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CAREFULLY READ ALL INSTRUCTIONS PRIOT TO USE OBSERVEAIL L WARNINGS AND PRECAUTINONS NOTED THROUGHOUT THESE INSTRUCTINS.FAILURE TO DO SO MAY RESULT IN COMPLIATIONS

1.0 Device Description
The Mecross CTO (Rx type) device is a coronary dilatation catheter designed for easy guidewireexchange . The catheter working length is 140 cm . Balloon diameters range from 1.0 mm to 4.0mm . The balloon material is made of semi-compliant Pebax material for diameter 1.0 mm to 4.0mm with a rated burst pressure of 16 atmospheres . The proximal shaft of the catheter is composed of a female Luer connector bonded to a PTFE coated stainless steel tube with a wire .The proximal shaft joins with a smooth transition to a distal shaft composed of an outer tube anda triextrusion inner tube with a balloon laser welded to both tubes at the distal tip . Two radiopaque platinum / iridium marker bands are located within the balloon segment with the exceptionof balloon diameters less than 2.0 mm which incorporate a centrally positioned single markerband . The inner tube accepts a standard 0.014 inch PTCA guide wire . The guidewire enters thecatheters tip and advances coaxially out of the distal Rx port , thereby allowing both coaxialguidance and rapid exchange of catheter with a single standard length guide wire . Two marked sections of 5mm length each located on the proximal shaft indicate catheter position relative tothe tip of either a brachial or femoral guiding catheter The design of this dilatation catheter doesnot incorporate a lumen for distal dye injections or distal pressure measurements

2.0 How supplied

Contents	One (1) Balloon Dilatation Catheter
	One (1) Flushing Needle
	One (1) Re-wrap tool
Sterile	Sterilized with ethyle e oxide gas . Non-pyrogenic
Storage	Store in a dry , dark , normal temperature

3.0 Intended Purpose
■ The balloon dilatation catheter is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.
■ The MECROSS CTO (balloon models 1.0 mm to 1.5 mm) is intended for treatment in complex lesion subsets such as chronic total occlusions.

4.0 Patient Target Group
Patients who need coronary angioplasty.

Special population
The safety and effectiveness of MECROSS CTO in pediatric patients and pregnancy have not been established.

5.0 Indication
The balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (including chronic total occlusions) for the purpose of improving myocardial perfusion.

6.0 Contraindications
The catheter is contraindicated for use in :
■ Unprotected left main coronary artery
■ Coronary artery spasm in the absence of significant stenosis

7.0 Clinical Benefit
Improvement of myocardial ischemia can be expected by dilating stenotic lesion.

8.0 Lifetime
These coronary dilatation catheter are designed to be used on individual during a single procedure,with a device lifetime normally intended for continuous use for less than 60 minutes.

9.0 Summary of safety and clinical performance
The Summary of Safety and Clinical Performance (SSCP) for this device can be found at https://ec.europa.eu/tools/eudamed using the Basic UDI-DI: 697371064MC01H5.

10.Warnings
■ For single patient , single procedure use only . Do NOT resterilize and / or reuse , as this canpotentially result in compromised device performance and increase risk of inappropriateresterilization and cross contamination .
■ Do NOT use the catheter if its package has been opened of damaged
■ To reduce the potential for vessel damage in the inflated diameter of the balloon shouldapproximate the diameter of the vessel just proximal and distal to the stenosis
■ PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgeryrequires careful consideration , including possible hemodynamic support during PTCA , astreatment of this patient population carries special risk
■ When the catheter is exposed to the vascular system , it should be man-ipulated while fluoroscopic observation . Do NOT advance or retract the catheter unless theballoon is fully deflated under vacuum as this can potentially result in damage to the vessewall . If resistance is met during manipulation , determine the cause of the resistance beforeproceeding .
■ Balloon pressure should not exceed the rated burst pressure indicated on the package label foreach balloon . The rated burst pressure is based on the results of in vitro testing . Use of apressure monitoring device is recommended to prevent over pressurization
■ PTCA should only be performed at hospitals where emergency coronary artery bypass graftsurgery can be quickly performed in the event of a potentially injurious or life-threateningcomplication
■ Use only the recommended balloon inflation medium . To prevent the possibility of an airembolus , never use air or any gaseous medium to inflate the balloon.
■ Use the catheter prior to the " Use by " date (Expiration Date) specified on the package.
■ This device contains Cobalt (CAS No. 7440-48-4, EC No. 231-158-0), classified as CMR* 1B, in a concentration above 0.1% weight per weight. Current scientific evidence supports that medical devices manufactured from alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.
■ ***CMR: carcinogenic, mutagenic and toxic to reproduction (CLP regulation EU 1272/2008)**

11.0 Precautions
■ Prior to angioplasty , the catheter should be examined to verify functionality and ensure that itssize and shape are suitable for the procedure for which it is to be used .
■ The catheter system should be used only by physicians trained in the performance ofpercutaneous transluminal coronary angioplasty .
■ The appropriate anticoagulant and coronary vasodilator should be administered to the patient asneeded during the surgical procedure . After the operation , the physician should decide tocontinue the anticoagulant treatment for a period of time .
■ When using two guide wires , care should be taken when introducing , torqueing and removingone or both guide wires to avoid entanglement . It is recommended that one guide wire becompletely withdrawn for the patient before removing any additional equipment The used PTCA catheter disposal shall follow individual medical institution / hospitalInes
■ Do not reinsert the PTCA catheter into the hoop dispenser after normal use
■ Do not use oil-based contrast agents , organic solvents or alcohol to prevent catheter leakage ,damage or lubricant loss .
■ The design and construction of the catheter does not provide the user with remote pressuremonitoring capabilities

12.0 Adverse Events
Possible adverse effects include , but are not limited to the following
■ Death
■ Acute myocardial infarction

■ Total occlusion of the coronary artery or bypass graft
■ Coronary vessel dissection , perforation , rupture or injury
■ Restenosis of the dilated vessel
■ Hemorrhage or hematomaUnstable angina
■ Arhythmias , including ventricular fibrillation
■ Drug reactions , allergic reaction to contrast medium
■ Hypo / hypertension
■ Infection
■ Coronary artery spasm
■ Arteriovenous fistula
■ Embolism

13.0 Reporting of serious adverse events
The user and/or patient should report any serious incident that has occurred in relation to this device to the manufacture and the competent authority of the European Member State in which the user and/or patient is established.

14.0 Materials to be used in combination with a balloon catheter include.
■ Arterial Sheath
■ Femoral or brachial guiding catheter in the appropriate size and configurationhemostatic valve(s)
■ Contrast medium diluted 1: 1 with normal saline
■ Sterile heparinized normal saline
■ 20 cc Luer-lock syringe
■ Inflation device
■ Guidewire diameter not to exceed 0.014"see product label
■ Guidewire introducer
■ Guidewire torque device
Note : The above materials are not included with this product

15.0 Preparation for userior to use
prior to use, examine all equipment carefully for defects . Examine the dilatation catheter forbends , kinks , or other damage . Do not use any defective equipment Prepare equipment to belsed following manufacturers instructions or standard procedure Complete the followingsteps to prepare the PTCA catheter for use
1. Remove the protective mandrel from the catheter tip
2. Slide the protective sheath off the balloon
3. Flush the guidewire lumen of the PTCA catheter .
4. Attach the syringe with heparinized normal saline to the flushing needle packaged with thecatheter ; gently insert the needle into the tip of the catheter and flush the guide wire lumenwith heparinized normal saline until fluid is seen exiting the guidewire port
5. Prepare an inflation device with the recommended contrast medium according to themanufacturer's instructions
6. Evacuate air from the balloon segment using the following procedure .air from the balloon segment using the following procedure .
7. Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommendedcontrast medium
8. After attaching the syringe or inflation device to the balloon inflation lumen , orient thedilatation catheter with the distal tip and the balloon pointing in a downward vertical position .
9. Apply negative pressure and aspirate for 15 seconds . Slowly release the pressure to neutr allowing contrast to fill the shaft of the dilatation catheter
10. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter
11. Remove all air from the syringe or inflation device barrel Reconnect the syringe or inflationdevice to the inflation port of the dilatation catheter . Maintain negative pressure on the balloonuntil air no longer returns to the device
12. Slowly release the device pressure to neutral
13. Disconnect the 20 cc syringe (if used) and connect the inflation device to inflation port of thdilatation catheter without introducing air into the system .
Caution : All air must be removed from the balloon and displaced with contrastprior to inserting into the body . Otherwise complications may occur

16.0 Instruction for Use.
1.Insert a guidewire through the hemostatic valve that is on the guiding catheter , following themanufacturer's instructions
2. Advance the guidewire carefully into and through the guiding catheter . Withdraw theguidewire introducer , if used .
3. Attach a torque device to the guidewire , if desired . Under fluoroscopy , proceed with acceptedPTCA techniques to advance the guidewire to and across the lesion .
4. Backload the distal tip of the dilatation catheter onto the guidewire ensuring that guidewireexits the catheter at approximately 25 cm proximal to the balloon .
5. Advance the dilatation catheter over the guidewire until it approaches the hemostatic valve .
6. Open the hemostatic valve , Insert the dilatation catheter while maintaining guidewire positionand tighten the hemostatic valve . To facilitate insertion , the balloon must be fully deflated tonegative pressure .
7. Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibitingmovement of the dilatation catheter . This will allow continuous recording of proxin
Note : It is important that the hemos tatic valve be closed tightly enough toprevent blood leakage around the dilata-tion catheter shaft , yet not sotight that it restricts theflow of contrast into and out of the balloon orestricts guidewire movement
8. Advance the dilatation catheter until the appropriate proximal marker aligns with the hemostatic valve hub . This indicates that the dilatation catheter tip has reached the guidingcatheter tip .
9. Advance the dilatation catheter over the guidewire and into the stenosis . Continue underfluoroscopy and use the radiopaque marker band (s) to position the usable (dilating) section ofthe balloon within the stenosis
10. Continue the procedure using accepted coronary angioplasty technique to dilate the stenosis
Note : Do not exceed the rated burst pressure printed on the package label Maintain negative pressure on the balloon between inflations .
WARNING : Due to the hydrophilic coating , the balloon may slip away fromthe target lesion during compression . Care should be taken under higresolution fluoroscopy so that the balloon does not change position on thetarget lesion .
11 . Withdraw the deflated PTCA catheter and guidewire into the guiding catheter . Using atechmique of choice , remove the PTCA catheter , guidewire and guiding catheter from thevasculature . Dispose of the PTCA catheter , guidewire , mmd guiding catheter appropriately .
12 . If the same balloon dilation catheter is reinserted , the guide wire lumen of the balloon dilationcatheter isflushed using the imigation needle as described in the Preparing for Use section .Before reinsertion , the balloon dilation catheter should be wiped clean with gauze soaked insterile salme . The balloon can be refolded (afler expansion) using the refolding tool providedin the package (attached to the upper right corner of the compliant card) . When placing orremoving the refolding tool , use the mandrel to support the guidewire lumen and be carefunot to damage the balloon . As described in the section on refolding tools.

17.0 Exchange procedure technique
1. The PTCA catheter has been specifically designed for rapid , single operator balloon exchanges .To perform a dilatation catheter exchangel - Loosen the hemostatic valve.
2. Hold the guidewire and hemostatic valve in one hand , while grasping the balloon shaft in theother hand
3. Maintain guidewire position in the coronary artery by holding the wire stationary , and beginpulling the dilatation catheter out of the guiding catheter while monitoring the wire positionunder fluoroscopy .
4. Withdraw the deflated dilatation catheter until the guidewire lumen is reached . Carefully puback the flexible , distal portion of the dilatation catheter out of the rotating hemostatic valvewhile maintaining the guidewire's position across the lesion .
5. Slide the distal tip of the dilatation catheter out of the hemostatic valve , and tighten valve ontothe guidewire to hold it securely in place .
6. Prepare the next dilatation catheter to be used , as previously described in the Preparation ForUse secti or
7 . Back load another dilatation catheter onto the guidewire as previously described under theInstructions For Use Section , Step 4 , and continue the procedure accordingly .

18.0 Rewrap Tool
This is an accessory component that allows the balloon to be rewrapped if required

rewrapped if required
1. Deflate the balloon by applying negative pressure to the inflation device and maintain undervacuum
2. Visually inspect the balloon to confirm that it is fully deflated .
3. Removed the Rewrap Tool from Compliance Card .
4. Load the non-flared end of the Rewrap Tool onto the styl
5.Carefully load the stylet back through the distal tip of the catheter and past the proximal end ofthe balloon
6. While holding the catheter just proximal to the balloon , push the Rewrap device over theballoon in a gentle twisting motion until the entire balloon is covered
7. Gently remove the rewrap device / stylet assembly .
8. Inspect the balloon for any potential damag Discard the balloon catheter if there is any visualdamage present on the balloon

19.0 Others

19.1 Packaging requirements

The PTCA balloon dilatation catheter is packaged in sterile packaging.(Oxidized with ethylene oxide),for single use only .

19.2 Reserve & x transportation

The product should be stored in a dry , cool place , and the storage environment is wellventilated and free of corrosive gases . The transportation process is strictly protected fromheavy pressure ,wetness exposure , etc , or transportation requirements as spocified in theorder contract .

19.3 Sterile

This product is sterilized by ethylene oxide gas and is not pyrophoric . If the package isdamaged do not use the PTCA balloon to dilate the catheter or attempt to sterilize it . Do notuse expired products .

19.4 Date of manufacture

See packing

19.5 Validity period

Sterilization is valid for three years under the specified storage conditions

20.0 Reference

Physicians should consult recent literature o current medical practice on balloon dilatation ,such a published by American College of Cardiology / American Heart Association

21.0 Disclaimer of Warranty

Descriptions or specifications in Medoo Medical printed matter , including this publication , aremeant solely to generally describe the product at the time of manufacture and do not constituteany express warranties . Medoo Medical will not be responsible for any direct , incidentalonsequential damages resulting from the misuse of the produc