Teleport® Microcatheter — TELEPORT MICROCATHETER — INSTRUCTION FOR USE — ENGLISH — CE 2797

READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DEVICE DESCRIPITION

1. Device Name: Teleport Microcatheter
2. Table of Catalog Numbers

Catalog Number	Microcatheter O.D.	Microcatheter I.D.	Length	Remark
220 -13-1000	2.0Fr (0.0265"/0.67mm)	0.0170" (0.43mm)	135cm	Teleport
220 -15-1000	2.0Fr (0.0265"/0.67mm)	0.0170" (0.43mm)	150cm	
221 -13-1000	2.1Fr (0.0275"/0.70mm)	0.0175" (0.44mm)	135cm	Teleport (Control)
221 -15-1000	2.1Fr (0.0275"/0.70mm)	0.0175" (0.44mm)	150cm	

3. Table of Materials

Out Layer	Tip	Reinforcing Material	Inner Layer	Surface Coating
Polyamide elastomer	Tungsten	Spring coil and braiding	PTFE	Hydrophilic coating

4. Specifications Table

Maximum Guidewire O.D.	0.014" (0.36mm)
Minimum Guiding catheter I.D.	0.041" (1.05mm)
Maximum Injection Pressure	2070 kPa (300 psi)
Tensile Strength	3N

DEVICE FUNCTION AND STRUCTURE

1. Indications
   Teleport is intended to support and facilitate the placement of guidewires in the coronary and peripheral vasculatures, and can be used to exchange guidewires. Teleport is also intended for the delivery of contrast media into the coronary, peripheral and abdominal vasculatures.
2. Device Structure
   Teleport is composed of a Microcatheter packed in a holder within a sterile pack. This sterile pack is packed in a carton with this Instruction for Use. Teleport's outer surface is coated with a hydrophilic polymer to provide lubricity when wet. Teleport's inner lumen shaft is lined with a fluoropolymer layer to facilitate movement of the guidewire and other devices. The distal end is distinguished by a radiopaque tip.

CONTRAINDICATIONS AND PRECAUTIONS

Teleport is for single use only. Do not resterilize and/or reuse. If Teleport is reused and/or resterilized, there is a strong possibility of one or more of the following adverse events occurring and the possibility of injury to the patient even if the product is used in an appropriate manner. In the worst case, life-threatening adverse events may result.

- Infection due to inappropriate and/or insufficient sterilization
- Deterioration, breakage and/or rupture of the product due to
  - Abrasion of coating on the product's surface
  - Metallic fatigue

1. Do not modify this product for any reason. Use of a modified product may cause damage to blood vessels.
2. It is recommended that this product only be used at a medical institution capable of promptly performing an emergency coronary bypass operation. If the emergency operation is not performed promptly when needed, for example, in the case of an accidental patient injury during a procedure using this product, in the worst case, life-threatening adverse events may occur.
3. This product must be used under fluoroscopy only by a physician who is fully trained in PTCA. (Inappropriate procedure may cause an error in operation or misjudgment, leading to damage to the blood vessel. In the worst case, life-threatening adverse events may occur.)
4. Do not use this product for patients with following disorders.
   a. Severe heart failure.
   b. Hemorrhagic diathesis or renal failure.
   c. Intractable severe arrhythmia.
   d. Fever or systemic severe infection.
   e. Uncompensated heart failure.
   f. Severe pulmonary disease.
   g. Critical serum electrolyte disorder.
   h. Acute myocardial infarction.
   i. Blood coagulation disorder or severe change in coagulation ability due to some other causes. (In case of applying this Microcatheter for patients described above in a-i, there is a possibility that the symptom may be worsened. In the worst case, life-threatening events may occur.)
   j. Patients who have had severe and distinct reaction against the agents necessary for the intended procedure. (Side effects such as allergic symptoms or shock disease may occur. In the worst case, events may be life-threatening.)
   k. Patients who cannot lie on their back on the table for angiography because of congestive heart failure or dyspnea.
   l. Patients with mental disease or patients who do not consent to angiography.
   m. Patients who are or could be pregnant. (The fetus may be affected by X-rays under fluoroscopy.)
   n. Any other patients who are judged unsuitable for the procedure by the physician.
   o. Do not apply this product to lesions on the left main trunk, which is not protected by a bypass or collateral circulation.
   p. Do not apply this product to patients with anamnesis of coronary spasm.
5. Do not use in advanced calcified lesions.
6. Do not use oleaginous contrast media. (The device may be damaged.)
7. The device must not be used for drug infusion. (The device is not designed for drug infusion and its safety has not been established.)
8. Agents containing organic solvent such as alcohol must not be used either alone or concurrently. These agents must not be used for immersing or wiping the device. (The catheter may be damaged or lose its lubricity.)
9. When using a Y-connector, excessive tightening to the product with the hemostasis valve and operation with a tightened Y-connector must be avoided. (The device may be damaged.)
10. Excess rotational load must not be applied if the device is bent. (The device may be damaged or cut.)
11. The device must not be used for cerebral vessels. (The device is not designed for cerebral vessels and its safety has not been established.)
12. Medical devices used together with the Microcatheter. When this Microcatheter is inserted in a guiding catheter fitted with a stopcock, do not manipulate the stopcock. Such manipulation may damage or rupture the Microcatheter. This Microcatheter is made of tungsten, stainless steel braiding, and a combination of polyamide elastomer and polyurethane. The inner lumen of the shaft is lined with fluoropolymer. When performing a diagnostic procedure, do not use substances such as alcohol, which may damage, dissolve or swell the materials used in this Microcatheter.

WARNINGS

Carefully read all warnings. Failure to do so may result in life-threatening events in the worst case.

- Do not use this Microcatheter in cerebral vessels.
- If abnormal resistance is detected during use of this product, do not continue the operation, avoid excessive manipulations, and carefully remove the entire catheter system while paying full attention to avoid complications. Continuing the operation while the cause of the problem is not identified may cause damage to or rupture of the catheter, and damage the blood vessel. In the worst case, life-threatening adverse events may occur.
- The device must always be operated under high-resolution fluoroscopic guidance. Particular attention should be paid when inserting or withdrawing the device into stenotic areas, highly calcified lesions, stent struts, and narrower vessels than the product. Abrasion may result in damage or rupture of the device. This may cause vascular injury and perforation, possibly leading to a life-threatening adverse event.
- Do not insert the guidewire by force or advance it rapidly when the Microcatheter is bent or twisted. Such manipulations may cause rupture or damage of the Microcatheter, or perforation of the blood vessel.
- Always advance the guidewire ahead of the Microcatheter before attempting any manipulation of the Microcatheter. If the guidewire is not advanced ahead of the Microcatheter, the blood vessel may be damaged or perforated, or the Microcatheter may be damaged.
- Always hold the connector with one hand and turn the catheter carefully while regularly releasing the accumulated torsion of the catheter. Never turn the catheter continuously while holding the connector with both hands or use any other means to apply force. When releasing the accumulated torsion, be sure to open the hemostatic valve on the Y-connector. Do not turn the catheter in the same direction, either clockwise or counterclockwise, for more than 20 consecutive turns. If resistance is felt while turning the catheter, do not proceed with further rotation even if the 20-turn limit has not been reached. Identify the cause of resistance under fluoroscopy, and take appropriate action. Never continue the operation without identifying the cause. (Continuing rotation may damage or rupture the catheter or damage the blood vessel. In the worst case, life-threatening adverse events may occur.)
- This Microcatheter is coated with hydrophilic coating. Therefore, the Microcatheter is highly lubricious. Always confirm the position of the distal end of this Microcatheter by fluoroscopy and manipulate this Microcatheter carefully.
- Do not use a power injector to infuse contrast media when the Microcatheter is bent or occluded. It may cause damage to the Microcatheter such as expansion or breakage.
- Injection pressure must not exceed 300 psi (the maximum injection pressure) when injecting contrast media using a power injector. Exceeding the maximum injection pressure may cause damage to the Microcatheter.
- When infusing contrast media, the device must be operated under high-resolution fluoroscopic guidance, confirming that the contrast media is being infused from the tip of the device. If the contrast media is not being infused, infusion must be stopped and the device must be replaced. (If the device lumen is occluded, the device may be dilated, damaged, or ruptured even at less than the maximum injection pressure (300 psi), resulting in a life-threatening adverse event due to spurting contrast media.)
- Do not use guidewires larger than the recommended size. (Resistance may be felt while advancing or withdrawing a guidewire larger than the recommended size, which may cause the catheter to become damaged or break, or the blood vessel to become damaged. In the worst case, life-threatening adverse events may occur.)
- If the device is inserted into vessels and the guidewire is to be replaced, insert the guidewire carefully. If there is any resistance is encountered, the operation must be discontinued immediately, and the device and the guidewire(s) withdrawn together. (The device may be damaged and the tip may be cut.)
- Do not wipe the surface of the Microcatheter with gauze or absorbent cotton soaked with alcohols, gluconic acid chlorhexidine aqueous solution, or similar solutions as it may significantly deteriorate the lubricity of the Microcatheter.
- The patient may suffer from subacute thrombosis, vascular complications, or bleeding complications by using this Microcatheter. Therefore, it should be well examined if the intervention procedure will be applicable for the patient.
- Repeated insertion and withdrawal of the device may lead to deterioration of the hydrophilic coating. (Continuous use of the device with deteriorated hydrophilic coating may cause vascular damage. This may also increase the risk of trapped tip, resulting in a life-threatening adverse event due to a damaged or ruptured tip.)
- Comply with instructions, precautions, and warnings described in the Instructions for Use supplied with medical devices used together with the Microcatheter.
- Do not manipulatthe stopcock of the guiding catheter when the Microcatheter is inserted in the guiding catheter fitted with a stopcock. It may cause damage of the Microcatheter or the guidewire.

INSTRUCTIONS FOR USE

This product can be used directly after opening the package following sterile procedures. It is sterilized by gas sterilization with ethylene oxide before shipment. The product is for single-use only and reuse is not permitted.

1. Take out the holder tube containing the Microcatheter from the sterile pack.
2. Inject the heparinized and sterilized saline into the holder tube through the flush connector by using a syringe. Ensure the ejection of heparinized and sterilized saline from distal end of the holder tube to make sure the holder tube is filled with heparinized and sterilized saline.
3. Remove the Microcatheter from the holder tube, and check the surface of the Microcatheter for sufficient lubricity. If any resistance is felt when withdrawing the Microcatheter from the holder tube, inject additional heparinized and sterilized saline into the holder tube to lubricate the Microcatheter.
4. Flush the lumen of the Microcatheter removed from the holder tube with the heparinized and sterilized saline by using a syringe. Fill the lumen of the Microcatheter with the heparinized and sterilized saline.

A. Instructions for use as an infusion catheter

5. Insert the appropriate guidewire (indicated on the label of product package) into the Microcatheter and advance carefully.
6. Insert the guiding catheter into the patient's blood vessel according to standard catheter procedure.
7. Insert the Microcatheter and the guidewire as a unit into the guiding catheter, from its hemostatic adaptor (Y-connector etc.), which is inserted in the patient's vessel. Advance the Microcatheter and the guidewire until the distal end of the guiding catheter appears under fluoroscopy.
8. After loosening the hemostasis valve of the Y-connector, if a stenosed area hinders this product, and/or when enough guidewire support is not obtained, secure tightly both the guidewire and the guiding catheter. Then, advance the product slowly along the guidewire and observe the movement of the radiopaque tip to determine if the tip passes through the stenosed area.
9. The user can rotate the device when inserting, withdrawing, and passing through stenotic areas. However, do not turn the catheter in the same direction, either clockwise or counterclockwise, for more than 20 consecutive turns. If the device is trapped, or suspected to be trapped, then rotating operation must be avoided.
10. Before injecting contrast medium, withdraw the guidewire. Connect (a) the power injector to the connector for angiographic injection of contrast medium that according to the manufacture's IFU and/or according to clinical practice is suitable for power injection infusion; or (b) a syringe to the connector for manual injection of contrast medium.
11. When thrombus adhesion is expected during the procedure, connect the hemostatic adaptor to the connector of the Microcatheter and inject heparinized and sterilized saline from the port of the hemostatic adaptor by using a syringe, or connect a pressured bag with heparinized and sterilized saline for continuous drip to prevent thrombus from adhering to the Microcatheter.
12. After completing the procedure, withdraw the Microcatheter immediately and discard.

B. Instructions for use as a support catheter

5. Insert a compatible guidewire through the connector and bring the tip of the guidewire in line with the tip of this Microcatheter. (If the guidewire is inserted through the tip of this Microcatheter, care should be taken not to cause any damage to the Microcatheter. Also, if the Microcatheter is bent or kinked, discontinue its use. If the Microcatheter is kinked it may cause severe damage to the patient.)
6. Loosen the hemostatic valve of the hemostatic adaptor connected to the guiding catheter and insert this Microcatheter (Ensure that the hemostatic valve of the hemostatic adaptor is already loosened. A tight hemostatic valve causes resistance during insertion of this Microcatheter and may damage the Microcatheter.)
7. Advance this Microcatheter under fluoroscopy until it reaches 2 to 3 cm proximal of the tip of the parent-guiding catheter.
8. Advance this Microcatheter under fluoroscopy until it is close to the stenotic area. Advance the guidewire carefully until it passes the target area. Continue advancing the guidewire as distal as possible into the blood vessel, and once it is placed there, check the position by imaging from the guiding catheter. The position of the guidewire must be checked by imaging from multiple angles to confirm that the guidewire is definitely inserted into the target blood vessel.
9. After loosening the hemostatic adaptor, hold the guidewire and guiding catheter firmly. Then advance this Microcatheter gradually along the guidewire until the tip has passed through the stenotic area, using the radiopaque tip of this Microcatheter as a guide. (Procedures inside the blood vessel should be conducted with care, because this Microcatheter is hydrophilic coated.)
10. When removing this Microcatheter, loosen the hemostatic valve of the hemostatic adaptor. Remove this Microcatheter while keeping the guidewire stable in the blood vessel. (When this Microcatheter is removed, check the position of the guidewire under fluoroscopy. Also, if any resistance is felt during the removal of this Microcatheter, remove all devices including the parent Microcatheter and the guidewire.) After removal of this Microcatheter, tighten the hemostatic valve of the hemostatic adaptor.
11. The user can rotate the device when inserting, withdrawing, and passing through stenotic areas. However, do not turn the catheter in the same direction, either clockwise or counterclockwise, for more than 20 consecutive turns. If the device is trapped, or suspected to be trapped, then rotating operation must be avoided.

PRECAUTIONS FOR USE

1. This product is intended for single use only. Do not resterilize and/or reuse. Do not use if the package is opened or damaged. Always open the package just prior to use.
2. Important precautions
   - This product must be used under fluoroscopy by a physician who is fully trained in interventional procedures.
   - Prior to use, check all devices, including this product, and confirm that they function normally. Check also if the product is not damaged during transportation. Do not use if the package and /or the product is suspected to be damaged.
   - Use by the expiration date indicated on the label of the product package.
   - Use immediately after opening the package. After use, discard the Microcatheter respecting the disposal policies and infection controls.
   - When inserting the guidewire into the Microcatheter that is already placed in the blood vessel, carefully operate the guidewire not to damage the Microcatheter at the bend sections.
   - Confirm that the inserted Microcatheter does not have a kink, knot, torsion, or occlusion before injecting contrast media.
   - Use the extension tube when contrast media is injected by using power injector.
   - Do not use this product for the purposes other than described in the indications for use written in this document.
   - Select the appropriate size of guiding catheter and guidewire to use in combination with this Microcatheter. (See Specifications Table.)
   - When using a guiding catheter fitted with a stopcock, do not manipulate the stopcock after inserting this Microcatheter into the guiding catheter. (The Microcatheter may be damaged if the stopcock is manipulated during the insertion.)
   - Operate the Microcatheter carefully to avoid damage, kinking, or bending, especially when inserting into the guiding catheter.
   - Check the patient's condition before the procedure. Provide appropriate anticoagulant therapy if necessary.
   - Manipulate the Microcatheter in the blood vessel very carefully by observing it through a high-definition X-ray fluoroscopy monitor screen. If any resistance is felt, stop the manipulation and identify the cause of the resistance. Continuing the manipulation while the cause of the problem is not identified may cause damage of the blood vessel, or damage or rupture of the Microcatheter.
   - When infusing contrast media, read the Instructions for Use provided with such contrast media and comply with instructions, precautions, and warnings.
   - The surface of this Microcatheter is coated with hydrophilic polymer. Flush the surface and the lumen of the Microcatheter continuously with heparinized and sterilized saline during its use to maintain lubricity.
   - Do not wipe the surface of this Microcatheter with a gauze or absorbent cotton soaked with alcohols, gluconic acid chlorhexidine aqueous solution, or the like to avoid damage of the lubricious coating.
   - When inserting or exchanging the Microcatheter, flush the lumen of the guiding catheter and the Microcatheter system continuously with heparinized and sterilized saline.
   - Flush the lumen of the Microcatheter sufficiently with heparinized and sterilized saline especially after injecting contrast media.
   - Discontinue injection if irregular resistance is felt at the syringe. The Microcatheter may be bent or blocked. Excessive pressure may cause expansion and/or rupture of the Microcatheter
3. Other precautions
   Take preventive measures against infection after use. Discard this product as medical waste.

DEVICE PACKAGE AND STORAGE

- Teleport is composed of a Microcatheter packed in a holder tube, packed within a sterile pack. This sterile pack is packed in a carton with this Instruction for Use.
- The device is sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.
- Store in a dry, dark, cool place.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

Descriptions or specifications in OrbusNeich Medical printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. OrbusNeich Medical will not be responsible for any direct, incidental, or consequential damages resulting from the misuse of the product.

EXPLANATION OF SYMBOLS

Description	Symbol
Catalog Number	REF
Lot Number	LOT
Microcatheter O.D.	PROFILE
Length	LENGTH
Conformity to the Council Directive 93/42/EEC	CE 2797
Sterilized Using Ethylene Oxide	STERILE EO
Use By	
Do Not Reuse	
Caution	
Consult Instructions For Use	

Description	Symbol
Do Not Resterilize	
Do Not Use If Package Is Damaged	
Contents (numeral represents quantity of units inside)	1
Keep Dry	
Keep Away from Sunlight / Heat	
Manufacturer	
EU Authorized Representative	EC REP
Minimum Guiding Catheter ID	
Maximum Guidewire OD	
Maximum Injection Pressure	

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