

## EPHESOS™ II CORONARY STENT DELIVERY SYSTEM

### DEFINITION

Alvimedica EPHESOS™ II Stent is a balloon-dilatable stent laser-cut from a 316 LVM stainless steel. EPHESOS™ II Stent is available in varying sizes of 6mm, 8mm, 9mm, 12mm, 15mm, 18mm, 20mm, 25mm, 28mm and 32mm. EPHESOS™ II is offered for use as mounted on TURQUOISE™ PTCA catheter.

### STENT DELIVERY SYSTEM

Alvimedica TURQUOISE™ PTCA Dilatation Catheter has been designed to dilate the stenotic atherosclerotic lesions in coronary arteries or in bypass grafts. The dilating part of the catheter is the balloon near the distal tip. The catheter is Hydromer™ Hydrophilic coated from the distal tip towards the proximal end for 105 cm excluding the effective length of the balloon and 45cm of proximal shaft. There are radioopaque marker tapes on both the proximal and distal shoulders of the balloon. There is a separate lumen on the catheter shaft to be used as guide wire lumen starting at approximately 27 cm from the distal tip. The proximal tip of the catheter is used as the balloon inflating port. The balloon is inflated by injecting a contrast material from this tip. The balloon material is capable of reaching a certain size at a certain pressure. The maximum guide wire diameter that can be used with the TURQUOISE™ Dilatation Catheter is 0.014".

**Warning:** EPHESOS™ II Stent reaches its nominal dilated diameter when the delivery system balloon is inflated at a pressure of 8 bars. The delivery system balloon should not be inflated at pressures so high as to dilate the stent more than the intended vessel lumen diameter or at pressures exceeding the pre-determined maximum pressure.

### INDICATIONS

EPHESOS™ II Stent system is indicated in;

- Patients who have symptomatic ischemic disease due to de novo or re-stenosis of coronary arteries and are eligible for PTCA operation.
- Treatment of acute obstruction complicating PTCA operation.
- Cases of unsuccessful PTCA operations.
- Decreasing the re-stenosis ratio.
- Patients should be eligible for coronary bypass surgery.

### CONTRAINDICATIONS

It is contraindicated in;

- Patients who cannot be given anti-platelet or anti-coagulant therapy,
- Patients who are not eligible for coronary bypass surgery,
- Patients who have diffuse distal vessel disease that would decrease blood flow through the stent lumen,
- Those with unprotected left main coronary artery,
- Ostial lesions,
- Lesions with coronary embolism,
- Patients with known metal allergy,
- Pregnant women,
- Tortuous lesions making angles of more than 30 degrees.

### WARNING

- This product has been designed for single-use and re-use is not recommended. Do not re-sterilize and re-use it!
- All the operations after the catheter is introduced into the body should be performed under high-quality fluoroscopy. Never pull or push the catheter unless the balloon is completely deflated under vacuum. Should any resistance be encountered during the operation, just stop and try to identify the cause and advance the balloon catheter with short distance to prevent the occurrence of the kink on the proximal shaft. If you fail to identify, remove the system as a whole (stent, delivery system and guiding catheter).
- Do not exceed the rated burst pressure mentioned in Instructions For Use while inflating the balloon. To monitor the pressure, it is recommended to use an

inflating device with a built-in manometer.

- The stent delivery operation should only be performed at centers capable of doing emergency coronary bypass surgery in case of life-threatening complications.
- Do not use the stent and the delivery system after the expiry date printed on the package.
- Alvimedica disclaims the responsibility for any damage or injury that may be caused by re-use of the stent and the delivery system.
- Do not try to remove the stent wedged on the delivery system and do not make any change in the operation. The stent should not be removed from the delivery system and placed in another balloon catheter, as this process may damage the balloon or the stent.
- Do not use contrast materials Ethiodol and Lipiodol.
- Do not expose the delivery system to organic solvents (i.e. alcohol, etc.).
- Do not inflate the balloon at a higher pressure than needed.
- Inappropriate anticoagulant and/or antiplatelet therapy may cause stent thrombosis.
- To prevent the possibility of metal corrosion, do not place stents made of different metals inside each other, next to each other or so as to contact each other.
- Do not use air or any other gas to inflate the balloon.

### **PRECAUTIONS**

- Prior to stent delivery operation, check whether the shape and the size of the stent and the delivery system to be used are suitable for the case.
- The stent and the delivery system should only be used by experienced physicians who have been adequately trained on angiography, stent delivery and PTCA operations.
- Do not use if the inner package has been opened or damaged.
- Do not sterilize in an autoclave.
- Keep it in a cool (15-30°C), dry and dark place.
- Prior to the stent delivery operation, the predilatation of the lesion should be performed using standard PTCA techniques.
- The delivered stent may be damaged as a result of physical contact with auxiliary materials.
- Re-dilatation of the delivered stent may cause dissection and this can be corrected by delivering another stent. In cases where more than one stent are delivered, their tips should be interlaced.
- When a completely or partially dilated stent should be passed through, due attention should be paid not to deform or damage the stent.
- It is recommended not to perform mechanical atherectomy or to use laser catheters in the stent-delivered area.
- The stent may cause artefacts in MR imaging because of the distortion in the magnetic field. Also in order to decrease the risk of stent migration in powerful magnetic field, MR imaging should not be performed until the stent is completely covered by endothelial tissue (for about 8 weeks).
- It is recommended not to perform hyperthermia in stent-delivered area.

### **ADVERSE EFFECT / COMPLICATIONS**

The following adverse effect may occur during or after stent delivery

- Acute myocardial infarction
- Unstable angina
- Complete obstruction
- Tearing or perforation of, or damage to, coronary artery
- Coronary artery dissection, perforation, injury or tearing
- Re-stenosis of stent-delivered vessel
- Spasm of coronary artery
- Deformation of stent symmetry during delivery or while passing another tool (such as catheter, balloon, guide wire, etc.) through the stent
- Hemorrhage or hematoma
- Arrhythmias, including ventricular fibrillation
- Drug reactions, allergic reaction to contrast material
- Hypo-/ hypertension
- Infection
- Arteriovenous fistula

- Embolism
- Urgent coronary artery bypass graft surgery
- Gastrointestinal bleeding due to anticoagulant/antiplatelet therapy
- Intimal tearing
- Formation of pseudo-aneurysm
- Migration of stent
- Thrombosis
- Tissue necrosis
- Death

## PREPARATION AND PRE-USE TESTING

Make sure that the diameter of the stent to be used exactly matches with vessel diameter.

### Preparation

1. Take the delivery system out of the package gently. Be careful while taking the stylet and the protection tube out of the distal tip of the catheter.

Check the integrity of the wedged stent the centering on the balloon and whether there is any jutting on the connections.

**Note:** The stent should be centered on the balloon.

**Warning:** Do not use a gauze as its fibers may clutch and impair the stent.

2. Fill the 20-cc syringe with 10 cc of saline solution. Put a needle on the syringe and carefully insert the needle through the distal tip of the catheter and rinse the guide wire lumen.
  3. Hold the stent carefully so as to keep the position of the stent wedged on the balloon, while taking the catheter out of the package, loading it onto the guide wire, inserting it into the guiding catheter and passing it through the Y-connector with hemostatic valve and pay utmost attention during all these operations.
  4. Fill the 20-cc syringe with a 50/50% mixture of contrast material and saline solution. Remove the air completely, connect the syringe to the stopcock and fill the stopcock lumen with contrast-saline mixture.
  5. Prepare the inflating device in accordance with the manufacturer's instructions.
  6. Connect the stopcock to the inflation port on the proximal part of the catheter. Connect the inflating device to the other arm of the stopcock. While carrying out these operations, tighten the connections to prevent entry of air into the system.
  7. Switch the stopcock to the "off" position for the inflating apparatus.
  8. While holding the syringe vertically so that its piston is above, pull the piston and aspirate until no air bubbles remain in the syringe.
  9. Switch the stopcock to the "on" position for the inflating apparatus.
- Note:** Do not apply a negative pressure to the system with the inflating apparatus

## ENTRANCE AND DELIVERY SYSTEM

**Note:** It is not recommended to use the Alvimedica EPHEOS™ II Stent and the delivery system for predilatation.

1. Dilate the lesion using the PTCA balloon. It is better to match the diameters of the balloon and the vessel.
  2. Advance the prepared stent and the delivery system towards the Y-connector with hemostatic valve (Inner diameter > 0.074"), via the guide wire (max. 0.014"). The Y-connector with hemostatic valve should be completely open while passing through it.
- Note:** If you encounter any resistance, do not push further, as this may damage the stent or cause it to avert from the balloon. Make sure that the guiding catheter is in correct position and its tip is stationary.
3. Advance the stent inside the guiding catheter, under fluoroscopy. Using the PTCA techniques known, insert the stent into the lesion.
  4. Expand the stent in the lesion applying the angioplasty techniques. Perform more than one inflation operations until the stent width is equal to the vessel width. While holding the balloon in deflated position, check the expansion of the stent by angiographic imaging.
- An inflation pressure of 8 bars is sufficient for the expansion of the stent.
- Warning:** Expanding the stent above the limit and exerting a more-than-specified inflation pressure may cause dissection.

## REMOVAL OF THE STENT DELIVERY SYSTEM

1. After the stent has been delivered, exert a negative pressure and deflate the balloon. After the balloon has been completely deflated, carefully

pull back and remove the delivery system from the guiding catheter under fluoroscopy while the guide wire remains in place.

2. Do the angiographic imaging of the stent-delivered area and check the expanded stent. If you observe insufficient dilatation, carefully position

the original delivery system or another catheter with appropriate balloon diameter in the stent and repeat the previous operations to expand the stent to the appropriate diameter.

## TERMS OF WARRANTY

Alvimedica guarantees that each and every component of this product has been manufactured, packed, tested and sterilized without any defect regarding workmanship or material. Each product has been tested prior to packaging. Alvimedica shall exchange any product with defect(s) from manufacturing or packaging with a new one. Due to biological variations among individuals, no product is 100 % effective in every case. Therefore and since we have no control over the use of the product after sales, the selection of patients and the methods of application; Alvimedica does not guarantee that the outcome will be good enough. Alvimedica is not directly or indirectly responsible for any injury or damage to or loss of the product resulting from the use of the product, nor is Alvimedica responsible for any injury, damage or loss that may result from re-use or re-sterilization.

## EPHESOS™ II STENT DELIVERY SYSTEM / BALLON DIAMETER VERSUS PRESSURE (BALLOON COMPLIANCE)

Pressure (Bar)	2.0 mm	2,5 mm	2.75 mm	3,0 mm	3,5 mm	4,0 mm	4,5 mm	
4	1,79	2,35	2,58	2,74	3,21	3,78	4,30	
5	1,84	2,40	2,64	2,85	3,29	3,83	4,36	
6	1,90	2,45	2,69	2,90	3,38	3,90	4,41	
7	1,96	2,48	2,72	2,94	3,45	3,95	4,46	
<b>8</b>	<b>2,00</b>	<b>2,50</b>	<b>2,75</b>	<b>3,00</b>	<b>3,50</b>	<b>4,00</b>	<b>4,50</b>	<b>Nominal Pressure</b>
9	2,06	2,53	2,81	3,05	3,55	4,03	4,52	
10	2,09	2,56	2,84	3,08	3,59	4,06	4,54	
11	2,14	2,60	2,87	3,11	3,65	4,09	4,57	
12	2,17	2,62	2,89	3,15	3,68	4,11	4,60	
13	2,20	2,65	2,91	3,18	3,71	4,14	4,62	
14	2,23	2,68	2,93	3,22	3,75	4,17	4,64	
15	2,25	2,70	2,95	3,25	3,78	4,20	4,66	
<b>16</b>	<b>2,28</b>	<b>2,74</b>	<b>2,97</b>	<b>3,28</b>	<b>3,81</b>	<b>4,23</b>	<b>4,69</b>	<b>Rated Burst Pressure</b>
17	2,30	2,77	3,00	3,32	3,85	4,26	4,71	
18	2,32	2,81	3,03	3,36	3,88	4,29	4,73	
19	2,34	2,84	3,06	3,40	3,92	4,32	4,75	
<b>20</b>	<b>2,36</b>	<b>2,87</b>	<b>3,10</b>	<b>3,43</b>	<b>3,96</b>	<b>4,36</b>	<b>4,78</b>	
21	2,37	2,91	3,14	3,46	4,00	4,40	4,81	
<b>22</b>	<b>2,39</b>	<b>2,94</b>	<b>3,19</b>	<b>3,49</b>	<b>4,05</b>	<b>4,44</b>	<b>4,85</b>	<b>Average Burst Pressure</b>