LEGFLOW RX®
PACLITAXEL RELEASING PERIPHERAL BALLOON DILATATION CATHETER

Description

The LEGFLOW RX balloon dilatation catheter is a single-use device for the treatment (balloon dilatation) of de novo and restenotic lesions in peripheral arteries: renal, iliac, femoropopliteal (superficial femoral and popliteal), native lesions below the knee (BTK), in-stent restenosis, lower limb ischemia. The LEGFLOW RX is a Rapid Exchange double lumen peripheral balloon dilatation catheter. The catheter consists of a proximal stainless steel hypotube shaft and a distal catheter with a balloon close to the distal tip. The outer lumen is used for balloon inflation and deflation, the lumen about 25 cm from the catheter tip permits the insertion of a 0.014" inch guide wire to facilitate the catheter advancement to the arterial lesion site. The Legflow balloon has two radiopaque markers at the proximal and distal end of the balloon to facilitate the correct positioning of the balloon at the lesion segment, under fluoroscopy. The Cardionovum PTA Catheters are supplied with a special, flexible “Y” connector. The balloon is inflated by injecting a diluted contrast medium solution through the distal Luer port (marked with the dimensions of the balloon e.g. “6 mm x 4 cm”).The maximum compatible guidewire size is printed on the package label.
Note: The maximum burst pressure is printed on the package label. In-*vitro* testing has shown that with 95% certainty, 99.9% of the balloons will not burst at or below the maximum working pressure. Balloons should not be inflated in excess of the maximum burst pressure.The LEGFLOW RX PTA-catheter is coated with the anti restenosis drug paclitaxel. The dose of 3.0 µg/mm² balloon surface is coated on the balloon.

STERILE. Sterilized with ethylene oxide gas. Non-pyrogenic. For one use only. Do not autoclave.
(**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.)

Indications

The treatment (balloon dilatation) of de novo and restenotic lesions in peripheral arteries: renal, iliac, femoropopliteal (superficial femoral and popliteal), native lesions below the knee (BTK), in-stent restenosis, lower limb ischemia.

Contraindications

- Known allergy or sensitivity to Paclitaxel
- Coronary arteries
- Patients who exhibit angiographic evidence of existing thrombus
- Patients with contraindication for anti-platelet/anticoagulant therapy, including allergy
- Known allergy to contrast media
- Pregnant women or women who are intending to become pregnant or men wishing to preserve their fertility
- Target lesions distal to a 50% or greater stenosis, which cannot be predilated or target lesions proximal to untreatable areas of significant flowcompromising disease
- Resistant (fibrotic or calcific) lesions, which cannot be predilated
- Total occlusion of the target vessel

Please note

The above-mentioned products are not intended for use in the central circulatory system, e.g. coronary arteries (pursuant to EC Directive 93/42/EEC, Appendix IX, Paragraph 1.7)

Warnings

- Thrombocyte aggregation inhibitor therapy (antiplatelet drug therapy) should not be given for less than 2 months (75 mg Clopidogrel + 100 mg Aspirin).
- This device is intended for one-time use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination
- To reduce the potential for vessel damage, the diameter of the inflated balloon should correspond to the diameter of the vessel located proximally and distally to the stenosis.
- When the catheter is introduced into the vascular system, it is necessary to check the manipulations using high quality fluoroscopic devices. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure must not exceed the maximum burst pressure. The maximum burst pressure is based on the result of in-vitro testing. At least 99.9 % of the balloons (with a 95 % certainty level) will not burst at or below their maximum burst pressure. Use of a pressure-monitoring device is urgently recommended to prevent excessively high pressures.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter by the end of the year indicated by month and year on the package label.

Precautions

- The physician must be sufficiently familiar with the products and their reference systems to avoid errors in the selection of equipment.
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its dimensions andconfiguration are suitable for the intended use.
- The catheter system should be used only by physicians trained in carrying out arteriography and who have received appropriate training in percutaneous transluminal angioplasty.
- Provide for the use of systemic heparinization. Rinse all devices entering the vascular system with sterile heparinized saline or a similar isotonic solution.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PT Acatheter through a smaller size sheath than that indicated on the label. Do not use a second drug-coated balloon at the same treatment site. Additional LEGFLOW RX balloon catheter can be used to treat the lesion longer than the maximum balloon length available under the following circumstances:
  – each individual segment should be treated only once with a drug-coated balloon
  – try to minimalize overlapping of treated segment
  – treat each segment with a new PTA balloon

  Overlapping of consecutively placed balloons with a treated segment should be avoided by precisely angiographically positioned catheter, using the marker bands.
- Not intended for precise monitoring of blood pressure.

Side Effects

Possible side effects include, but are not limited to, the following:

- Possible allergic reactions to Paclitaxel
- hemorrhage/hematoma
- embolism
- intimal tear
- arteriovenous fistula
- total occlusion
- perforation of the vessel wall
- pseudoaneurysm formation
- restenosis of the dilated artery
- thrombosis
- death.

IMPORTANT PATIENT INFORMATION:

Physicians should consider the following in counselling patients about this product:

- The potential associated risks with a Paclitaxel eluting balloon,
- The potential risks and the benefits of alternative PAD (peripheral artery disease) treatment options
- The balance between potential risks and benefits in using a Paclitaxel coated balloon considering the specific patient condition
- The need for a post-procedure antithrombotic therapy

Note regarding instructions for use:

Do not use with Ethiodol* or Lipiodol or with another contrast medium with the same components.
Note: Do not expose the catheter to organic solutions (e.g. alcohol). **Note:** Do not use if the sterile inner package is open or damaged. **Note:** Do not autoclave. Do not resterilize.
Note: Store in a cool, dark, dry place.

Preparation and Inspection Procedure

1. Do not let the balloon come into contact with fluids prior to insertion.
2. Do not allow the balloon to come into contact with the skin.
3. Carefully remove the catheter from the package.
4. Do not yet remove the balloon protection casing at the distal end of the catheter.
5. Attach a stopcock to the catheter's distal Luer port (inflation lumen), marked with the dimensions of the balloon, e.g. "6 mm x 4 cm".
6. Attach a 20 ml syringe to the stopcock, open the stopcock and exert negative pressure by pulling the syringeplunger as far back as possible without removing it from the syringe barrel.
7. Hold the syringe and proximal end of the dilatation catheter above the distal end of the catheter; the balloonshould be in a vertical position pointing downwards.
8. Close the stopcock to the inflation port.
9. Remove the syringe and remove air bubbles.
10. Reattach the 20 ml syringe to the stopcock, open the stopcock and again exert negative pressure by pulling the syringe plunger as far back as possible without removing it from the syringe barrel.
11. Close the stopcock to the inflation port and remove the syringe.

Note: To ensure all the air contained in the balloon and inflation lumen has been removed, it is recommended that negative pressure be exerted twice. Open the stopcock only when the syringe is in place and negativepressure is being exerted.

12. Fill the 20 ml syringe with 3 ml of a 50% solution of contrast medium in sterile saline solution or only saline solution and reattach it to the stopcock.
    Caution: The viscosity and precipitation levels of non-ionic contrast medium differ from those of ionic contrast medium, and may result in greater inflation/deflation times.
13. Remove the balloon protection casing from the distal end of the catheter.
14. Apply positive pressure and slowly open the stopcock so that the contrast solution gradually flows into the inflation lumen and balloon.
    Note: Do not exceed the maximum burst pressure printed on the package label.
15. Expel all air from the balloon and inflation lumen. If air bubbles are still visible in the system, point the balloon tip down, lightly tap the balloon, exert negative pressure with the syringe and repeat steps 5-12.
16. Conduct a visual examination to ensure all air has been removed from the balloon and inflation lumen.
17. Exert negative pressure and close the stopcock or attach an inflation device which is left at negative pressure until the balloon is ready to be used.

Assembly and Insertion Procedure

Note: If the user chooses not to use a guiding catheter, some of the details in the following procedures will not be applicable.

1. Attach a prepared angioplasty inflation system to the PTA catheter's distal Luer port, marked e.g. "6 mm x 4 cm".
2. Attach an additional hemostasis valve of your choice to the proximal Luer port for the purpose of introducing the guidewire. Insert the distal end of the guidewire into the hemostasis valve and proximal Luer port.
3. Introduce the catheter through a sheath percutaneously.
4. If a guiding catheter is used, attach an additional guidewire hemostasis valve of your choice to the proximal Luer port. Insert the distal end of the guidewire into the hemostasis valve and proximal Luer port.
5. Advance the guidewire through the catheter and Seal the hemostasis valve around the guidewire.
6. Attach a second hemostasis valve to the Luer port of an appropriate guiding catheter. Ensure that the hemostasis valve and the maximum catheter shaft diameter (see package label) are compatible.
7. After the guiding catheter has been positioned, rinse the guidewire lumen with sterile saline solution or a similar isotonic solution, and insert the PTA catheter through the hemostasis valve into the guiding catheter.
8. Advance the PTA catheter to the distal end of the guiding catheter.
   Caution: only advance or withdraw the PTA catheter when the balloon, by exerting negative pressure with their inflation system, is completely deflated. Do not inflate, deflate, advance or withdraw the PTA catheter unless a guidewire has been introduced. **Caution:** avoid over-tightening a Tuohy-Borst turning valve, since this restricts the flow of contrast media to and from the balloon, thereby slowing inflation/ deflation.
9. Using fluoroscopy and accepted PTA techniques, advance the guidewire through the lesion.
10. Using fluoroscopy continue with the examination and use the radiopaque marking(s) for the purpose of placing the balloon dilatation segment in the stenosis.
11. Continue the procedure and use accepted angioplasty technique to dilate the stenosis. **Note:** Do not exceed the maximum burst pressure printed on the package label. **Note:** Balloon inflation should only be carried outwith the guidewire extended beyond the catheter tip. It is imperative that the guidewire, the balloon catheter, or both remain within the lesion until the examination is complete and the dilatation system can be removed from the vessel.

Ending of the angioplasty

1. Withdraw the deflated PTA catheter and guidewire into the guiding catheter.
2. Using a technique of your choice, remove the PTA catheter, guidewire and guiding catheter from the vasculature.
3. Dispose of the PTA catheter, guidewire and guiding catheter.

Warning

If, during the removal of the balloon catheter, resistance can be felt from the entry sheath, the guiding catheter or via the guidewire, etc, all materials used should be removed at the same time, in order to prevent damage to a blood vessel, damage to a catheter, or the danger of losing parts of the catheter in the blood vessel.
If the dilation result is not satisfactory, the user may under certain circumstances decide to dilate once more with the same balloon catheter.

Warning

A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.

Summary of the meta-analysis: A meta-analysis of randomized controlled trials published in December 2018 by Katsanos et. al. identified an increased risk of late mortality at 2 years and beyond for paclitaxel-coated balloons and paclitaxel-eluting stents used to treat femoropopliteal arterial disease. In response to these data, the United States Food and Drug Administration (FDA) performed a patient level meta-analysis of long- term follow-up data from the pivotal premarket randomized trials of paclitaxel-coated devices used to treat femoropopliteal disease using available clinical data through May 2019. The meta-analysis also showed a late mortality signal in study subjects treated with paclitaxel-coated devices compared to patients treated with uncoated devices. Specifically, in the 3 randomized trials with a total of 1090 patients and available 5-year data, the crude mortality rate was 19.8% (range 15.9% - 23.4%) in patients treated with paclitaxel-coated devices compared to 12.7% (range 11.2% - 14.0%) in subjects treated with uncoated devices. The relative risk for increased mortality at 5 years was 1.57 (95% confidence interval 1.16 - 2.13), which corresponds to a 57% relative increase in mortality in patients treated with paclitaxel-coated devices. As presented at the June 2019 FDA Advisory Committee Meeting, an independent meta-analysis of similar patient-level data provided by VIVA Physicians, a vascular medicine organization, reported similar findings with a hazard ratio of 1.38 (95% confidence interval 1.06 - 1.80). Additional analyses have been conducted and are underway that are specifically designed to assess the relationship of mortality to paclitaxel-coated devices. The presence and magnitude of the late mortality risk should be interpreted with caution because of multiple limitations in the available data, including wide confidence intervals due to a small sample size, pooling of studies of different paclitaxel-coated devices that were not intended to be combined, substantial amounts of missing study data, no clear evidence of a paclitaxel dose effect on mortality, and no identified pathophysiologic mechanism for the late deaths. Paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. The benefits of paclitaxel-coated devices (e.g., reduced reinterventions) should be considered in individual patients along with potential risks (e.g., late mortality).

Additional information regarding clinical data on LEGFLOW OTW / RX

In the RAPID trial (ISRCTN47846578), Kaplan Meier estimates freedom from all-cause mortality at 12 months was 98.0% (95% CI 94.1% to 100%) in the Legflow + bare metal stent group alone versus 96.1% (95% CI 90.8% to 100%; p=0.483) in the bare metal stent group alone as reported by Katsanos et al. Similar results confirming safety of Legflow at 2 years follow up in the RAPID trial have been published: de Boer SW, de Vries JP, Werson DA, Fioole B, Vroegindeweij D, Vos JA, van den Heuvel D; RAPID trial investigators. Drug coated balloon supported Supera stent versus Supera stent in intermediate and long-segment lesions of the superficial femoral artery: 2-year results of the RAPID trial. J Cardiovasc Surg (Torino). 2019 Oct 9. doi: 10.23736/S0021-9509.19.11109-3.

Balloon dilatation and Paclitaxel release

To ensure a clinically effective drug release of Paclitaxel into the vessel wall at the lesion site the balloon should be inflated not below the nominal balloon inflation pressure of 6 bar with a balloon inflation time of at least 2 minutes.

After dilation of the lesion

Further procedure according to current medical standards.

Recommended medication

The pre-operative, intra-operative and post-operative medication must be carried out according to current medical standards.

General precautionary measures

The packed product must be stored in a dry place at a temperature of between 0°C and 25°C.
The packed product must be protected from direct daylight.
The product must not be used if the sterility date on the package has been exceeded.

Disposal after use

Medical products and their accessories can constitute a potential biological danger after their use. Recognised medical procedures are therefore to be complied with and consideration taken of the respective legal regulations and local provisions when handling and disposing of the used medical products and their accessories.

Note

Individual Cardionovum products and sets are compatible with one another. Despite this, the user must, prior to use, ensure that the products are compatible with one another. This applies in particular if the user uses Cardionovum products in connection with products of other manufacturers.

References

The user should be familiar with the most recent publications on current medical practice regarding balloon dilatation.

Advice

The Products are for single use only and should not be cleaned, disinfected and re-sterilised. This form of conditioning would lead to unsterile Products and could cause infections to the patient and also risk of balloon rupture.

Explanation of symbols used on the package labels.


Do not re-use


Consult instructions for use


Date of manufacture

Reference number

Batch code

Sterilized using ethylene oxide


Use by Date


Outer Diameter


Keep Dry

F
French size

Temperature limit


Do not use if package is damaged


Keep away from sunlight

Do not resterilize

Medical Device


Manufacturer

CE
1434

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LEGFLOW RX®
PACLITAXEL FREISETZENDER PERIPHERER BALLON-DILATATIONSKATHETER

Beschreibung

Der LEGFLOW RX Ballon-Dilatationskatheter ist ein Einmalartikel zur Behandlung (Ballondilatation) von neu stenosierten und restenosierten Läsionen in peripheren Arterien: A. renalis, A. iliaca, femoropopliteal (A. femoralis superficialis und A. poplitea) und von Läsionen körpereigener Arterien unterhalb des Knies (BTK), In-Stent-Restenosen sowie Ischämien des Unterschenkels.
Der LEGFLOW RX ist ein doppellumiger Rapid Exchange Ballon-Dilatationskatheter für den peripheren Zugang. Der Katheter besteht aus einem proximalen Hypotubeschaft aus Edelstahl und einem distalen Katheter mit einem Ballon in der Nähe der distalen Spitze.
Das äußere Lumen dient der Ballonfüllung und -entleerung; das Lumen, das etwa 25 cm von der Katheterspitze entfernt ist, ermöglicht das Einführen eines Führungsdrahtes der Stärke 0,014 Zoll, was das Vorschieben des Katheters zur Läsion in der Arterie erleichtert.
Am proximalen und distalen Ende des Legflow-Ballons befindet sich jeweils eine röntgensichtbare Markierung, die die richtige Positionierung des Ballons im veränderten Segment unter Durchleuchtung erleichtert. Cardionovum PTA-Katheter werden mit einem speziellen, flexiblen „Y"-Verbindungsstück geliefert. Der Ballon wird mit verdünntem Kontrastmittel gefüllt, das am distalen Luer-Anschluss (beschriftet mit den Ballonmaßen, z. B. 6 mm x 4 cm) injiziert wird.
Die maximal zulässige Führungsdrahtdicke ist auf dem Packungsetikett angegeben.