MOZEC™ SEB

Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter

Instructions for use - English

1. Device Name:

The device brand name is Mozec™ SEB , the generic name is Sirolimus Eluting Rx (Rapid Exchange) PTCA Balloon Dilatation Catheter.

2. Device Description:

Mozec™ SEB Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter is designed for delivering drug while dilating stenotic atherosclerotic lesions in coronary arteries and post-delivery expansion of balloon expandable stents.

Mozec™ SEB Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter (Mozec SEB) consists of a drug (Sirolimus) coated balloon (dilatation element) near the distal tip, a dual lumen distal shaft and single lumen proximal shaft. The balloon has two radiopaque marker bands, one at each end of the balloon, which represents the approximate balloon working length at nominal pressure for correctly positioning the balloon under fluoroscopy.

The catheter has a soft tip. The two co-axial lumens permit movement of guide wire and balloon inflation. The two markers on the proximal shaft approximately indicate the exit of the balloon catheter tip from the guiding catheter (Brachial 90 cm, Femoral 100 cm). The proximal portion of the shaft has PTFE coating.

The balloon coating consists of a blend of biocompatible Solid-Lipid Nano (SLN) formulation of anti-proliferative drug (Sirolimus) and excipients.

The compliance chart on the inner and outer label indicates how the balloon diameter increases with increasing pressure. The compliance data is based on in-vitro testing of balloons at 37°C temperature.

2.1. Device Components Description:

Table - 1 Device Components Description

Parameters	Mozec™ SEB Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter
Available Balloon Lengths (mm)	9, 12*, 14, 15*, 17, 20, 25, 30. * For 2.00mm balloon diameter only.
Available Balloon Diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50
Delivery system usable length	142 cm
Balloon	Drug coated semi compliant nylon balloon. Its length and location is indicated by double swaged radiopaque markers.
Shaft Outer Diameters	Proximal 1.98 F (For all balloon diameters) Distal 2.40 F(For 2.00 mm diameters) Distal 2.70 F(For 2.25 to 4.50 mm diameters)
Balloon Inflation Pressure	Nominal Pressure: 7 atm Rated Burst Pressure: 16 atm for balloon diameters 2.0 to 4.0 mm. 14 atm for balloon diameter 4.5 mm
Minimum Guide Cather Inner Diameter	Min Guide Catheter I.D 0.056" / 1.42 mm Guide Catheter Compatibility 5F
Max. Guide Wire Outer Diameter	0.014" / 0.36 mm diameter
Product code format MOZSxxxyy	MOZS = Mozec™ SEB - Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter xxx = nominal balloon diameter (mm) yy = nominal balloon length (mm) For example MOZS30017 xxx = 300 = Diameter 3.00 mm yy = 17 = Length 17 mm
Coating	Sirolimus loaded SLN Coating

2.1.1 Compliance Chart:

Table - 2: Mozec™ SEB Compliance Chart

Pressure (atm)	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.50 mm	4.00 mm	4.50 mm
4	1.90	2.11	2.37	2.59	2.85	3.36	3.88	4.30
5	1.95	2.15	2.43	2.64	2.91	3.41	3.94	4.35
6	1.98	2.19	2.46	2.69	2.96	3.46	3.98	4.42
7	2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50
8	2.04	2.29	2.53	2.77	3.03	3.53	4.05	4.54
10	2.08	2.35	2.58	2.82	3.08	3.59	4.11	4.60
12	2.12	2.39	2.63	2.87	3.12	3.63	4.15	4.66
14	2.16	2.41	2.67	2.91	3.16	3.67	4.20	4.72
16	2.20	2.43	2.71	2.95	3.20	3.72	4.25	

Nominal Dilatation Pressure: 7 atm for all diameters.
Grey Background: Nominal pressure, **Black Background:** RBP (Rated Burst Pressure)

2.2. Drug Component Description:

2.2.1 Coating:

The coating on the balloon consists of a blend of the drug Sirolimus (the active component) formulated in solid lipid nano formulation and excipients (the inactive component).

2.2.2 Sirolimus:

Sirolimus is also known as Rapamycin.

Sirolimus is a macrocyclic lactone produced by *Streptomyces hygroscopicus.*

The chemical name of Sirolimus (also known as rapamycin) is

(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-

9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-Hexadecahydro-9,27-dihydroxy -3-[(1R)-2-[(1S,3R,4R)-4-hydroxy-3-ethoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclohentriacontine1,5,11,28,29 (4H,6H,31H)-pentone. Its molecular formula is $C_{51}H_{79}NO_{13}$ and is molecular weight is 914.2.

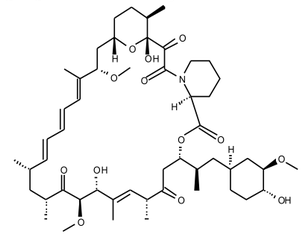


Fig.1 Sirolimus Drug Chemical Structure

Sirolimus is a white to off-white powder and is insoluble in water, but freely soluble in benzyl alcohol, chloroform, acetone, and acetonitrile and has a melting temperature of approximately 183-185°C. Sirolimus belongs to a class of therapeutic agents known as macrocyclic lactones or macrolides. It's a cytostatic drug and an immunosuppressant. It inhibits cell motility by suppression of m-TOR mediated 56K1 and 4E-BP1 pathways. It inhibits T-lymphocyte activation and proliferation occurring in response to antigen and cytokine. It also inhibits antibody production. It demonstrates antiproliferative activities.

The drug content on Mozec™ SEB - Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter is 3.0 $\mu g/mm^2$ of balloon outer surface area.

2.2.3 Excipients:

The inactive ingredient of the coating consists of :

1. Hydrogenated Castor Oil which acts as a Drug Reservoir.
2. Polyvinylpyrrolidone (PVP).
3. Additives.

3. How Supplied:

Sterile: This device is sterilized with Ethylene oxide (ETO) and is non-pyrogenic. It is intended for single patient use during single procedure only. Do not resterilize. Do not use if the package is opened or damaged.

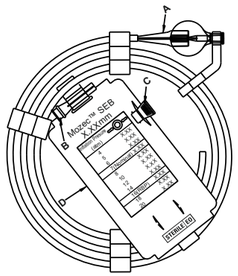
Contents: One (1) Mozec™ SEB Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter housed in a protective circular hoop dispenser,

One (1) Instructions for use, One (1) Flushing needle,

One (1) Looper clip, One (1) Compliance chart.

Storage: Store between 15-25°C (59-77°F) temperature in a dry, dark, cool place. Protect from light.

The figure below shows the placement of the contents in the package.



Note:
A - Mozec™ SEB - in Hoop Dispenser
B - Flushing Needle
C - Looper Clip
D - Compliance chart

4. Indications:

Mozec™ SEB Sirolimus Eluting Rx PTCA Balloon Dilatation Catheter is indicated for the coronary native arteries. It is indicated for the dilatation of stenotic portions also including total occlusions, AMI patients and it can be used also for the post dilatation of balloon expandable stents.

5. Contraindications:

The Mozec™ SEB is contraindicated in the following patient types:

- Patients with hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticlopidine, bivalidurin, prasugrel, ticagrelor and drug such as Sirolimus (Rapamycin) or similar drugs or any analogue or derivative, hydrogenated castor oil, PVP or any contrast media.
- Patients in whom anti-platelet and/or anti coagulant therapy are contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Transplant patients.
- Patients with calcified lesion requiring other type of treatment such as Rotational Atherectomy.
- Unprotected left main coronary artery lesions
- Coronary artery spasm in the absence of a significant stenosis.
- Patients whose diseased segment cannot be pre-dilated or prepared before drug coated balloon treatment.

6. Warnings:

- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Reuse, reprocessing or re-sterilization may also 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.
- Mozec™ SEB should only be used at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use of Mozec™ SEB in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including potential haemodynamic support during the procedure, as treatment of this patient population carries special risk.
- Use the product before the "Use By" date specified on the product label.
- Guiding catheters used must have lumen sizes that are suitable to accommodate the introduction of Mozec™ SEB.
- Do not use if the inner package is opened or damaged. Carefully remove the Mozec™ SEB from the pouch to prevent damage and premature removal of the balloon cover.
- Use only the 50% solution of contrast medium in sterile heparinised saline. Do not use air/any other gaseous media/oil based inflation media/alcohol/organic solvents to inflate the catheter as this may cause uneven expansion/catheter leakage/loss of lubrication.
- Do not expose the device to water or organic solvents e.g. alcohol.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract catheter unless the balloon is fully deflated under vacuum. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the Rated Burst Pressure (see Compliance Chart). Use of a pressure monitoring device is recommended to prevent over pressurization.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- Judicious patient selection is necessary during use of this device since it carries the associated risks of subacute thrombosis, vascular complications and/or bleeding events.

7. Precautions:

7.1. General Precautions:

- Prior to use, examine the Mozec™ SEB to verify functionality. Ensure that its size is suitable for the specific procedure for which it is to be used and that it is free of any kind of kinks or physical damage.
- Only the physicians trained in the performance of PTCA should use the catheter system.
- Appropriate anticoagulant/antiplatelet therapy should be used during the procedure.
- After the procedure, anticoagulant therapy should be continued as recommended by the physician.
- Prior to re-insertion or withdrawal of the catheter, wipe the guide wire with saline-soaked gauze to remove blood or other residues.
- Never inflate Mozec™ SEB prior to reaching the target lesion.
- Mozec™ SEB should be advanced to the target site and inflated as fast as possible to appropriate pressure to ensure full wall apposition.

7.2. Balloon Handling Precautions:

- Drug coated balloons are used to deliver drug in arterial segment with short inflation times. It is required to pre-dilate and prepare the lesion with a non-drug eluting balloon before the product usage.
- Special care must be taken while handling the device, especially during removal from the packaging, to prevent damage or disruption of the coating on balloon.B
- alloon manipulation, trying to refold may damage the coating, cause contamination or fragmentation of coating on the balloon.

7.2.1 Balloon Removal Precautions:

- Should any unusual resistant be felt at any time during either lesion access or removal of balloon catheter, the entire system must be removed as a single unit.
- While removing the system as a single unit, advance the guide wire into the coronary anatomy as far as distally possible. Tighten the rotating hemostasis valve to secure the Mozec™ SEB balloon with the guiding catheter; then remove the balloon catheter system and guide catheter as a single unit.

7.2.2 Drug Interaction:

- Consideration should be given to the potential drug interaction while deciding treatment with Mozec™ SEB for a patient who is taking a drug that could interact with Sirolimus. The effect of drug interactions on safety and effectiveness of Mozec™ SEB has not been determined.
- While no specific clinical data are available, drugs like Tacrolimus that act through the same binding protein (FKBP) may interfere with the efficacy of Sirolimus.
- Drug interaction studies have not been performed. Sirolimus is metabolized by CYP3A4. Strong inhibitors of CYP3A4 (e.g. ketoconazole) might cause increased Sirolimus exposure to levels associated with systemic effects, especially if treatment with multiple Mozec™ SEB is performed. Systemic exposure of Sirolimus should also be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

8. Adverse Effects:

Potential adverse events, which may be associated with the use of a catheter, include but are not limited to:

- Acute myocardial infarction.
- Allergic reactions to anti-coagulant and /or antithrombotic therapy/ contrast medium.
- Arrhythmia, including ventricular fibrillation (VF).
- Arteriovenous fistula.
- Coronary embolism.
- Coronary artery spasm.
- Coronary vessel dissection/injury/perforation/rupture.
- Death.
- Emergency or non-emergent Coronary Artery Bypass Graft Surgery.
- Hematoma.
- Hemorrhage, requiring transfusion.
- Hypotension / Hypertension.
- Infection and / or pain at the access site.
- Restenosis of treated segment.
- Thrombosis
- Total occlusion of coronary artery/bypass graft.
- Unstable angina pectoris.
- Stroke, air embolism and embolization or fragmentation of thrombotic or atherosclerotic material.
- Potential adverse events, not captured above, that may be related to Sirolimus following oral administration:
- Abnormal liver function tests
- Anemia
- Arthralgias
- Diarrhea
- Hypercholesterolemia
- Hypersensitivity, including anaphylactic/anaphylactoid type reactions
- Hypertriglyceridemia
- Hypokalemia
- Infections
- Interstitial lung disease
- Leukopenia
- Lymphoma and other malignancies
- Thrombocytopenia
- There may be other potential adverse events that are unforeseen at this time.

9. Operator's Manual:

- The following instructions provide guidance but do not obviate the necessity of training in the use of the device.
- The Mozec™ SEB procedure should be carried out according to standard PTCA guidelines.
- Read Instructions for Use.

9.1. Preparation:

a. Open product box to remove the inner Tyvek pouch containing a hoop dispenser with sterile Mozec™ SEB. Remove carefully to avoid damage.

Note: Do not use if the package is open or damaged.

b. Remove protective sheath and stylet from the tip carefully.

c. Prior to using Mozec™ SEB, carefully inspect for bends, kinks, and other damages. Do not use if any such damage is noticed.

Caution: Never try to straighten a kinked hypotube. This may result in breakage of the shaft.

d. Insert the flushing needle into the distal tip of the catheter. Flush the guide wire lumen of the Catheter with sterile heparinised normal saline solution by gently applying pressure on the syringe for at least 10 seconds. The heparinised normal saline should exit from the guide wire port. Remove the syringe after flushing.

e. Attach a stopcock/manifold to the Catheter's inflation hub.

f. Attach an appropriate size of syringe filled with a minimum of 3cc of 50% solution of contrast medium in sterile heparinised saline to the stopcock.

g. Open the stopcock and induce negative pressure, pulling the syringe plunger back as far as possible without dislodging it from the syringe barrel. Aspirate for 15 seconds till the air is fully evacuated.

h. Gently release the negative pressure to fill the Catheter lumen with the solution.

i. Close the stopcock, remove the syringe and purge the air.

j. Repeat steps (g) through (j), if necessary, till there are no air bubbles left.

k. Fill an Angioplasty Inflation Device with a minimum of 3cc of a 50% solution of contrast medium in sterile heparinised saline and attach it to the purged Catheter.

Note: Purge the Angioplasty Inflation Device with air prior to connecting to the Catheter.

l. Induce negative pressure and close the stopcock. Purge any air from the Angioplasty Inflation Device through the stopcock. Leave the Catheter under negative pressure until it is ready to be used.

9.2. Assembly and Insertion Procedure for Mozec™ SEB:

a. Attach a haemostatic valve connector to the proximal luer of the guide catheter already positioned within the vasculature.

b. Insert the guide wire carefully through the haemostatic valve connector. While observing under fluoroscopy, cross the lesion with the guide wire according to the accepted PTCA technique.

c. Gradually tighten the haemostatic valve to avoid back flow of blood.

d. Pre-dilate the lesion with a PTCA balloon catheter. Limit the longitudinal length of pre-dilatation by the PTCA balloon to avoidcreating a region of vessel injury that is outside the boundaries of the Mozec™ SEB drug coated balloon.

e. Backload the distal end of the guide wire into the tip of the Balloon Catheter. The guide wire will exit through the guide wire exit port.

Note: When back loading the Catheter, provide adequate support to all shaft segments. Do not try to straighten a kinked catheter.

f. Open the valve to facilitate easy movement of the balloon catheter over the guide wire, yet preventing backflow of blood.

g. Advance the catheter until appropriate shaft markers correspond to the haemostatic valve hub. This indicates that the tip of the balloon catheter has reached the distal end of the guiding Catheter.

Warning: If a Tuohy-Borst type adjustable haemostatic valve is used, avoid over tightening since this may restrict the flow of contrast medium in and out of the inflation lumen, there by slowing inflation/deflation.

Caution: To avoid shaft movement restrictions, adjust haemostatic valve when advancing/withdrawing catheter, allowing for changes in the shaft diameter.

Caution: During the advancing the catheter, ensure that negative pressure is maintained in the Inflation Device to keep the balloon fully deflated.

Caution: Do not advance or withdraw the PTCA catheter within the coronary vasculature unless it is preceded by a guide wire.

Caution: Care should be taken when inserting the catheter into the haemostatic valve in order to avoid kinking.

h. Determine the correct position of the balloon catheter under fluoroscopy with the help of radiopaque markers.

i. If resistance is encountered during advancing, do not use force to advance the catheter. Determine the cause of resistance and take corrective action.

9.3. Inflation:

a. Dilate the stenotic lesion following standard PTCA technique.

Caution: Use of oversized balloon may cause dissection. Do not exceed the Rated Burst Pressure mentioned on the product labels.

b. Under fluoroscopic visualization, inflate the balloon to at least the nominal pressure but do not exceed the labelled rated burst pressure of 16 bar. Refer to balloon compliance chart for further details on diameters and sizes.

c. Inflation and dilatation of balloon releases drug in a controlled manner. Majority of the drug is released within the first 30 seconds of balloon inflation. The duration of the inflation should be between 30 seconds (in a single inflation) to 60 seconds (in multiple inflations) for optimal drug release. If required, inflation time can be extended to optimize lesion dilatation.

d. If needed, carry out repeat inflations. Maintain negative pressure between inflations.

e. After each subsequent inflation, determine the distal blood flow.

f. If significant stenosis persists, the lesion may require successive inflations/further treatment.

g. Determine the results under fluoroscopy.

9.4. Catheter Exchange/Withdrawal and Disassembly Procedure:

a. Apply negative pressure to the inflation device to achieve complete deflation of the balloon. Confirm this under fluoroscopy.

b. Loosen the haemostatic valve to facilitate removal.

c. While holding the guide wire and the haemostatic valve with one hand, gradually remove the deflated balloon catheter from the guide catheter.

d. In case of exchange procedure, follow steps (e) through (i). For withdrawal or disassembly, follow steps (j) and (k).

e. Maintain the guide wire position by holding it stationary if reinsertion /further procedure is planned.

f. Withdraw the catheter till the guide wire exit port is exposed.

g. Slide the remainder of the catheter along the guide wire until the tip of the catheter exits the haemostatic valve. Re tighten the haemostatic valve onto the guide wire to hold it securely in place.

h. Completely remove the catheter from the guide wire. Clean guide wire with gauze soaked in sterile normal saline to wipe residues of blood and other substances. The mandrel and the protective sheath can be used to cover the balloon by sliding the distal pin into the tip and the protective sheath over the balloon with the flared side of the protector sheath first.

i. Prepare and insert the next catheter according to manufacturer's instructions.

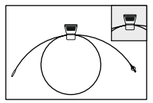
j. Withdraw the deflated catheter and guide wire from the guide catheter.

k. Remove the guide catheter from the vasculature following an accepted technique for removal.

9.5. Instructions for use of Accessories:

9.5.1 Looper clip:

The Looper clip is an accessory component that allows the catheter to be fastened in a coiled configuration for ease of handling during use (See the figure).



Instructions for use:

a. Form the catheter into a single or double loop as needed.

b. Press down the arms of the Looper clip to open the clipping section for retention of the hypotube.

c. Release the arms of the Looper clip with the hypotube inside to secure the catheter in a coiled configuration. Discard the catheter if any bend or kink is observed upon placement or removal of the Looper clip.

9.5.2 Flushing needle:

This needle is used to flush the guide wire lumen.

9.5.3 Compliance chart:

This chart provides balloon compliance information.

9.6. Disposal:

- After usage, dispose off the hardware in accordance with accepted latest regulations in-force for medical waste management.

Note: The product should be discarded in a proper way after use as if may have residual drug (Sirolimus) on its surface.

10. Individualization of Treatment:

- The risk and benefits should be considered for each patient before use of Mozec™ SEB. Patient selection criteria should include a judgement regarding risk of antiplatelet therapy. Special consideration should be given to those patients with gastritis or peptic ulcer, history of blood transfusion rejection and history of bleeding disorder etc. which may limit use of dual antiplatelet therapy.
- Pre-morbid conditions that increase the risk of a poor initial result or the risks of emergency referral for bypass surgery (cardiac failure, diabetes mellitus, renal failure and severe obesity, etc.), should be assessed.
- A review of the vessel location, reference vessel size, lesion length, qualitative target lesion characteristics and the amount of myocardium in jeopardy from acute or subacute thrombosis must also be considered.

11. Use in Special Populations:

The safety and efficacy of the Mozec™ SEB has not been established in the following patient populations:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with unprotected lesions located in the left main coronary artery.
- Patients under high risk of primary Percutaneous Coronary Intervention (PCI) for acute myocardial infarction characterized by presence of cardiogenic shock or evidence of massive thrombus in the infarct-related artery.
- Patients with brachytherapy treatment of the target lesion.
- There are no adequate and well controlled studies in pregnant women or men intending to father children. Effective contraception should be initiated before using Mozec™ SEB. The Mozec™ SEB should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or fetus.
- **Lactation:** It is not known whether Sirolimus is distributed in human breast milk. Because of the risk of adverse reactions in nursing infants, a decision on whether to discontinue nursing infants for use the drug eluting balloon should be based on benefit of the procedure to the mother.
- The safety and effectiveness of using brachytherapy treatment, mechanical artherectomy devices (directional artherectomy catheters, rotational artherectomy catheters) or laser angioplasty catheters prior to treatment with Mozec™ SEB has not yet been established.

12. Antiplatelet Regimen:

Physician should use the information from the current Drug Eluting Stent literature, guideline and specific needs of individual patients to determine the specific antiplatelet/anticoagulation regime to be used for their patients in general practice.

It is very important that the patient is compliant with the post procedure antiplatelet recommendation. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infraction or death. Prior to PCI, if a surgical or dental procedure is anticipated that requires early discontinuation of antiplatelet therapy, the interventionalist and patient should carefully consider whether a Drug Eluting Stent and its associated recommended antiplatelet therapy is the appropriate PCI choice. Following PCI, should a surgical or dental procedure be recommended, the risk and benefits of the procedure should be weighed against the possible risk associated with premature discontinuation of antiplatelet therapy.

Patients who require premature discontinuation of antiplatelet therapy secondary to significant bleeding, should be monitored carefully for cardiac events and, once stabilized, have their antiplatelet therapy restarted as soon as possible per the discretion of their treating physicians.

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Symbols used in labeling

Balloon outer diameter

Balloon length

Temperature limit

Keep dry

Contains one unit

LOT — Lot number

MGCID — Min guide catheter I.D.

REF — Reference number

STERILE EO — Sterilized using ethylene oxide

Non-pyrogenic

Max. guide wire diameter

Use-by date

Consult instructions for use

Manufacturer

Do not re-use

Date of manufacture

Do not use if package is damaged

Do not resterilize

Keep away from sunlight

Caution

EC REP — Authorized representative in the European community

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Meril

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An ISO 13485 & GMP Certified Company

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