DCB Paclitaxel Coated PTCA Balloon Catheter

A Description

The GENOSS DCB Paclitaxel Coated PTCA Balloon Catheter is a Rapid Exchange PTCA Balloon Catheter with a drug coated balloon system for the treatment of coronary vessels. The GENOSS DCB is designed to improve the lumen diameter and to reduce restenosis in the treatment of lesions in native coronary arteries. GENOSS DCB has been demonstrated to reduce restenosis for the treatment of in-stent restenosis and de-novo lesions in coronary arteries narrowed by atherosclerosis. The GENOSS DCB active drug coating is located on the surface of the balloon, which contains 3ug Paclitaxel per $1mm^2$. The drug is embedded in a physiologically harmless and degradable delivery matrix (main component: Shellac and vitamin E-TPGS). The expansion of the balloon causes a surface contact of the coated balloon with those vessel parts, which should be treated.
The distal shaft consists of two lumens. One lumen enables inflation and deflation of the balloon, other permits the insertion of a 0.014" guide wire. Two radiopaque markers indicate the length of the cylindrical portion of the balloon. The balloon is protected with a removalble sheath, which keeps the factory-made profile. The balloon is designed to provide an inflatable sement of known diameter and length at recommended pressures. The two markers on the shaft of the catheter appear when the tip of the balloon-tipped catheter leaves the guiding catheter (brachial: 92cm / femoral: 102cm). The proximal section of the catheter is a single-lumen, stainless steel hypotube with a luer adaper connected to the balloon lumen. GENOSS DCB is available in balloon lengths from 10 mm to 40mm and balloon diameters from 2.0mm to 4.0mm.
The nominal pressure of GENOSS DCB is 8 atm, the rated burst pressure of 2.0 to 3.5mm in balloon diameter is 16 atm, and the rated burst pressure of 3.75 to 4.0mm in balloon diameter is 14 atm. Catheter shaft of GENOSS DCB with working length up to 145cm and a balloon situated at the distal end of the shaft. GENOSS DCB has Hydrophilic coating on the shaft for easy use, and has double-bagged packaging with a moisture barrier inside a cardboard outer carton. GENOSS DCB is intended for single use only and is sterilized by Ethylene Oxide gas.

B Indications

The GENOSS DCB Paclitaxel Coated PTCA Balloon Catheter is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (including SVD, small vessel disease) and in-stent restenosis with reference vessel diameters of 2.0 mm to 4.0 mm.

C Contraindications

The GENOSS DCB Paclitaxel Coated PTCA Balloon Catheter is contraindicated for use in patients:

1. Patients with sensitive or allergic reactions to paclitaxel and/or delivery matrix (Shellac, Vitamin E-TPGS)
2. Patients with severe allergic reactions to contrast media
3. Patients with complete obstructive lesion
4. Patient who have experienced cardiogenic shock
5. Patients with coronary artery seizures in situations where no specific stenosis develops, shows a tendency to bleed, or has a history of allergies known to aspirin, heparin, ticlopidine, clopidogrel, or any antiplatelet or anticoagulant
6. Pregnant woman
7. Patients with a vessel diameter of less than 2mm
8. Patients with acute myocardial infarction (AMI) within the last week
9. Treatment of the unprotected left main coronary artery
10. Patients with lesions that inhibit complete expansion of the angioplasty balloon
11. Patients with less than 30% ejection fraction
12. Patients with perforated vessels

D Warnings

This product should be used only by physicians with experience in angiography, in percutaneous transluminal coronary angioplasty (PTCA) and in implanting stents in coronary vessels.
When removing GENOSS DCB from the packaging and when passing the hemostatic valve, great care must be taken to ensure that the balloon system does not become damaged or non-sterile.
Touching or wiping the balloon surface or contact with liquids should be strictly avoided, since this may cause delamination of the balloon coating. It is possible to rinse the guide wire lumen with sterile/isotonic saline solution.
Do not inflate the balloon prematurely. The recommended inflation pressure of the balloon must not be exceeded. It is also recommended that a pressure gauge is used to measure the inflation pressure.
Do not treat the same lesion segment with more than one GENOSS DCB.
If any resistance becomes apparent at any time during the insertion procedure. The catheter must not be pushed with applied force. The resistance can indicate damage to the balloon catheter. If resistance occurs while advancing through the guiding catheter, the entire delivery system should be pulled back.
Pre-dilatation with a uncoated balloon is recommended. The catheter should be advanced into the target lesion as soon as possible. Extended manipulation of the GENOSS DCB can cause delamination of the coating. The catheter should not be rotated during the intervention.

E Precautions

The inflated diameter of the balloon should correspond to the lumen of the target artery. Never use a balloon with a larger diameter. Never shake the catheter before use to de-air the balloon. Do not advance the guide wire into the balloon catheter guide wire lumen if resistance is felt without first identifying the cause for the resistance force and taking remedical action. Inflation in excess of the maximum inflation pressure is not recommended as the pressure may cause the balloon to rupture, or cause the balloon joint to fail respectively. Should this occur, deflate the balloon and remove it.
Do not use if the sterile packaging is damaged or open. Do not re-sterilize. Before use, the GENOSS DCB must be inspected to ensure that it was not damaged during transport.
For treatment to be successful and to ensure long term satisfactory result, the entire lesion length should ideally be covered by the coated GENOSS DCB balloon section.
Do not bend or squeeze the balloon portion of the GENOSS DCB before the procedure.
This device is designed and intended for single use only. Do not reinsert! Balloon pressure should not exceed the manufacture's recommended inflation pressure. The catheter system is to be used only by physicians trained to perform this intervention. Use only the appropriate liquid balloon inflation medium. Failure to use the appropriate fluid (e.g. having a higher concentration of contrast dye) may lead to prolonged in-and deflation times. Never use air or gaseous inflation media.
The diameter of the balloon should not be less than the reference diameter of the target vessel.
Do not expose the catheter to organic solvents, e.g. alcohol. Before angioplasty procedure is started, all equipment to be used for the procedure., including the balloon catheter should be carefully examined to verify its functionality. The appropriate anticoagulant and vasodilator therapy must be provided to the patient prior to the angioplasty and must be maintained during the procedure. Use of a pressure gauge is strongly recommended during the procedure. These catheters should only be manipulated in the body while they are under fluoroscopic observation with high quality radiographic imaging equipment. To decrease the potential for the introduction of air into the catheter system, special attention must be paid to the ensure that tight catheter connections are maintained. Use the protective balloon sheath until the catheter is being prepared for insertion.

F Potential Adverse Events/Complications

Possible adverse events associated with PTCA techniques include, but are not limited to:

- Acute myocardial infarction
- Allergic reaction
- Aneurysm or false aneurysm
- Rupture of a coronary artery
- Arrhythmias including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Heart tamponade or pericardial effusion
- Cardiac shock / pulmonary edema
- Coronary artery spasm (CAS, coronary artery spasm)
- Death
- Heat
- Heart failure
- Hematoma
- Bleeding/bleeding requiring transfusion
- Local or systemic infection
- Inflammation
- Blood vessel occlusion
- Pain or tenderness at the access site
- Kidney failure
- Stroke, cerebrovascular disorder /TIA, transient ischemic attack
- Systemic Embolic Occlusion
- Thrombosis

Potential adverse events related to Paclitaxel include but not limited to:

- Allergy / immune response
- Alopecia
- Anemia
- Blood transfusion
- Digestive system symptoms
- Blood diseases (leukopenia, neutropenia, thrombocytopenia)
- Liver enzyme modification
- Deformation of blood vessel wall tissue, including infection, cell damage, or necrosis
- Muscle pain / joint pain
- Peripheral neuropathy (syndrome)
- Heart conduction abnormalities
- Pseudomembranous colitis

G Individual Treatment

Before using GENOSS DCB, the benefits and risks for each patient must be individually assessed. When establishing the patient exclusion criteria, the risk associated with anti-platelet therapy should be taken into account. Special consideration is required for patients with recent active gastritis or peptic ulcer disease(PUD).

H Drug Interactions

The amount of Paclitaxel on the balloon surface corresponds to a few hundredths of the quantity usually used in anti-neoplastic treatment, which makes it rather improbable that interactions with other drug will occur. However, caution should be exercised when concomitantly administration known CYP3A4 and/or CYP2C8 substrates (including terfenadine, cyclosporine, lovastatin, midazolam, ondansetron) or drugs with high plasma protein binding (PPB) (expecially sulfonureas, anticoagulants of the coumarin type, salicylic acid, sulfonamides, digitoxin). For possible interactions of Paclitaxel and other administered drugs e.g. for oncologic indications, the relevant instructions for use should be consulted. A complete study of possible interactions of Paclitaxel in combination with comedications has not been esta blished.

I Pregnancy

The use of Paclitaxel during pregnancy is contraindicated. It is not possible to state the effects of GENOSS DCB on the unborn child. There are no clinical data available on the use GENOSS DCB in pregnant women and reproduction-relevant contraindications while these risks are unknown.

J Instructions for Use

Material required to perform a balloon catheter procedure
- PTCA Balloon catheter
- Guiding catheter
- 10-20cc Syringes (two or three)
- 0.014 inch guidewire
- Rotary hemostatic valve with appropriate inner diameter
- Contrast media diluted 1:1 with saline
- Inflation device with gauge
- Introducer sheath with dilator
- 3-way stopcock

Caution: Always perform pre-dilation with an non drug coated PTCA catheter before the GENOSS DCB procedure.
The pre-dilatation method is the same as the operation procedure of the GENOSS DCB as shown below.
*Pre-dilation: This is a procedure to widen the target lesion using a standard balloon that is not coated with drugs before GENOSS DCB procedure. After completely improving the plaque of the lesion with a standard balloon of the optimal size (balloon-to-vessel ratio 1:1), GENOSS DCB is applied.

Catheter selection
Select an appropriate Catheter for the target vessel. The diameter of the balloon should closely match the reference diameter of the target vessel.
Caution: The inflation diameter of the balloon must not exceed the diameter of the coronary artery proximal or distal to the stenosis. Select a balloon length which closely matches the lesion length. If the occluded vessel cannot be crossed with the desired Catheter, a smaller diameter non drug coated PTCA catheter can be used to pre-dilate the lesion before finally dilating with a Catheter.
Caution: For prevention of local overdosing it is not indicated to use a second Catheter or any other drug coated balloon at the same treatment site respectively. Also the implantation of a drug eluting stent at the same site should be avoided since an overdosing or interaction between the active agents cannot be excluded.
Caution: In case of the treatment of long lesions (Longer than max. balloon length available) the individual segments should be treated with only one Catheter. For each segment another Catheter should be used while an overlapping with an already treated segment should be avoided in order to prevent any local overdosing.

Catheter preparation
1. Take the protection ring with the Catheter out of the package and place it onto a sterile field.
Caution: It is recommended to use gloves, mouth, nose and eye protection for the unlikely event that the active compound of the balloon coating is released during the retrieval of the Catheter from the protection ring.
2. Gently pull out the catheter from the protection ring without removing the balloon protector in order to avoid any contact with the balloon coating.
Caution: Keep the transportation wire in place while preparing.
Warning: DO NOT flush the guide wire lumen because this may increase the risk of damaging or washing away the drug coating before treatment of target vessel takes place.
Warning: DO NOT bend or squeeze the balloon portion of the Catheter before the procedure to prevent delamination of the drug coating. Purge air from the Catheter with the balloon protector and transportation wire still in place.
3. Connect a 3-way stopcock to the Luer-Lock of the catheter.
4. Prepare and remove air from the inflation/deflation device according to manufacturer's recommendations and instructions.
5. Attach the inflation/deflation device containing 3 ml of balloon inflation zmedium to the stopcock.
Warning: Use only an appropriate balloon inflation medium (e.g., 50:50 mixture by volume of contrast medium and saline). Never use air or any gaseous medium to inflate the balloon.
6. Open the stopcock so that the fluid path between the catheter and the inflation/deflation device is established.
7. Pull the plunger of the inflation/deflation device and aspirate air from the catheter for at least 30 seconds.
Warning: DO NOT use the Catheter if a vacuum cannot be held, as this indicates a system failure.
8. Close the stopcock so that the fluid path to the catheter is closed and evacuate all air from the inflation/deflation device through the stopcock, i. e. until the inflation/deflation device is free of any bubbles.
9. Repeat steps 7–8 if necessary, to ensure air contained in the balloon and inflation lumen are removed. Release the inflation/deflation barrel to normal pressure.
10. Open the stopcock so that the fluid path between the catheter and the inflation/deflation device is established.

Insertion technique
Caution: Pre-treatment of significant stenosis (> 50%) proximal to targetlesion is required to prevent delamination of the balloon coating during crossing with the balloon.
Caution: A double guide wire technique may increase the risk of losing the drug coating while accessing the lesion.
11. Attach a hemostatic valve to the Luer-port of the guiding catheter positioned within the vasculature.
12. Position the guide wire under fluoroscopy, in accordance with PTCA techniques.
13. Carefully remove the balloon protector together with the transportation wire.
Caution: Touching of the balloon, wiping of the balloon surface or any contact with liquids prior to insertion should be strictly avoided, since this could damage the balloon coating.
14. Carefully back load the proximal end of the guide wire, into the distal tip of the Catheter until it exits at the guide wire exit port 25 cm from the distal tip.
15. Open the hemostatic valve to an extent that allows inserting the Catheter without any friction. Carefully insert the Catheter through the hemostatic valve.
16. Advance the Catheter through the guiding catheter using fluoroscopic guidance to determine when the catheter tip approaches the distal tip of the guiding catheter.
Note: The proximal exit markers may be used to approximate when the Catheter has reached the distal end of the guiding catheter.
17. Advance the Catheter into the target vessel and following the guide wire toward the lesion.
Note: The radiopaque balloon markers facilitate balloon positioning within the lesion.
Warning: If strong resistance is met during manipulation, stop the procedure and determine the cause of the resistance before proceeding. Advancement by force may result in damage to the vessel and/or laceration or separation of the guide wire or the Catheter. This may necessitate recovery of device fragments.

Balloon inflation
18. A GENOSS DCB is inserted into the lesion according to the standard PTCA techniques. The GENOSS DCB should be inflated to an optimal size (balloon-to-vessel ratio 1:1), and both ends of the balloon should extend 2-3 mm (total 4-6 mm) beyond both edges of the lesion.
Caution: Depending on patient situation and vessel morphology the inflation should be kept for a period of 40 to 60 seconds. At this time, if it is difficult for the patient to endure the maintenance time after inflation, it can be performed over 2 times.
Warning: DO NOT exceed Rated Burst Pressure (RBP).
Warning: To reduce the potential for vessel damage, the inflated diameter of the balloon must not exceed the original diameter of the vessel proximal and distal to the lesion.
19. If a significant stenosis persists, inflate the balloon again increasing pressure gradually until the lesion does not further improve.
Note: Administration of adequate drug contents occurs only during the first inflation.
20. After each inflation, assess the distal coronary blood flow by arteriography through the guiding catheter.

Compliance Chart

(atm)	(MPa)	Balloon Diameter (mm)								
		2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
8 (NP)	0.81	2.01	2.25	2.50	2.75	3.00	3.25	3.50	3.73	4.00
9	0.91	2.04	2.27	2.52	2.77	3.04	3.30	3.55	3.76	4.02
10	1.01	2.06	2.29	2.55	2.80	3.07	3.34	3.60	3.79	4.05
11	1.11	2.08	2.31	2.57	2.82	3.10	3.37	3.64	3.82	4.08
12	1.22	2.11	2.34	2.60	2.85	3.14	3.41	3.68	3.86	4.11
13	1.32	2.14	2.36	2.63	2.87	3.17	3.44	3.72	3.89	4.14
14	1.42	2.17	2.38	2.66	2.89	3.20	3.48	3.76	3.92	4.17
15	1.52	2.19	2.40	2.69	2.92	3.24	3.51	3.79	3.95	4.20
16 (RBP)	1.62	2.22	2.43	2.72	2.95	3.28	3.56	3.84	3.97	4.24
17	1.72	2.25	2.46	2.75	2.99	3.31	3.59	3.88	4.01	4.27
18	1.82	2.29	2.49	2.79	3.02	3.34	3.63	3.93	4.04	4.30

NP (Nominal pressure) RBP (Rate Burst Pressure)

Balloon deflation
21. Deflate the balloon in accordance with standard PTCA procedures. Apply negative pressure to the balloon for at least 30 seconds before carefully pulling back the Catheter out of the target vessel.
Caution: It is recommended to maintain negative pressure whenever the Catheter is withdrawn.
22. Pull the completely deflated Catheter into the guiding catheter.

Catheter removal/Exchange procedure
23. Loosen the hemostatic valve.
24. Hold the guide wire and hemostatic valve in one hand, while grasping the Catheter shaft in the other hand.
25. Maintain the guide wire position in the coronary artery by keeping the guide wire stationary, and begin pulling the Catheter out of the guiding catheter.
Note: Monitoring the guide wire position under fluoroscopy is highly recommended during the exchange.
26. Pull on the Catheter until the guide wire exit point is reached. Carefully remove the flexible, distal portion of the Catheter off the guide wire while maintaining the guide wire position across the lesion. Close the hemostatic valve.
Note: In case of difficulties during removal of the Catheter, remove the entire system at once, i.e., the guiding catheter, the guide wire and the Catheter simultaneously.
27. Completely remove the Catheter from the guide wire.
Note: Inspect the Catheter integrity immediately upon removal from the patient.
28. If required, prepare and introduce the next Catheter to be used, as previously described.
Caution: For prevention of local overdosing it is not indicated to use a second Catheter or any other drug coated balloon at the same treatment site respectively. Also the implantation of a drug eluting stent at the same site should be avoided since an overdosing or interaction between the active agents cannot be excluded.
29. After use dispose the product and packaging in accordance with hospital, administrative and/or local government policy.

K 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.

L Contents

- One (1) GENOSS DCB Paclitaxel Coated PTCA Balloon Catheter in a sealed, peel-open pouch.
- One (1) Instructions for Use Manual.
- One (1) Compliance Chart.

M Storage

Store the device between 1 ~ 30 °C in the aluminum pack.

N 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.
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These limitations of liability and warranty are not intended to contrave ne 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.

O Available sizes

D (mm) / L (mm)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
10	X	X	X	X	X	X	X	X	X
15	X	X	X	X	X	X	X	X	X
18	X	X	X	X	X	X	X	X	X
20	X	X	X	X	X	X	X	X	X
23	X	X	X	X	X	X	X	X	X
25	X	X	X	X	X	X	X	X	X
30	X	X	X	X	X	X	X	X	X
35	X	X	X	X	X	X	X	X	X
40	X	X	X	X	X	X	X	X	X

D: Balloon diameter, L: Balloon length

P Symbols

	Manufacturer		Keep away from sunlight
	Date of manufacture		Keep dry
	Use by date	10°C 30°C	Temperature limit
LOT	Batch code		Do not re-use
REF	Catalogue number		Consult instructions for use
STERILE EO	Sterilized using ethylene oxide		Caution
	Do not resterilize	MD	Medical device
	Do not use if package is damaged		Contains a medicinal substance
	Single Sterile barrier system with protective packaging outside		
UDI	Unique device identifier		

MS-P3087/IFU-DS1001(Rev.3,2601)

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