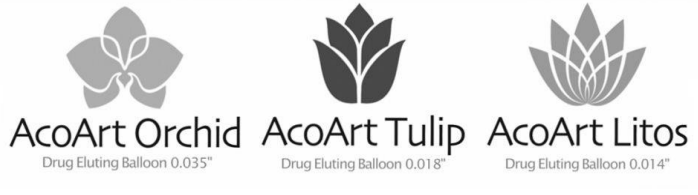
acotec Scientific Co., Ltd

DRUG ELUTING BALLOON CATHETER



Medical Device

Contains a medicinal substance

Translation

Balloon Nominal Diameter

Balloon Nominal Length

Usable Catheter Length

Recommended Introducer

Maximum recommended guide wire

Nominal Pressure

Rated Burst Pressure

Date of manufacture

Manufacturer

CE Marking of Conformity. Notified Body number

Do not re-use

Consult instructions for use

Keep dry. keep away from sunlight

Do not use if package is damaged

Only one product in the package

Catalogue Number

Batch, code// Lot-Nummer

Use-by date

Authorized representative in the European Community

Sterilized using ethylene oxide. Single sterile barrier system with protective packaging outside

Unique device identifier

EN

DEVICE NAME

The drug eluting balloon catheters (DEB): AcoArt Orchid (DEB 0.035˝), AcoArt Tulip (DEB 0.018˝) and AcoArt Litos (DEB 0.014˝) are percutaneous transluminal angioplasty (PTA) catheters with different guide-wire compatibilities and are manufactured by Acotec Scientific Co., Ltd.

DESCRIPTION

The DEB catheters are over the wire (OTW) peripheral balloon catheter, specifically designed for percutaneous transluminal angioplasty in atherosclerotic obstructed vessels and for the treatment of stenotic lesions in dysfunctional native arteriovenous dialysis fistulae. The catheter has a dual-lumen shaft, onto the distal tip of which a balloon is welded. The double-lumen shaft is branched at the proximal end so that one tube forms the entrance to the central lumen for the guide wire, while the other tube is used to inflate and deflate the dilatation balloon with a mixture of contrast medium and saline solution.

DEB catheters are paclitaxel coated balloon dilatation catheter, the dose of paclitaxel is 3µg per square millimeter.

The DEB catheters are available in different balloon sizes. Nominal balloon diameter/ lengths and guide wire compatibility are printed on the hub.

INDICATIONS

The drug eluting balloon (DEB) catheters are indicated for percutaneous transluminal angioplasty (PTA) in patients with obstructive disease of peripheral arteries and for the treatment of stenotic lesions in dysfunctional native arteriovenous dialysis fistulae.

INTENDED PATIENT POPULATION

The intended patient population is adult patients with obstructive disease of peripheral arteries and/or stenotic lesions in dysfunctional native arteriovenous dialysis fistulae.

CONTRAINDICATIONS

- The DEB catheters are contraindicated for the use in coronary arteries, supra-aortic vessels and cerebrovascular.
- Inability to cross lesion with a guide wire.
- The DEB catheters should not be used in pregnant or breast feeding women or in patients with known hypersensitivity to paclitaxel.
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy

WARNINGS

- This device is designed and intended for single use only. DO NOT RESTERILIZE AND/OR REUSE. Reuse or resterilization may create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness and death. ACOTEC will not be responsible for any direct, incidental or consequential damages resulting from resterilization or reuse. The coating excludes any reuse of the device.
- **The maximal treated lesion length should not be more than 75 cm to avoid potential systemic effects of paclitaxel (e.g. myelosuppression). If the sum of lesions is longer than 75 cm a second intervention has to be scheduled at a later point in time.**
- Inspect the device, prior to procedure, to verify functionality and lack of damaged parts. Do not use the device if the outer or the inner package is damaged or opened.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just distal to the stenosis.
- When the catheter is in the body, it should be manipulated while under sufficient and/or high quality fluoroscopy. Prior to withdrawing the balloon catheter from the lesion, the balloon must be completely deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Never use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium.
- Do not expose the device to organic solvents, e.g. alcohol
- Do not manipulate the balloon catheter in inflated state. The position of the balloon catheter may only be changed with the guide wire in place.
- If resistance occurs during manipulation, the cause must first be ascertained by fluoroscopy, road mapping or DSA before the balloon catheter is moved backwards or forwards.
- The guide wire may under no circumstances be moved during inflation of the balloon.
- The balloon must be completely deflated before retrieving the catheter from the vascular system.
- Do not exceed the Rated Burst Pressure (RBP). The RBP is based on the results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization. Inflation in excess of the rated burst pressure may cause the balloon to rupture.
- Only the physician trained and after training of the balloon dilatation catheter could use the device.
- To reduce the risk of vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just distal to the stenosis.
- Use only a mixture of contrast medium and saline solution to fill the balloon (1:1). Never use air or any gaseous medium to inflate the balloon of the catheter.
- Use by the labeled date.
- Do not use with Lipiodol™ and Ethiodol™ contrast media, or similar relevant ingredients contrast agents.
- Never apply positive pressure to the balloon during preparation.

PRECAUTIONS

- Appropriate drug therapy (anticoagulant, vasodilator, etc.) should be administered to the patient according to standard protocols for PTA before insertion of the dilatation catheter.
- To minimize the possible introduction of air into the system, it is imperative that before proceeding careful attention is paid to the maintenance of tight catheter connections and through aspiration and flushing of the system.
- Precautions to prevent or reduce clotting should be taken when any catheter is used. Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution via the guide wire access port prior to use. Consider the use of systemic heparinization.
- The balloon catheter should be used with caution for procedures involving calcified lesions due to the abrasive nature of these lesions.
- Allergic reactions to contrast medium should be identified before treatment.
- Catheter applications vary and the technique must be selected on the basis of the patient's condition and the experience of the interventionalist.
- Never advance the balloon catheter without the guide wire extending from the tip.
- Never attempt to move the guide wire when the balloon is inflated.
- Do not advance the catheter against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
- Store at controlled room temperature, in a dry place. Keep away from sunlight.
- Don't exceed dilatation pressures to "rated burst pressure". In any case, always use manometer controlled inflation.

CAUTION: Larger sizes of the balloon catheter may exhibit slower deflation times particularly on long catheter shafts.

POTENTIAL COMPLICATIONS/ ADVERSE EFFECTS/ RESIDUAL RISKS

Complications associated with the use of the DEB balloon catheter are similar to the ones associated with standard PTA procedures. Possible complications may include, but are not limited to:

Puncture related:

- Local hematoma/Local hemorrhage
- Local or distal thromboembolic episodes
- Thrombosis/Total occlusion of the peripheral artery
- Arterio-venous fistula
- Pseudoaneurysm

Dilatation related

- Dissection/perforation in the dilated artery wall
- Prolonged spasms
- Acute re-occlusion necessitating surgical intervention
- Restenosis of the dilated artery

Angiography related
- Hypotension
- Pain and tenderness
- Arrhythmias
- Sepsis/infection
- Systemic embolization
- Endocarditis
- Short-term hemodynamic deterioration
- Death
- Drug/allergic/pyrogenic reactions

PHARMACOLOGICAL INTERACTION
Due to the low dose and local administration, the pharmacological interactions are not to be expected

INSTRUCTIONS FOR USE
Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the dilatation catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.
Handle the device with extreme caution in order to avoid any damage to the folded balloon. Moistening of the device with saline, insertion through the sheath and contact with blood will not reduce the efficacy of the drug coating as long as the balloon remains uninflated.

1. PREPARATION EXPANDING DEVICE
- Prepare the inflation device according to the manufacturer's instructions.
- Carefully remove the balloon protective sheath. Prior to use, carefully examine the unit to verify that the catheter or sterile package has not been damaged in shipment. In case of resistance, twist the protection with one hand holding the shaft with the other.

2. CATHETER SELECTION
- The nominal balloon size must be chosen equal to the inner diameter of the artery distal to the lesion. If the stenosis cannot be crossed with the desired dilatation catheter, use a smaller diameter (non drug coated) catheter to pre-dilate the lesion to facilitate the passage of a more appropriate-sized dilatation catheter.
- In cases of total occlusion or subocclusive lesions a predilatation with a (non drug coated) balloon is recommended.

3. DILATATION CATHETER PREPARATION
- The catheter is packaged in a protective tube. Carefully remove the catheter from the protective tube.
- The folded balloon catheter contains tiny air bubbles that should be purged prior use. To do this, keep the balloon catheter in a downward vertical position. Keep the protective sheath in place during the purging procedure. Connect a Luer-lock syringe partially filled with saline-contrast mixture solution to the inflation port of the catheter hub. Apply negative pressure for 15 seconds until air is completely evacuated and release the plunger. Repeat this operation a couple of times until migration of air bubbles towards the syringe stops. **Never use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium. Never apply positive pressure to the balloon during preparation.**
- Remove the protective tube from the balloon.
- Flush the wire lumen properly through the connector luer connector.

4. 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.

5. USE OF THE DRUG ELUTING BALLOON CATHETER
- Insert a guidewire through the hemostatic valve following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guiding catheter/ introducer sheath. When complete, withdraw the guidewire/ introducer, if used.
- Attach a torque device to the wire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel, then across the stenosis.
- Thoroughly aspirate and flush the guiding catheter in preparation (when guiding catheter is used) for introduction of the dilatation catheter. Back load the distal tip of the dilatation catheter onto the guidewire.

NOTE: To avoid kinking, advance the dilatation catheter slowly, in small increments until the proximal end of the guidewire emerges from the catheter.
- 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 as to prevent blood return yet permitting easy movements of the dilatation catheter. If resistance is encountered, do not advance the catheter through the adapter.
- 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).
- The majority of the drug is released within the first 30 seconds of balloon inflation. The duration of the inflation should therefore be between 30 seconds and 1 minute for optimal drug release. In order to optimize lesion dilatation, longer inflation times are possible at the discretion of the operator.
- Completely deflate the balloon catheter. Withdraw the deflated dilatation catheter and guidewire from the guiding catheter/introducer sheath, through the hemostatic valve. Tighten the knurled knob on the hemostatic valve.
- If necessary the balloon catheter can be exchanged over the guidewire which remains in the vessel, for different balloon types or sizes.

WARNING: The same vessel segment must not be dilated with more than one drug eluting balloon. Should a postdilatation be necessary after the utilization of a drug eluting balloon, so should this be done with a standard (non drug coated) dilatation balloon. Drug Eluting Stents must not be implanted into the vessel segment that has been treated with a drug eluting balloon.
- If more than one balloon is required to treat a single lesion, balloons must overlap by at least 1 cm. A second new balloon catheter has to be used because the drug is almost completely released during the first expansion. Additional overlapping should be avoided.

6. PRE- AND POST- PROCEDURE ANTIPLATELET REGIMEN
- Dual antiplatelet therapy (ASS and clopidrogel or ticlopidine) should be administered pre-procedure and for a minimum of 4 weeks after the intervention. Prolonged antiplatelet therapy can be given at the discretion of the physician and should be considered after placement of stents.

PRODUCT SUPPLY
The DEB catheters are supplied sterile and intended for single use only. The DEB catheters are sterilized by ethylene oxide gas, and is nonpyrogenic. It will remain sterile as long as the packaging remains unopened and undamaged. Use product prior to labeled Expiration Date.
CAUTION: Do not use if the inner package is open or damaged.

SHIPMENT CONDITION
Product should be shipped, avoiding heavy weight, direct sunlight, snow and rain.

STORAGE CONDITION
The packed catheter shall be stored in a dry, cool and clean place free of corrosive gases.

DISPOSAL PROCEDURES
Used Drug Eluting Balloon Catheters devices should be disposed of using standard hospital biohazard procedures.

WARRANTY/LIABILITY
The product and each component of its system have been designed, manufactured, tested and packaged with all reasonable care. The warnings contained in Acotec's instructions for use are expressly to be considered as an integral part of this provision. Acotec guarantees the product until the expiry date indicated on the same. The warranty is valid provided that the use of the product was consistent with the instructions for use. Acotec disclaims any warranty of merchantability or fitness for a particular purpose of the product. Acotec is not liable for any direct, indirect, incidental or consequential damages caused by the product. Except in the case of fraud or grave fault on Acotec's part, compensation of any damage to the buyer will not, in any event, be greater than the invoice price of the disputed products. The guarantee contained in this provision incorporates and substitutes the legal guarantees for defects and compliance, and excludes any other possible liability of Acotec, however originating, from the product supplied. These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable. 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 Acotec's legitimate interest in limiting its liability or warranty. No person has any authority to bind Acotec to any warranty or liability regarding the product.

SAFETY AND CLINICAL PERFORMANCE

A copy of the Summary of Safety and Clinical Performance can be viewed by searching the device name on the EUDAMED website: https://ec.europa.eu/tools/eudamed

Additional information regarding paclitaxel medical devices 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:

In the ACOART I trial, the Kaplan Meier estimates freedom from all-cause mortality at 2, 3 and 5 years (within 5.5 years) are 91.9% (95%CI, 86.7% to 97.4%), 87.8% (95%CI, 81.6% to 94.5%), and 82.7% (95%CI, 75.6% to 90.5%), respectively, for the Acotec DCB treatment device and 93.9% (95%CI, 89.3% to 98.8%), 86.7% (95%CI, 80.2% to 93.7%) and 73.2% (95%CI, 64.0% to 83.6%), respectively, for the PTA control device.

ACOART ORCHID DRUG ELUTING BALLOON CATHETER 0.035"							
Usable Catheter Length: 45 cm							
ORC03020HG	ORC35020HG	ORC04020HG	ORC45020HG	ORC05020HG	ORC55020HG	ORC06020HG	ORC07020HG
ORC03030HG	ORC35030HG	ORC04030HG	ORC45030HG	ORC05030HG	ORC55030HG	ORC06030HG	ORC07030HG
ORC03040HG	ORC35040HG	ORC04040HG	ORC45040HG	ORC05040HG	ORC55040HG	ORC06040HG	ORC07040HG
ORC03060HG	ORC35060HG	ORC04060HG	ORC45060HG	ORC05060HG	ORC55060HG	ORC06060HG	ORC07060HG
ORC03080HG	ORC35080HG	ORC04080HG	ORC45080HG	ORC05080HG	ORC55080HG	ORC06080HG	ORC07080HG
ORC03100HG	ORC35100HG	ORC04100HG	ORC45100HG	ORC05100HG	ORC55100HG	ORC06100HG	ORC07100HG
ORC03120HG	ORC35120HG	ORC04120HG	ORC45120HG	ORC05120HG	ORC55120HG	ORC06120HG	ORC07120HG

ORC08020HG	ORC09020HG	ORC10020HG	ORC12020HG
ORC08030HG	ORC09030HG	ORC10030HG	ORC12030HG
ORC08040HG	ORC09040HG	ORC10040HG	ORC12040HG
ORC08060HG	ORC09060HG	ORC10060HG	ORC12060HG
ORC08080HG	ORC09080HG	ORC10080HG	ORC12080HG
ORC08100HG	ORC09100HG	ORC10100HG	ORC12100HG
ORC08120HG	ORC09120HG	ORC10120HG	ORC12120HG

ACOART ORCHID DRUG ELUTING BALLOON CATHETER 0.035"							
Usable Catheter Length: 80 cm							
ORC03020AG	ORC35020AG	ORC04020AG	ORC45020AG	ORC05020AG	ORC55020AG	ORC06020AG	ORC07020AG
ORC03030AG	ORC35030AG	ORC04030AG	ORC45030AG	ORC05030AG	ORC55030AG	ORC06030AG	ORC07030AG
ORC03040AG	ORC35040AG	ORC04040AG	ORC45040AG	ORC05040AG	ORC55040AG	ORC06040AG	ORC07040AG
ORC03060AG	ORC35060AG	ORC04060AG	ORC45060AG	ORC05060AG	ORC55060AG	ORC06060AG	ORC07060AG
ORC03080AG	ORC35080AG	ORC04080AG	ORC45080AG	ORC05080AG	ORC55080AG	ORC06080AG	ORC07080AG
ORC03100AG	ORC35100AG	ORC04100AG	ORC45100AG	ORC05100AG	ORC55100AG	ORC06100AG	ORC07100AG
ORC03120AG	ORC35120AG	ORC04120AG	ORC45120AG	ORC05120AG	ORC55120AG	ORC06120AG	ORC07120AG
ORC03150AG	ORC35150AG	ORC04150AG	ORC45150AG	ORC05150AG	ORC55150AG	ORC06150AG	ORC07150AG
ORC03200AG	ORC35200AG	ORC04200AG	ORC45200AG	ORC05200AG	ORC55200AG	ORC06200AG	ORC07200AG
ORC03250AG	ORC35250AG	ORC04250AG	ORC45250AG	ORC05250AG	ORC55250AG	ORC06250AG	ORC07250AG
ORC03300AG	ORC35300AG	ORC04300AG	ORC45300AG	ORC05300AG	ORC55300AG	ORC06300AG	ORC07300AG

ORC08020AG	ORC09020AG	ORC10020AG	ORC12020AG
ORC08030AG	ORC09030AG	ORC10030AG	ORC12030AG
ORC08040AG	ORC09040AG	ORC10040AG	ORC12040AG
ORC08060AG	ORC09060AG	ORC10060AG	ORC12060AG
ORC08080AG	ORC09080AG	ORC10080AG	ORC12080AG
ORC08100AG	ORC09100AG	ORC10100AG	ORC12100AG
ORC08120AG	ORC09120AG	ORC10120AG	ORC12120AG

ACOART ORCHID DRUG ELUTING BALLOON CATHETER 0.035"							
Usable Catheter Length: 130 cm							
ORC03020BG	ORC35020BG	ORC04020BG	ORC45020BG	ORC05020BG	ORC55020BG	ORC06020BG	ORC07020BG
ORC03030BG	ORC35030BG	ORC04030BG	ORC45030BG	ORC05030BG	ORC55030BG	ORC06030BG	ORC07030BG
ORC03040BG	ORC35040BG	ORC04040BG	ORC45040BG	ORC05040BG	ORC55040BG	ORC06040BG	ORC07040BG
ORC03060BG	ORC35060BG	ORC04060BG	ORC45060BG	ORC05060BG	ORC55060BG	ORC06060BG	ORC07060BG
ORC03080BG	ORC35080BG	ORC04080BG	ORC45080BG	ORC05080BG	ORC55080BG	ORC06080BG	ORC07080BG
ORC03100BG	ORC35100BG	ORC04100BG	ORC45100BG	ORC05100BG	ORC55100BG	ORC06100BG	ORC07100BG
ORC03120BG	ORC35120BG	ORC04120BG	ORC45120BG	ORC05120BG	ORC55120BG	ORC06120BG	ORC07120BG
ORC03150BG	ORC35150BG	ORC04150BG	ORC45150BG	ORC05150BG	ORC55150BG	ORC06150BG	ORC07150BG
ORC03200BG	ORC35200BG	ORC04200BG	ORC45200BG	ORC05200BG	ORC55200BG	ORC06200BG	ORC07200BG
ORC03250BG	ORC35250BG	ORC04250BG	ORC45250BG	ORC05250BG	ORC55250BG	ORC06250BG	ORC07250BG
ORC03300BG	ORC35300BG	ORC04300BG	ORC45300BG	ORC05300BG	ORC55300BG	ORC06300BG	ORC07300BG

ORC08020BG	ORC09020BG	ORC10020BG	ORC12020BG
ORC08030BG	ORC09030BG	ORC10030BG	ORC12030BG
ORC08040BG	ORC09040BG	ORC10040BG	ORC12040BG
ORC08060BG	ORC09060BG	ORC10060BG	ORC12060BG
ORC08080BG	ORC09080BG	ORC10080BG	ORC12080BG
ORC08100BG	ORC09100BG	ORC10100BG	ORC12100BG
ORC08120BG	ORC09120BG	ORC10120BG	ORC12120BG

ACOART ORCHID DRUG ELUTING BALLOON CATHETER 0.035"							
Usable Catheter Length: 150 cm							
ORC03020DG	ORC35020DG	ORC04020DG	ORC45020DG	ORC05020DG	ORC55020DG	ORC06020DG	ORC07020DG
ORC03030DG	ORC35030DG	ORC04030DG	ORC45030DG	ORC05030DG	ORC55030DG	ORC06030DG	ORC07030DG
ORC03040DG	ORC35040DG	ORC04040DG	ORC45040DG	ORC05040DG	ORC55040DG	ORC06040DG	ORC07040DG
ORC03060DG	ORC35060DG	ORC04060DG	ORC45060DG	ORC05060DG	ORC55060DG	ORC06060DG	ORC07060DG
ORC03080DG	ORC35080DG	ORC04080DG	ORC45080DG	ORC05080DG	ORC55080DG	ORC06080DG	ORC07080DG
ORC03100DG	ORC35100DG	ORC04100DG	ORC45100DG	ORC05100DG	ORC55100DG	ORC06100DG	ORC07100DG
ORC03120DG	ORC35120DG	ORC04120DG	ORC45120DG	ORC05120DG	ORC55120DG	ORC06120DG	ORC07120DG
ORC03150DG	ORC35150DG	ORC04150DG	ORC45150DG	ORC05150DG	ORC55150DG	ORC06150DG	ORC07150DG
ORC03200DG	ORC35200DG	ORC04200DG	ORC45200DG	ORC05200DG	ORC55200DG	ORC06200DG	ORC07200DG
ORC03250DG	ORC35250DG	ORC04250DG	ORC45250DG	ORC05250DG	ORC55250DG	ORC06250DG	ORC07250DG
ORC03300DG	ORC35300DG	ORC04300DG	ORC45300DG	ORC05300DG	ORC55300DG	ORC06300DG	ORC07300DG

ORC08020DG	ORC09020DG	ORC10020DG	ORC12020DG
ORC08030DG	ORC09030DG	ORC10030DG	ORC12030DG
ORC08040DG	ORC09040DG	ORC10040DG	ORC12040DG
ORC08060DG	ORC09060DG	ORC10060DG	ORC12060DG
ORC08080DG	ORC09080DG	ORC10080DG	ORC12080DG
ORC08100DG	ORC09100DG	ORC10100DG	ORC12100DG
ORC08120DG	ORC09120DG	ORC10120DG	ORC12120DG

ACOART TULIP DRUG ELUTING BALLOON CATHETER 0.018"							
Usable Catheter Length: 40 cm							
TUL20020EG	TUL25020EG	TUL30020EG	TUL35020EG	TUL40020EG	TUL45020EG	TUL50020EG	TUL55020EG
TUL20030EG	TUL25030EG	TUL30030EG	TUL35030EG	TUL40030EG	TUL45030EG	TUL50030EG	TUL55030EG
TUL20040EG	TUL25040EG	TUL30040EG	TUL35040EG	TUL40040EG	TUL45040EG	TUL50040EG	TUL55040EG
TUL20060EG	TUL25060EG	TUL30060EG	TUL35060EG	TUL40060EG	TUL45060EG	TUL50060EG	TUL55060EG
TUL20080EG	TUL25080EG	TUL30080EG	TUL35080EG	TUL40080EG	TUL45080EG	TUL50080EG	TUL55080EG
TUL20100EG	TUL25100EG	TUL30100EG	TUL35100EG	TUL40100EG	TUL45100EG	TUL50100EG	TUL55100EG
TUL20120EG	TUL25120EG	TUL30120EG	TUL35120EG	TUL40120EG	TUL45120EG	TUL50120EG	TUL55120EG
TUL20150EG	TUL25150EG	TUL30150EG	TUL35150EG	TUL40150EG	TUL45150EG	TUL50150EG	TUL55150EG
TUL20200EG	TUL25200EG	TUL30200EG	TUL35200EG	TUL40200EG	TUL45200EG	TUL50200EG	TUL55200EG
TUL20250EG	TUL25250EG	TUL30250EG	TUL35250EG	TUL40250EG	TUL45250EG	TUL50250EG	TUL55250EG
TUL20300EG	TUL25300EG	TUL30300EG	TUL35300EG	TUL40300EG	TUL45300EG	TUL50300EG	TUL55300EG

TUL60020EG	TUL70020EG	TUL80020EG	TUL90020EG	TUL10020EG	TUL12020EG
TUL60030EG	TUL70030EG	TUL80030EG	TUL90030EG	TUL10030EG	TUL12030EG
TUL60040EG	TUL70040EG	TUL80040EG	TUL90040EG	TUL10040EG	TUL12040EG
TUL60060EG	TUL70060EG	TUL80060EG	TUL90060EG	TUL10060EG	TUL12060EG
TUL60080EG	TUL70080EG	TUL80080EG	TUL90080EG	TUL10080EG	TUL12080EG
TUL60100EG	TUL70100EG	TUL80100EG	TUL90100EG	TUL10100EG	TUL12100EG
TUL60120EG	TUL70120EG	TUL80120EG	TUL90120EG	TUL10120EG	TUL12120EG
TUL60150EG	TUL70150EG				
TUL60200EG	TUL70200EG				
TUL60250EG	TUL70250EG				
TUL60300EG	TUL70300EG				

ACOART TULIP DRUG ELUTING BALLOON CATHETER 0.018"							
Usable Catheter Length: 90 cm							
TUL20020CG	TUL25020CG	TUL30020CG	TUL35020CG	TUL40020CG	TUL45020CG	TUL50020CG	TUL55020CG
TUL20030CG	TUL25030CG	TUL30030CG	TUL35030CG	TUL40030CG	TUL45030CG	TUL50030CG	TUL55030CG
TUL20040CG	TUL25040CG	TUL30040CG	TUL35040CG	TUL40040CG	TUL45040CG	TUL50040CG	TUL55040CG
TUL20060CG	TUL25060CG	TUL30060CG	TUL35060CG	TUL40060CG	TUL45060CG	TUL50060CG	TUL55060CG
TUL20080CG	TUL25080CG	TUL30080CG	TUL35080CG	TUL40080CG	TUL45080CG	TUL50080CG	TUL55080CG
TUL20100CG	TUL25100CG	TUL30100CG	TUL35100CG	TUL40100CG	TUL45100CG	TUL50100CG	TUL55100CG
TUL20120CG	TUL25120CG	TUL30120CG	TUL35120CG	TUL40120CG	TUL45120CG	TUL50120CG	TUL55120CG
TUL20150CG	TUL25150CG	TUL30150CG	TUL35150CG	TUL40150CG	TUL45150CG	TUL50150CG	TUL55150CG
TUL20200CG	TUL25200CG	TUL30200CG	TUL35200CG	TUL40200CG	TUL45200CG	TUL50200CG	TUL55200CG
TUL20250CG	TUL25250CG	TUL30250CG	TUL35250CG	TUL40250CG	TUL45250CG	TUL50250CG	TUL55250CG
TUL20300CG	TUL25300CG	TUL30300CG	TUL35300CG	TUL40300CG	TUL45300CG	TUL50300CG	TUL55300CG

TUL60020CG	TUL70020CG	TUL80020CG	TUL90020CG	TUL10020CG	TUL12020CG
TUL60030CG	TUL70030CG	TUL80030CG	TUL90030CG	TUL10030CG	TUL12030CG
TUL60040CG	TUL70040CG	TUL80040CG	TUL90040CG	TUL10040CG	TUL12040CG
TUL60060CG	TUL70060CG	TUL80060CG	TUL90060CG	TUL10060CG	TUL12060CG
TUL60080CG	TUL70080CG	TUL80080CG	TUL90080CG	TUL10080CG	TUL12080CG
TUL60100CG	TUL70100CG	TUL80100CG	TUL90100CG	TUL10100CG	TUL12100CG
TUL60120CG	TUL70120CG	TUL80120CG	TUL90120CG	TUL10120CG	TUL12120CG
TUL60150CG	TUL70150CG				
TUL60200CG	TUL70200CG				
TUL60250CG	TUL70250CG				
TUL60300CG	TUL70300CG				

ACOART TULIP DRUG ELUTING BALLOON CATHETER 0.018"							
Usable Catheter Length: 130 cm							
TUL20020BG	TUL25020BG	TUL30020BG	TUL35020BG	TUL40020BG	TUL45020BG	TUL50020BG	TUL55020BG
TUL20030BG	TUL25030BG	TUL30030BG	TUL35030BG	TUL40030BG	TUL45030BG	TUL50030BG	TUL55030BG
TUL20040BG	TUL25040BG	TUL30040BG	TUL35040BG	TUL40040BG	TUL45040BG	TUL50040BG	TUL55040BG
TUL20060BG	TUL25060BG	TUL30060BG	TUL35060BG	TUL40060BG	TUL45060BG	TUL50060BG	TUL55060BG
TUL20080BG	TUL25080BG	TUL30080BG	TUL35080BG	TUL40080BG	TUL45080BG	TUL50080BG	TUL55080BG
TUL20100BG	TUL25100BG	TUL30100BG	TUL35100BG	TUL40100BG	TUL45100BG	TUL50100BG	TUL55100BG
TUL20120BG	TUL25120BG	TUL30120BG	TUL35120BG	TUL40120BG	TUL45120BG	TUL50120BG	TUL55120BG
TUL20150BG	TUL25150BG	TUL30150BG	TUL35150BG	TUL40150BG	TUL45150BG	TUL50150BG	TUL55150BG
TUL20200BG	TUL25200BG	TUL30200BG	TUL35200BG	TUL40200BG	TUL45200BG	TUL50200BG	TUL55200BG
TUL20250BG	TUL25250BG	TUL30250BG	TUL35250BG	TUL40250BG	TUL45250BG	TUL50250BG	TUL55250BG
TUL20300BG	TUL25300BG	TUL30300BG	TUL35300BG	TUL40300BG	TUL45300BG	TUL50300BG	TUL55300BG

TUL60020BG	TUL70020BG	TUL80020BG	TUL90020BG	TUL10020BG	TUL12020BG
TUL60030BG	TUL70030BG	TUL80030BG	TUL90030BG	TUL10030BG	TUL12030BG
TUL60040BG	TUL70040BG	TUL80040BG	TUL90040BG	TUL10040BG	TUL12040BG
TUL60060BG	TUL70060BG	TUL80060BG	TUL90060BG	TUL10060BG	TUL12060BG
TUL60080BG	TUL70080BG	TUL80080BG	TUL90080BG	TUL10080BG	TUL12080BG
TUL60100BG	TUL70100BG	TUL80100BG	TUL90100BG	TUL10100BG	TUL12100BG
TUL60120BG	TUL70120BG	TUL80120BG	TUL90120BG	TUL10120BG	TUL12120BG
TUL60150BG	TUL70150BG				
TUL60200BG	TUL70200BG				
TUL60250BG	TUL70250BG				
TUL60300BG	TUL70300BG				

ACOART TULIP DRUG ELUTING BALLOON CATHETER 0.018"							
Usable Catheter Length: 200 cm							
TUL20020FG	TUL25020FG	TUL30020FG	TUL35020FG	TUL40020FG	TUL45020FG	TUL50020FG	TUL55020FG
TUL20030FG	TUL25030FG	TUL30030FG	TUL35030FG	TUL40030FG	TUL45030FG	TUL50030FG	TUL55030FG
TUL20040FG	TUL25040FG	TUL30040FG	TUL35040FG	TUL40040FG	TUL45040FG	TUL50040FG	TUL55040FG
TUL20060FG	TUL25060FG	TUL30060FG	TUL35060FG	TUL40060FG	TUL45060FG	TUL50060FG	TUL55060FG
TUL20080FG	TUL25080FG	TUL30080FG	TUL35080FG	TUL40080FG	TUL45080FG	TUL50080FG	TUL55080FG
TUL20100FG	TUL25100FG	TUL30100FG	TUL35100FG	TUL40100FG	TUL45100FG	TUL50100FG	TUL55100FG
TUL20120FG	TUL25120FG	TUL30120FG	TUL35120FG	TUL40120FG	TUL45120FG	TUL50120FG	TUL55120FG
TUL20150FG	TUL25150FG	TUL30150FG	TUL35150FG	TUL40150FG	TUL45150FG	TUL50150FG	TUL55150FG
TUL20200FG	TUL25200FG	TUL30200FG	TUL35200FG	TUL40200FG	TUL45200FG	TUL50200FG	TUL55200FG
TUL20250FG	TUL25250FG	TUL30250FG	TUL35250FG	TUL40250FG	TUL45250FG	TUL50250FG	TUL55250FG
TUL20300FG	TUL25300FG	TUL30300FG	TUL35300FG	TUL40300FG	TUL45300FG	TUL50300FG	TUL55300FG

TUL60020FG	TUL70020FG	TUL80020FG	TUL90020FG	TUL10020FG	TUL12020FG
TUL60030FG	TUL70030FG	TUL80030FG	TUL90030FG	TUL10030FG	TUL12030FG
TUL60040FG	TUL70040FG	TUL80040FG	TUL90040FG	TUL10040FG	TUL12040FG
TUL60060FG	TUL70060FG	TUL80060FG	TUL90060FG	TUL10060FG	TUL12060FG
TUL60080FG	TUL70080FG	TUL80080FG	TUL90080FG	TUL10080FG	TUL12080FG
TUL60100FG	TUL70100FG	TUL80100FG	TUL90100FG	TUL10100FG	TUL12100FG
TUL60120FG	TUL70120FG	TUL80120FG	TUL90120FG	TUL10120FG	TUL12120FG
TUL60150FG	TUL70150FG				
TUL60200FG	TUL70200FG				
TUL60250FG	TUL70250FG				
TUL60300FG	TUL70300FG				

ACOART LITOS DRUG ELUTING BALLOON CATHETER 0.014"				
Usable Catheter Length: 90 cm				
LTS20020CG	LTS25020CG	LTS30020CG	LTS35020CG	LTS40020CG
LTS20030CG	LTS25030CG	LTS30030CG	LTS35030CG	LTS40030CG
LTS20040CG	LTS25040CG	LTS30040CG	LTS35040CG	LTS40040CG
LTS20060CG	LTS25060CG	LTS30060CG	LTS35060CG	LTS40060CG
LTS20080CG	LTS25080CG	LTS30080CG	LTS35080CG	LTS40080CG
LTS20100CG	LTS25100CG	LTS30100CG	LTS35100CG	LTS40100CG
LTS20120CG	LTS25120CG	LTS30120CG	LTS35120CG	LTS40120CG
LTS20150CG	LTS25150CG	LTS30150CG	LTS35150CG	LTS40150CG
LTS20200CG	LTS25200CG	LTS30200CG	LTS35200CG	LTS40200CG
LTS20250CG	LTS25250CG	LTS30250CG	LTS35250CG	LTS40250CG
LTS20300CG	LTS25300CG	LTS30300CG	LTS35300CG	LTS40300CG

ACOART LITOS DRUG ELUTING BALLOON CATHETER 0.014"				
Usable Catheter Length: 150 cm				
LTS20020DG	LTS25020DG	LTS30020DG	LTS35020DG	LTS40020DG
LTS20030DG	LTS25030DG	LTS30030DG	LTS35030DG	LTS40030DG
LTS20040DG	LTS25040DG	LTS30040DG	LTS35040DG	LTS40040DG
LTS20060DG	LTS25060DG	LTS30060DG	LTS35060DG	LTS40060DG
LTS20080DG	LTS25080DG	LTS30080DG	LTS35080DG	LTS40080DG
LTS20100DG	LTS25100DG	LTS30100DG	LTS35100DG	LTS40100DG
LTS20120DG	LTS25120DG	LTS30120DG	LTS35120DG	LTS40120DG
LTS20150DG	LTS25150DG	LTS30150DG	LTS35150DG	LTS40150DG
LTS20200DG	LTS25200DG	LTS30200DG	LTS35200DG	LTS40200DG
LTS20250DG	LTS25250DG	LTS30250DG	LTS35250DG	LTS40250DG
LTS20300DG	LTS25300DG	LTS30300DG	LTS35300DG	LTS40300DG

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