<table>
<thead>
<tr>
<th><strong>REF</strong></th>
<th>CATALOGUE NUMBER</th>
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<tbody>
<tr>
<td><strong>LOT</strong></td>
<td>LOT NUMBER</td>
</tr>
<tr>
<td><strong>STERILE EO</strong></td>
<td>STERILE, STERILISED WITH ETHYLENE OXIDE</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>FOR SINGLE USE ONLY. DO NOT REUSE</td>
</tr>
<tr>
<td><strong>!</strong></td>
<td>READ THE INSTRUCTIONS CAREFULLY BEFORE USE.</td>
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<tr>
<td><strong>clock</strong></td>
<td>USE PRIOR TO “USE BEFORE” DATE</td>
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<td><strong>mountain</strong></td>
<td>DATE OF MANUFACTURE</td>
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<td><strong>factory</strong></td>
<td>MANUFACTURER</td>
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<td><strong>EC REP</strong></td>
<td>AUTHORISED REPRESENTATIVE</td>
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<td><strong>CE</strong></td>
<td>IN CONFORMITY WITH THE EUROPEAN DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES.</td>
</tr>
<tr>
<td><strong>umbrella, sun</strong></td>
<td>KEEP IN COOL, DRY AND DARK PLACE</td>
</tr>
</tbody>
</table>

**GB**
Latex free. Non-pyrogenic. Do not use if the package is open or damaged.

**D**

**F**

**I**
Senza lattice. Apirogeno. Non utilizzare se la confezione è aperta o danneggiata.

**E**
Libre de latex. No pirogenico. No usar si la envoltura está abierta o danada.
Description

The **MOMO** coronary stent system identifies a range of coronary balloon expandable stents pre-mounted on balloon catheters featuring Stent Delivery Systems (SDS).

The MOMO coronary stent system is a balloon expandable coronary stent pre-mounted onto a TRACK PLUS balloon catheter. **MOMO** stents are slotted tube types, obtained by laser cut of L605 Cobalt chromium alloy tubes of different size (diameter and thickness) in relation to the final stent expansion diameter with DLC (Diamond Like Carbon) coating. The DLC coating provides the substrate with the bio-and haemocompatible characteristics of pyrolitic carbon, without affecting the physical and structural properties of the substrate itself. The closed-cell design is based on a uniform interconnection of monotype cells without sharp joints or welding points. In addition, specific and different designs have been developed for small (2.5 – 3.0 mm) and large (3.5 – 4.0 mm) vessels in order to achieve a high standard of performance in both cases. The Stent Delivery System is based on a hypotube balloon catheter, Rapid Exchange type. A distal coaxial lumen extending 25 cm from the tip, allows for the advancement of the catheter over a maximum 0.014” (0.36 mm) diameter guide wire. The controlled compliance of the particular balloon material allows the achieving of specific stent diameters at specific pressures. The diameter of the balloon catheter depends on the pressure achieved and determines the deployed diameter of the stent. Please refer to the attached “Compliance Chart” for proper balloon diameter and balloon pressure relation. Stent length, once the stent is expanded at the desired diameter, shows an average shortening of about 5 %. The stent is pre-mounted on the balloon right in the middle between two swaged Platinum Iridium radiopaque markers allowing precise stent deployment in the target lesion.

Japan Stent Technology (JSTec)’s advanced technology provides a secure and stable fixation (crimping) of the stent on the balloon while achieving a low crossing profile. **MOMO** are supplied in different sizes. Nominal stent diameter and length are printed on the hub.

The profile of the MOMO coronary stent system is ~1 mm for all 3 nominal diameter stents. The Coronary stent system is compatible with 5Fr Outer diameter Guiding catheters with a 0.058”/1.47mm minimum Inner Diameter.

Indications

**MOMO** coronary stent systems are indicated for use in patients eligible for balloon angioplasty with symptomatic ischemic heart disease caracterised by discrete de novo and restenotic coronary artery lesions in reference vessel diameter from 2.5 mm to 4.0 mm and in the treatment of acute or threatened closure associated with a coronary intervention. Operator must select proper size (diameter and length) in order to match reference vessel diameter and lesion length.

Warnings

- This device is designed and intended for single use only. DO NOT RE-STERILISE AND/OR REUSE. JSTec will not be responsible for any direct, incidental or consequential damages resulting from re-sterilisation or reuse.
- 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.
- Select proper device size suiting lesion length and reference vessel diameter.
- Do not attempt to reposition a partially deployed stent as this may result in severe vessel damage.
- Do not attempt to remove or readjust the stent on its delivery-system. The stent cannot be removed and placed on another balloon catheter.
- Balloon pressure should not exceed the Rated Burst Pressure (RBP). Use of a pressure-monitoring device is mandatory to prevent over-pressurisation.
- Use only an appropriate balloon inflation medium (50:50 mixture by volume of contrast medium and saline). Never use air or gaseous medium to inflate the balloon.
- Do not expose the stent system to organic solvents, e.g. alcohol.
- When the catheter is in the body, it should be manipulated while under sufficient and/or high quality fluoroscopy.
- Never implant stents of different material close together or cross the struts (risk of galvanic potential).
- Only physicians thoroughly trained and educated in the performance of percutaneous transluminal coronary angioplasty (PTCA) and coronary stenting should use this device.
- Appropriate antiplatelet and/or anticoagulant therapy as determined by the physician in accordance with standard protocols for stent implantation should be administered to the patient.
- PTCA and coronary stent implantation are recommended only at hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of a potential injury or life-threatening complication. A surgeon team should be on standby when an interventional procedure is being performed.
- The use of mechanical atherectomy devices or laser catheter is not recommended in stented area.
- MRI is not recommended until the stent is completely endothelialised (in about 8 weeks) to minimise the possibility of stent migration. Stent may potentially cause artefacts in MRI scans due to distortion of the magnetic field.

Contra indications

General contraindications for coronary stenting and for the use of this device are:

• Patients who are not suitable for bypass surgery and/or PTCA
• Contraindication for antiplatelets and/or anticoagulation therapy
• Angiographic evidence of large amount of thrombus in the vessel or adjacent or inside the target lesion.
• Allergy to contrast media and / or to stainless steel, nickel and chrome alloys.
• Unprotected left main coronary artery disease.
• Excessive vessel tortuosity.
• Extremely angulated lesions.
• Lesions involving a bifurcation.
• Recent myocardial infarction (<72 hours).
• Ejection fraction <30%.
• Target lesions distal to previously implanted stents
• Lesions involving a bifurcation
• Patients in whom insufficient predilatation of the lesion is possible
• Reference vessel diameter <[2.5] or >[4.0] mm.
• Diffuse distal disease with low blood flow.
• Renal insufficiency or an allergy to contrast media
• Coronary artery spasm.

Please also consider the latest medical research findings.

Complications

Possible complications associated with coronary stent implantation may include, but are not limited to:

• Death.
• Acute myocardial infarction.
• Coronary artery spasm.
• Restenosis of the stented artery.
• Acute or sub-acute stent thrombosis.
• Total occlusion of the coronary artery or bypass graft.
• Dissection, perforation or rupture of the coronary artery.
• Hypo / hypertension.
• Sepsis / Infection.
• Arrhythmia, including ventricular fibrillation.
• Haemorrhage or haematoma.
• Arteriovenous fistula.
• Embolisation.
• Stent migration.
• Allergic reactions.
Please also consider the latest medical research findings.

**Preparation requirements**

The techniques and procedures described do not represent all medically accepted stent implantation procedures but are offered as a guide only. Only trained Physicians experienced in Percutaneous Transluminal Coronary Angioplasty (PTCA) and coronary stenting techniques should perform the procedures.

- Perform coronary angiography to localise and define coronary stenosis.
- Place the relevant guide catheter into the coronary ostium and pass the stenosis with a PTCA guidewire (0.014”/0.36mm).

**Directions for use**

The stent should be deployed after pre-dilatation of the target lesion using a PTCA catheter. Remove the initial PTCA catheter from the coronary system keeping the 0.014” (0.36 mm) coronary guide wire in position.

**Stent Delivery System preparation**

- Using sterile technique, remove the stent-delivery-system and dispenser from the package and place it onto the sterile field.
- Gently pull out the catheter from the dispenser.
- Carefully remove the stylet and the balloon/stent protective sheath.
- Visually check the stent crimping for uniformity, no protruding struts, and centring on the balloon. Do not use the device if any defects are noted.

**Accessory Requirements**

- Prepare the required accessories according to the accessory manufacturer’s instructions for use and ensure their compatibility prior to use.

**Flushing of Guide-Wire Lumen**

- Using a flushing needle, connect a syringe containing sterile saline to the distal tip of the catheter and flush the guide wire lumen.
- Remove the syringe.

Avoid manipulation of the stent during removal from packaging and flushing of guide wire lumen.

- Do not pre-inflate the balloon prior to stent deployment. Use balloon purging technique described further:
  a. Partially fill the inflation device/Syringe with diluted contrast medium, taking care not to entrap air bubbles in the solution.
  b. Connect the inflation device/Syringe to the stopcock and hold the tip upwards and expel all the air; connect to the inflation port.
  c. With the distal tip down, orient the delivery system vertically.
  d. Open the stopcock to the delivery system; withdraw the plunger and apply negative pressure for 30 seconds to evacuate the air from the delivery system; release negative pressure by slowly releasing the plunger to infuse contrast medium into the balloon.
  e. Close the stopcock to the delivery system; purge the inflation device / syringe of all air.
  f. If air is seen in the shaft, repeat steps c, d and e until all air is expelled. Do not flick or tap the balloon.

**Caution:** Do not apply negative pressure to the catheter prior to placement of the stent across the lesion. This may cause premature dislodgement of the stent.

**Insertion Technique**

- Attach a haemostatic valve to the Luer-port of the guiding catheter positioned within the vasculature.
• In case the coronary guide wire has not already been positioned across the lesion, under fluoroscopy, insert a 0.014" (0.36 mm) guide wire across the lesion, following standard PTCA techniques.
• Insert the proximal end of the guide wire, into the distal tip of the catheter.
• Carefully insert stent delivery system through the haemostatic valve and advance the catheter.

Note: Make sure that the haemostatic valve is completely open before inserting the delivery system, since a partially open valve might damage the stent or dislodge it from the centred location on the dilation balloon.
• Under fluoroscopic guidance, carefully advance the stent system through the guiding catheter and into the coronary artery following the guide wire towards the target lesion.
• Position the stent within the lesion using the two radiopaque markers located on the balloon catheter as reference points for precise placement across the target lesion.

Caution: Do not attempt to withdraw an unexpanded stent back through the guiding catheter. It might be dislodged from the balloon and cause distal embolisation. If you feel any resistance when the catheter is pushed out of the end of the guiding catheter, be sure to determine the cause. If you cannot determine and eliminate the cause, then retract the entire system (guide wire, delivery system and guiding catheter) together, as a single unit.

Stent deployment
• Connect a syringe containing contrast medium to the luer port of the balloon lumen located in the proximal hub of the catheter and apply negative pressure for about 15 seconds until no bubbles appear in the contrast medium solution. Return to atmospheric pressure allowing contrast medium flow into the catheter lumen. Remove the syringe leaving a meniscus of contrast in the hub of the balloon lumen.
• Remove air bubbles from the inflation device following the manufacturer’s instructions.
• Using stopcock, attach inflation device to the stent delivery system. Avoid air entering the system.
• Open stopcock on inflation device. Inflate the dilation balloon gradually to expand the stent to the calculated diameter in accordance with the Compliance Chart. Apply a constant pressure for at least 30 seconds.

Stent should be expanded to a vessel diameter/stent diameter ratio of no more than 1:1.15

Caution
• Do not expand the stent if it is not properly positioned in the target lesion.
• Stent placement may compromise side branch patency.
• Do not exceed Rated Burst Pressure (RBP).
• In case stent size is still inadequate (under-dilated) with respect to vessel diameter, in order to achieve optimal stent deployment, inflate the balloon once more with the same balloon or perform a post dilatation using a non-compliant high-pressure balloon. Use multiple fluoroscopy views to ensure that the stent has been completely expanded.

Balloon deflation and catheter removal
• Deflate the balloon in accordance with standard PCTA procedures. Apply negative pressure to the balloon for about 30 secs. Ensure balloon is fully deflated before carefully pulling the catheter out of the vessel.
• Observation of the patient and angiographic evolution should be performed periodically in the 15 minutes after stent implantation.

Storage
• The MOMO coronary stent system is provided packaged in a sterile and non-pyrogenic condition. The package must be stored in a clean and dry environment within a temperature range of 5°C to 55°C.
Compliance Charts for MOMO Stent System: relationship between pressure and stent diameter

<table>
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<tr>
<th>(atm)</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
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<th>12</th>
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<tbody>
<tr>
<td>2.5mm</td>
<td>2.32</td>
<td>2.40</td>
<td>2.48</td>
<td>2.50</td>
<td>2.66</td>
<td>2.80</td>
<td>2.94</td>
<td>3.03</td>
<td>3.12</td>
</tr>
<tr>
<td>3.0mm</td>
<td>2.80</td>
<td>2.88</td>
<td>2.95</td>
<td>3.00</td>
<td>3.14</td>
<td>3.21</td>
<td>3.29</td>
<td>3.35</td>
<td>3.45</td>
</tr>
<tr>
<td>3.5mm</td>
<td>3.30</td>
<td>3.35</td>
<td>3.46</td>
<td>3.50</td>
<td>3.67</td>
<td>3.80</td>
<td>3.89</td>
<td>4.04</td>
<td>4.15</td>
</tr>
<tr>
<td>4.0mm</td>
<td>3.73</td>
<td>3.87</td>
<td>3.96</td>
<td>4.00</td>
<td>4.15</td>
<td>4.26</td>
<td>4.39</td>
<td>4.58</td>
<td>4.68</td>
</tr>
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Nominal Pressure | RBP (Rated Burst Pressure)

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 JSTec’s instructions for use are expressly to be considered as an integral part of this provision. JSTec warrants 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. JSTec disclaims any warranty of merchantability or fitness for a particular purpose of the product. JSTec 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 the JSTec'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 JSTec, however originating, from his 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 JSTec’s legitimate interest in limiting its liability or warranty. No person has any authority to bind JSTec to any warranty or liability regarding the product.

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MOMO is a trademark of Japan Stent Technology Co., Ltd.
Track plus is a trademark of Vasmed Technologies Ltd

Made in United Arab Emirates