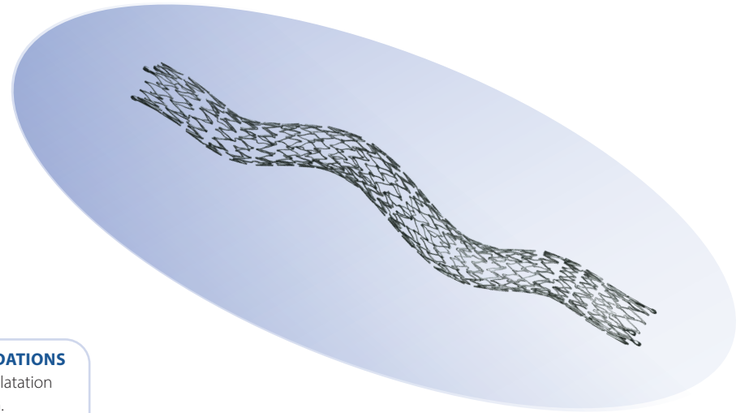
BioMimics 3D

The Swirling Flow® Stent

Veryan

Preparation and Deployment Guide



CREATED WITH DESIGN INTELLIGENCE

Select your stent

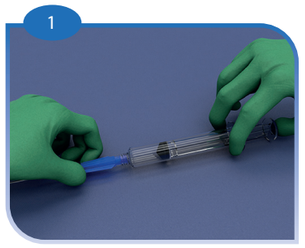
Choose a stent that will extend proximal and distal to healthy vessel. Measure the diameter of the reference vessel proximal and distal to the lesion and, with reference to the table below, use the larger reference diameter to determine the appropriate stent size.

Stent diameter (mm)	Stent length (mm)	Reference vessel diameter (mm)	Stent delivery system OD (inch)	Sheath compatibility*: Fr/Minimum ID (mm)	Guidewire compatibility (inch)
5	60, 80, 100, 125, 150	4.0	0.079	6 / 2.2	0.035
6	60, 80, 100, 125, 150	4.0-5.0	0.079	6 / 2.2	0.035
7	60, 80, 100, 125, 150	5.0-6.0	0.079	6 / 2.2	0.035

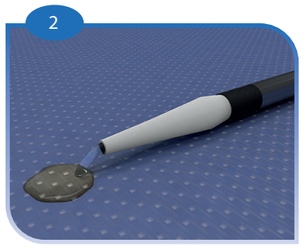
* Evaluated with 6Fr Terumo® Radifocus Introducer II sheath introducers

PRE AND POST STENT DILATATION RECOMMENDATIONS
Pre-dilatation before stent placement and post stent dilatation are both optional and at the discretion of the physician.

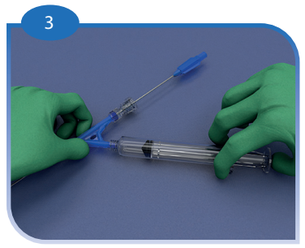
Preparing the delivery system



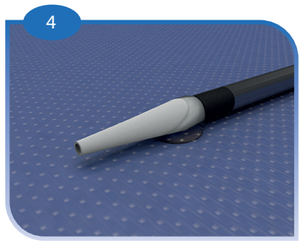
Attach a 5-10 cc syringe filled with heparinised saline to the Luer hub.



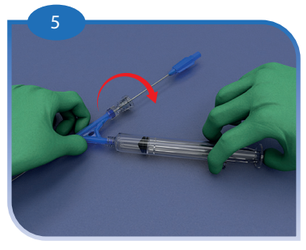
Flush saline solution through the guidewire lumen until it comes out of the Stent Delivery System (SDS) tip.



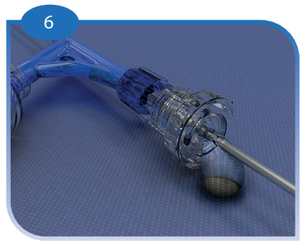
Attach the syringe to the bifurcated Luer.



Flush heparinised saline solution through the outer sheath lumen until it comes out of the distal end.

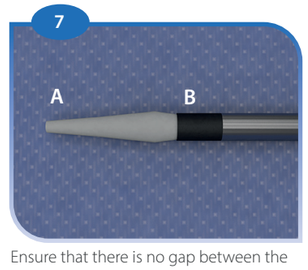


Release the Tuohy Borst valve by turning the thumb screw counter-clockwise and flush the proximal portion of the bifurcated Luer and Tuohy Borst valve.

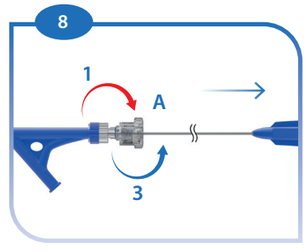


Verify that the heparinised saline solution comes out of the valve cap, and then tighten the Tuohy Borst valve.

Prior to delivery system introduction

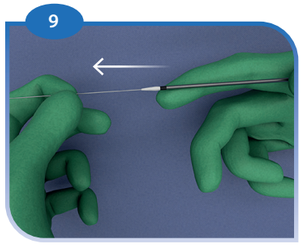


Ensure that there is no gap between the SDS radiopaque tip (A) and the distal end of the outer sheath marker (B). Examine the distal end of the SDS. Do not use if the stent is partially deployed.

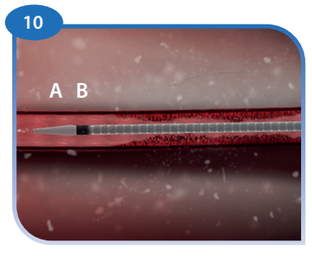


If a gap exists, (1) loosen the Tuohy Borst valve (A) and (2) retract the Luer hub until the SDS tip is flush with the outer sheath marker. (3) Tighten the Tuohy Borst valve once the adjustment is complete.

Delivery system introduction

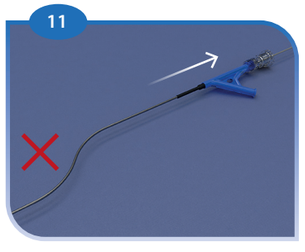


Advance the SDS over the guidewire through the sheath/guide catheter.

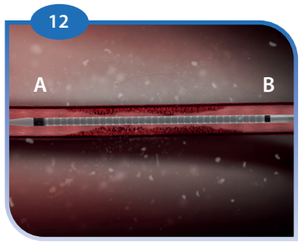


Advance the SDS over the guidewire until the radiopaque tip (A) and distal stent marker (B) are both distal to the target lesion site.

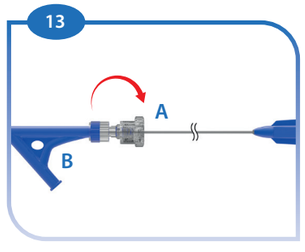
Stent deployment



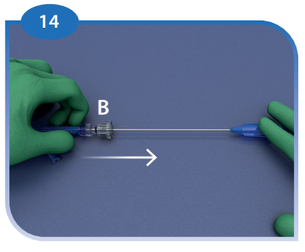
Before stent deployment it is important to ensure that there is no excess slack in the delivery system. If excess slack is apparent in the delivery system prior to deployment, slightly retract the SDS.....



.....to remove the slack while ensuring that the distal stent tantalum markers (A) remain distal to the target lesion and the proximal tantalum markers (B) remain proximal to the target lesion.

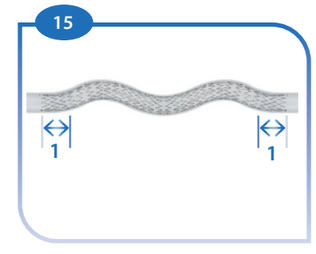


Open the Tuohy Borst valve (A) by holding the bifurcated Luer (B) in a fixed position and rotate the Tuohy Borst valve counter-clockwise.

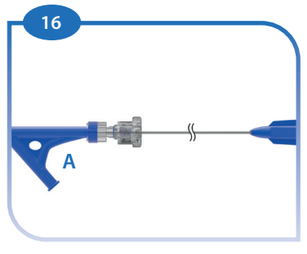


Deploy the stent by holding the Luer hub (A) in a fixed position and move the bifurcated Luer (B) towards the fixed Luer hub (A) until the outer sheath marker passes proximal to the inner shaft marker band and the stent is released and fully expands.

Removing the delivery system



If a second stent is required to cover the target lesion, place the most distal stent first followed by the proximal stent. The length of stent overlapping should be no more than 10mm or the length of three stent crowns (1).



Under fluoroscopic guidance, holding the bifurcated Luer (A), withdraw the entire delivery system, over the guidewire.

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The BioMimics 3D Vascular Stent System is FDA approved.
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PAM-250-Version-2.0

Contraindications, warnings and precautions

CONTRAINDICATIONS

All customary contraindications for angioplasty must be considered when using the BioMimics 3D® Vascular Stent System.
There are additional contraindications:

- Patients whose lesions cannot be crossed with a wire and/or balloon catheter and cannot be dilated sufficiently to allow passage of the delivery system.
- Patients with known intolerance to antiplatelet and/or anticoagulation therapies.
- Patients who are judged to have a lesion that prevents proper placement or deployment of the stent.
- A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion.
- Patients with a known hypersensitivity to nickel, titanium or tantalum.

WARNINGS

General Warnings

- DO NOT use after the "use by" date specified on the label.
- DO NOT use if the sterile package is opened or damaged or any information provided is obscured.
- DO NOT use if the device is damaged or if the stent is partially deployed.
- DO NOT reuse the BioMimics 3D® Stent Delivery System (SDS) – this may lead contamination, infection, and non-performance (limb loss or death). DO NOT re-sterilize the BioMimics 3D® Vascular Stent System.
- This delivery system contains stainless steel which contains a hazardous substance. Cobalt (CAS No. 7440-48- 4) is classified as a carcinogenic, mutagenic, or toxic for reproduction (CMR) substance of Category 1A or 1B, or as an endocrine disruptor (ED), and is present at a concentration >0.1% weight/weight.

Deployment Warnings

- DO NOT force passage if resistance is encountered at any time during delivery of the SDS. This may cause damage to the stent, the SDS, or vessel or may lead to partial deployment. If the stent cannot be deployed, remove the entire delivery system (a partially deployed stent may require surgical removal).
- DO NOT push or advance the SDS forward (distally) once stent deployment has commenced.
- DO NOT attempt to recapture a partially deployed stent using the stent delivery system.
- DO NOT force removal of the delivery system if resistance is encountered at any time during withdrawal (post stent deployment); instead hold the Bifurcated Luer stationary and retract the Inner Shaft until the Distal Tip contacts the Outer Sheath Markerband and withdraw the system as one unit. Applying excessive force could result in loss of delivery system components or damage to the stent, delivery system, or vessel.

PRECAUTIONS

- The SDS is not designed for use with power injection systems.
- Always use an introducer or guide sheath for the implant procedure, to protect the access site.
- Never post-dilate the stent using a balloon that is larger in diameter than the nominal (labelled) diameter of the stent.
- The minimally acceptable introducer or guide sheath size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size introducer or guide sheath than indicated on the label.
- Prior to deployment, ensure adequate distance between the proximal end of stent and the introducer/guide sheath to prevent deployment within introducer/guide sheath.
- This device has not been tested in patients who are pregnant or patients who may be pregnant.
- Take caution when considering whether to use this device in a vessel in which there may be a residual stenosis of 50% diameter or larger in the target vessel after the planned intervention.
- In patients with poor kidney function, contrast agents may precipitate kidney failure.
- The stent is intended for use by physicians who have received appropriate training in endovascular intervention and placement of vascular stents.
- Failure to hold the Luer Hub in a fixed position during stent deployment may result in partial or inaccurate deployment, incorrect deployed stent length or increased deployment forces.
- The reference vessel diameter should be measured accurately to reduce the possibility of stent migration or vessel damage due to incorrect sizing.
- The SDS is not intended for repositioning or recapturing a partially or completely deployed stent.
- If a second BioMimics 3D® stent is required, deliver the most distal stent first to minimize the risk of stent dislodgement/damage or unsuccessful delivery of the second stent.
- If a second BioMimics 3D® stent is placed in sequence and overlapped, the overlap should be less than 10mm. Overlapping more than two stents has not been evaluated.
- If the procedure requires additional non-BioMimics 3D® stent placement, a Nitinol stent should be selected. The risk of corrosion increases if stents of differing metals contact one another.
- Caution should be used when crossing the deployed stent with any ancillary devices.
- The BioMimics 3D® SDS is not designed for guidewire exchanges. If a guidewire exchange is needed or desired, remove the delivery system first.
- Carefully inspect the sterile package and device prior to use to verify that neither has been damaged during shipment.
- The BioMimics 3D® SDS is provided sterile for single use only and should be used by the end of the month of the "Use By" date printed on the package.
- After use the BioMimics 3D® SDS is a potential biohazard. Handling and disposal should be in accordance with medical practice and local regulations.
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