
- If treating a long lesion (longer than the maximum balloon length available), each individual segment should be treated only once with a drug-coated balloon. Treat each segment with a new balloon and minimize overlapping of treated segments.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- Administer appropriate drug therapy to the patient according to standard protocols for PTA before insertion of the dilatation catheter.
- Take precautions to prevent or reduce clotting when any catheter is used. Flush and rinse all products entering the vascular system with heparinized normal saline or a similar solution. For the GENOSS™ Peripheral DCB PTA catheter, flush the guidewire lumen through the guidewire port with heparinized normal saline until the fluid exits the distal tip. Do not rinse or wipe the GENOSS™ Peripheral DCB PTA catheter.
- Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure.
- Prior to the procedure, inspect the product to verify that the product is intact.
- Handle the product with caution to avoid any damage to the balloon coating or folded balloon.
- This product is not intended for the expansion or delivery of a stent.
- Do not use the GENOSS™ Peripheral DCB PTA catheter for pre dilation or for post dilatation.
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Do not expose the product to organic solvents such as alcohol.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximately match the diameter of the vessel just distal to the lesion.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.

1. Pregnancy / Lactation

This product has not been tested in pregnant or breastfeeding women or in men intending to father children; effects on the developing fetus have not been studied and the risks and reproductive effects remain unknown. It is not recommended that the GENOSS™ Peripheral DCB be used in women attempting to conceive, or who are pregnant.
Prior to use, careful consideration should be given to the continuation of breastfeeding, taking into account the importance of the procedure to the mother. It is not known whether paclitaxel is distributed in human milk. In lactating rats, milk concentrations appeared to be higher than maternal plasma levels and declined in parallel with the maternal levels. Mothers should be advised of the potential for serious adverse reactions to paclitaxel in nursing infants.

2. Drug Information

The mechanism of action by which paclitaxel reduces or reverses neointima formation and proliferation, leading to restenosis, as demonstrated in clinical studies has not been established.
It is known that paclitaxel promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions.

3. Drug Interaction

Possible interactions of paclitaxel with concomitantly administered medications have not been formally investigated. Drug interactions of systemic chemotherapeutic levels of paclitaxel with possible concomitant medications are outlined in the labeling for finished pharmaceuticals containing paclitaxel, such as TAXOL.

4. Carcinogenicity, Genotoxicity, and Reproductive Toxicology

No long-term studies in animals have been published to evaluate the carcinogenic potential of the drug paclitaxel. Paclitaxel inhibits cell proliferation by stabilizing microtubules during cell division, and one consequence is the possible loss of chromosomes during cell division. This indirect action is consistent with positive responses in vitro and in vivo micronucleus genotoxicity assays, which detect DNA fragments. Positive results have also been reported for chromosomal aberrations in primary human lymphocytes. It is not known whether paclitaxel has a separate direct action on DNA in the generation of DNA breaks or fragments. Paclitaxel was not mutagenic in the Ames or CHO/HPRT assays for gene mutation.
There are no adequate and well-controlled studies published in pregnant women or in men intending to father children. Studies performed in rats and rabbits receiving IV paclitaxel during organogenesis revealed evidence of maternal toxicity, embryotoxicity, and fetotoxicity at dosages of 3 mg/kg/day. No teratogenicity was observed at paclitaxel doses of 1 mg/kg/day.

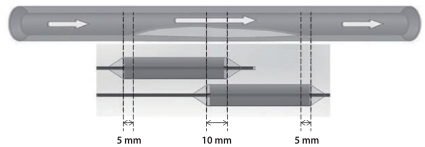
5. Pre and Post Procedure Antiplatelet Therapy

It is strongly advised that the treating physician follow the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy pre- and post-procedure.

6. Use of multiple balloons

If multiple GENOSS™ Peripheral DCBs are required to treat a lesion, the sequentially used GENOSSTM Peripheral DCBs should be angiographically positioned so that the marker bands of consecutively placed balloons overlap a minimum of 10 mm and the most proximal and most distal balloons extend 5 mm beyond the pre-dilated segment. The use of an arterial land marking system (eg, radiopaque ruler) must be used to ensure appropriate placement of the GENOSS™ Peripheral DCBs.

Figure 2: Multiple GENOSS™ Peripheral DCB



7. Use in Conjunction with Other Procedures

Potential interactions of the GENOSS™ Peripheral DCB PTA catheter with alternative therapies such as drug-coated stents, lasers, atherectomy, cryoplasty, cutting/scoring balloons, and brachytherapy have not been evaluated and should be avoided whenever possible.

8. Balloon Handling and Preparation Precautions

- Do not remove the device from the pouch until it is needed for immediate use.
- Handle the device with caution to avoid any damage to the balloon coating or folded balloon.
- Keep the protective sheath in place when purging the balloon catheter of air bubbles.
- Carefully remove and discard the balloon's protective sheath and stylet.
- Do not use the protective sheath or stylet as an introduction aid or a rewrapping tool.
- Do not apply positive pressure to the balloon during preparation.

9. Balloon Placement Precautions

- Manipulate the catheter under fluoroscopic observation when it is exposed to the vascular system. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- Do not move the guidewire during inflation of the balloon.
- Do not manipulate the GENOSS™ Peripheral DCB PTA catheter while inflated.
- Catheter applications vary. Select the technique on the basis of the patient's condition and the experience of the interventionalist.
- Introducer sheaths used must have lumen sizes that are suitable to accommodate the GENOSS™ Peripheral DCB PTA catheter.
- If resistance occurs during manipulation, ascertain the cause via fluoroscopy, road mapping, or digital subtraction angiography (DSA) before moving GENOSS™ Peripheral DCB PTA catheter backward or forward.
- Do not manipulate the GENOSS™ Peripheral DCB PTA catheter without sufficient fluoroscopy.
- Use a pressure-monitoring device to prevent overpressurization (nominal pressure: 10 atm [1.01 MPa], Rated Burst Pressure: 14 atm [1.42 MPa].
- To ensure full coverage of the entire lesion, the balloon diameter mu

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Peripheral DCB PTA Catheter

st match the reference vessel diameter distal to the lesion and the ballo on length must exceed the lesion length by approximately 1 cm on both ends. When using multiple balloons, do so only as described in Using Multiple GENOSS™ Peripheral DCB PTA catheters.
- Never advance the GENOSS™ Peripheral DCB PTA catheter without the guidewire extending from the tip.
- Maintaining balloon inflation is strongly recommended for 180 seconds. Adequate drug transfer occurs in the first 60 seconds of inflation.
- Pre-dilatation with an uncoated PTA catheter is required prior to use of the GENOSS™ Peripheral DCB PTA catheter.

10. Balloon Catheter Removal Precautions
- Prior to withdrawing the balloon catheter from the lesion, completely def late the balloon under vacuum.
- Center the GENOSS™ Peripheral DCB PTA catheter relative to the intro ducer sheath when withdrawing, and use caution when removing GENOSS™ Peripheral DCB PTA catheter.
- Should unusual resistance be felt at any time when withdrawing the ball oon catheter back into the introducer sheath, remove the balloon cathe ter and the introducer sheath as a single unit to reduce the risk of vasc ular damage.
  This must be done under direct visualization with fluoroscopy.
- If removal of the GENOSS™ Peripheral DCB PTA catheter is required pri or to deployment and a repeat attempt is desired, use a new GENOSS™ Peripheral DCB PTA catheter.

11. Post-procedure Precautions
- Administer post-procedure antiplatelet therapy as described in Pre-pro cedure and Post-procedure Medication Regimen.

G Potential Adverse Events

Below is a list of the potential adverse effects (e.g., complications) associa ted with the use of the device:

- Access-site complications
- Allergic reaction to medication, paclitaxel or contrast medium
- Amputation
- Aneurysm
- Arterial dissection or perforation
- Arterial rupture
- Arterial spasm
- Arterio-venous fistula
- Bleeding Complications
- Cardiac arrest
- Cardiac arrhythmia
- Death
- Device malfunction or failure
- Emboli (air, tissue, thrombi, mate rial from device(s) used in the procedure)
- Emergency or non-emergency arterial bypass surgery
- Extravasation of contrast media
- Fracture of the guide wire or any component of the device that may or may not lead to device embolism, serious injury or surgi cal intervention
- Gastrointestinal bleed
- Hemorrhage or hematoma
- Hypotension
- Infection, local or systemic
- Inflammation
- Myocardial infarction or coronary ischemia
- Neurological deficit
- Pain or tenderness
- Peripheral limb ischemia
- Placement of a bail-out stent
- Pseudo-aneurysm
- Radiation exposure
- Reaction to contrast media / medication
- Renal insufficiency or failure
- Respiratory distress or failure
- Restenosis of treated artery or segment
- Sepsis or systemic infection
- Stroke or TIA
- Surgical repair of vascular access site
- Thrombosis
- Transfusion
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair (conversion to open surgery)
- Worsening of peripheral arterial disease

Potential complications of balloon catheterization include, but are not limited to, the following:

- Balloon rupture
- Detachment of a component of the balloon and/or catheter system
- Failure of the balloon to perform as intended
- Failure to cross the lesion.

Potential complications which may be associated with the use of paclitaxel include, but are not limited to:

- Allergic/immunological reaction to paclitaxel
- Alopecia
- Anemia
- Gastrointestinal symptoms (diarrhea, nausea, pain, vomiting)
- Hematologic changes in vessel wall including inflammation, cellular damage, or necrosis
- Myalgia/Arthralgia
- Myelosuppression
- Peripheral neuropathy

H How Supplied

Device is sterilized with ethylene oxide. DO NOT use if the package is opened or damaged, or if any information provided is obscured or damaged.
CONTENTS: The package contains one (1) GENOSS™ Peripheral DCB PTA catheter.
STORAGE: Store the device between 1 – 30℃ in the aluminum pack.
DISPOSAL INSTRUCTIONS: After use, this product may be a biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable hospital, administrative, and government regulations.

I Instructions for Use

1. Recommended Materials
One or more of each of the following materials are recommended for PTA with the Ranger Drug-Coated Balloon:
- 0.035 in Guidewire
- Introducer sheath
- Pre-dilatation PTA catheter
- Contrast medium
- Sterile saline
- Inflation device with manometer
- Hemostasis valve
- Three-way stopcock

2. Balloon catheter size selection
Select an appropriately sized balloon catheter for the diameter of the targeted artery. The nominal length of the balloon may exceed the length of the lesion/stenosis by approximately 10 mm on either side. Select an appropriate catheter shaft length considering the distance between the arterial access point and the location of the targeted lesion.
Caution: If treating a long lesion (longer than the maximum balloon length available), each individual segment should be treated only once with a drug-coated balloon. Treat each segment with a new balloon and minimize overlapping of treated segments.
Warning: The safety of using multiple GENOSS™ Peripheral DCB PTA catheter with a total drug dosage exceeding 28,586 μg of Paclitaxel in a patient has not been studied.
Warning: Using a drug-coated stent in conjunction with GENOSS™ Peripheral DCB PTA catheter at the same treatment site has not been studied.

3. Inspection Prior to Use
Carefully examine all equipment to be used during the procedure, including the balloon catheter, to verify proper function. Verify that the balloon catheter and sterile packaging have not been damaged. Do not use if sterile package is damaged. Verify that the catheter size is suitable for the specific procedure for which it is intended.
Caution: Do not touch, wipe, bend, or squeeze the balloon. Do not allow it to contact any liquids including organic solvents such as alcoh ol or detergents prior to insertion. Damage to the balloon coating or premature release of the drug may occur.
Note: Do not use the balloon catheter if damage occurs or sterility is com promised.

4. Inflation Device Preparation
a. Prepare the inflation device according to the manufacturer's instructions.
b. Purge the system of air.

5. GENOSSTM Peripheral DCB PTA catheter Preparation
a. The catheter is packaged in a protective blister. Verify that the catheter and sterile packaging have not been damaged in shipment. After all preparation has been completed, carefully remove the catheter from the package. Do not remove the GENOSS™ Peripheral DCB PTA catheter from the packaging until it is ready for insertion.
Note: Avoid exposing the balloon drug coating to excessive handling or contact with liquids prior to preparation and delivery as the coating may be susceptible to damage or premature drug release.
b. The folded balloon catheter may contain air that should be purged prior to use. Connect a stopcock to the balloon port of the catheter hub. Connect a luer-lock syringe partially filled with saline solution to the stopcock. Open the stopcock. Keeping the syringe in a downward vertical position, draw back the plunger of the syringe and create a vacuum for 30 seconds in the balloon inflation line until air is comple tely evacuated.
Caution: If the air bubbles cannot be completely evacuated, there may be a leak in the catheter. Discard the device and select a new GENOSS™ Peripheral DCB PTA catheter.
Note: It is important to maintain the vacuum seal in order to keep the balloon profile tight before insertion into the introducer sheath.
Note: Keep the protective sheath in place during the purging procedure.
c. After air is completely evacuated, close the stopcock and remove the syringe.
d. Remove the stylet and the protective sheath from the balloon and discard. Do not use the protective sheath as an introduction aid or rewrapping tool.
e. Connect the filled syringe to the guidewire port. Flush the guidewire lumen through the guidewire port with heparinized normal saline until the fluid exits the distal tip.
Note: Drops of saline must emerge from the device tip.
Note: To minimize the introduction of air, aspirate and flush the system and keep a tight catheter connection throughout the procedure.
Note: Balloon diameter as a function of pressure refer Table 2.

Table 2: Balloon diameter as a function of pressure

(atm)	(MPa)	Balloon Diameter (mm)			
10 (NP)	1.01	4	5	6	7
11	1.11	4.05	5.05	6.05	7.05
12	1.22	4.10	5.10	6.10	7.10
13	1.32	4.15	5.15	6.15	7.15
14 (RBP)	1.42	4.20	5.20	6.20	7.20

6. Delivery and dilatation procedure
a. Load the distal tip of the balloon catheter over the prepositioned guide wire, which has been placed through the lesion.
b. Advance the catheter under direct fluoroscopic visualization. To avoid kinking, advance the catheter through the hemostatic valve slowly and in small increments while the stopcock is closed. Open the hemostatic valve to allow for easy passage of the balloon and to prevent damage to the balloon coating. Once the balloon has passed through, the hemostatic valve should be closed as much as is needed to preven t blood return while still permitting easy movements of the catheter.
Note: If significant resistance is encountered, do not advance the catheter through the introducer sheath.
c. Under fluoroscopy, use the balloon radiopaque markers to position the balloon within the lesion to be dilated. If the inflation device has not already been connected, connect the inflation device according to instructions in Inflation Device Connection to the GENOSS™ Peripheral DCB PTA catheter.
d. Open the stopcock and inflate the balloon to the appropriate pressure as described in the Compliance Chart included in the device packa ging, then close the stopcock to maintain pressure. For optimal mechanical dilatation of the vessel, balloon inflation time of 180 seconds is strongly recommended. Adequate drug transfer occurs in the first 60 seconds of inflation. If the GENOSS™ Peripheral DCB PTA catheter was inflated for at least 60 seconds but the vessel requires additional dilatati on due to suboptimal PTA results, a plain PTA balloon of the operator's choice can be used (PTA balloon should be of shorter length compared to the GENOSS™ Peripheral DCB PTA catheter).
Warning: Do not exceed rated burst pressure as indicated on the device label. Use of pressures higher than those specified on the devi ce label may result in a ruptured balloon with possible intimal damage and dissection.
Note: The GENOSS™ Peripheral DCB PTA catheter is intended for single inflation only

7. Removal procedure
a. Confirm with angiography that the lumen of the dilated vessel has not abruptly occluded.
Also ensure the balloon is fully deflated.
b. While maintaining negative pressure, withdraw the deflated balloon catheter and guidewire from the guiding sheath through the hemostasis valve.
Warning: If unusual resistance is felt during manipulation, determine the cause of the resistance before proceeding. If the source of resistance cannot be determined, it is recommended to extract the entire system with the guiding sheath.

J Warranty/Liability

The product and each component of its system (hereinafter "the product") have been designed, manufactured, tested and packaged with all reasonable care. However, GENOSS has no control over the conditions under which the product is used and a disturbance of the intended function of the product may occur for various reasons. In this respect, the warnings in this product publication/ instructions for use are expressly to be considered as an integral part of this Disclaimer and provide more detailed information. For this reason, GENOSS disclaims all warranties, expressed or implied regarding the product, including but not limited to, any warranty of merchantability or fitness for a particular purpose of the product. Product descriptions or user guidelines in publications do not constitute any expressed representation or any expressed or implied warranty. GENOSS is not liable for any direct, incidental or consequential damages or medical expenses caused by any use, defect, failure or malfunction of the product whether the claim is based on contract, warranty, tort or otherwise. This does not apply in the case of intention or in the case of gross negligence of legal representatives or executive staff of GENOSS. In commercial transactions relating to merchants, the liability is limited to the compensation of typical damages: compensation for any untypical or incidental damage is excluded. These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable in the respective country. If any clause of the Disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects GENOSS' s legitimate interest in limiting its liability or warranty without infringing any mandatory provisions of applicable law. No person has any authority to bind GENOSS to any warranty or liability regarding the product.
Due to biological variability between different individuals no product can be 100% effective under all conditions. For this reason and as GENOSS has no influence on the diagnosis of the patients, the methods applied, and the handling of the device after it has left the GENOSS warehouse, GENOSS does not guarantee the effectiveness nor the absence of complications associated with its use.

K Symbols

REF	Catalogue Number	LOT	Batch code
	Do not reuse		Date of manufacture
	Caution		Use by
STERILE EO	Sterilized using ethylene oxide		Manufacturer
	Temperature limitation		Do not use if package is damaged
	Consult instruction for use		Keep away from sunlight
	Do not resterilize		

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