BioMimics 3D
The Swirling Flow® Stent

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BioMimics 3D Vascular Stent System

- A peripheral self-expanding nitinol stent with a three dimensional (3D) helical shape. Laser cut from a straight nitinol tube the 3D helical shape is stored in the nitinol shape memory. (Figure 1)
- 6Fr over-the-wire (OTW) stent delivery system (SDS) for use with a 0.035" guidewire. (Figure 2)
- Radiopaque proximal marker band and distal tip that aid placement of the stent.
- Available in a range of lengths and diameters.

INDICATIONS:

The BioMimics 3D Vascular Stent System is indicated to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery and/or proximal popliteal artery, with reference vessel diameters ranging from 4.0 - 6.0 mm and lesion lengths up to 140 mm.

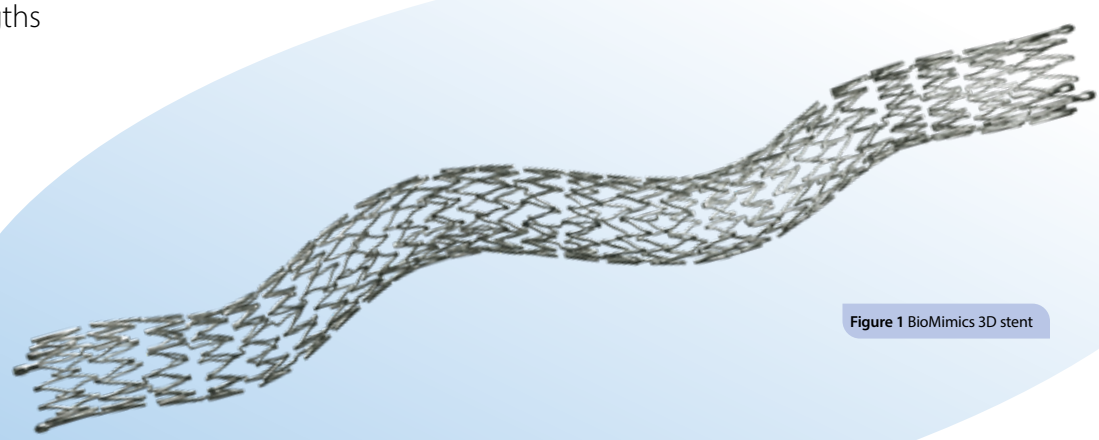


Figure 1 BioMimics 3D stent

Figure 2 Stent delivery system

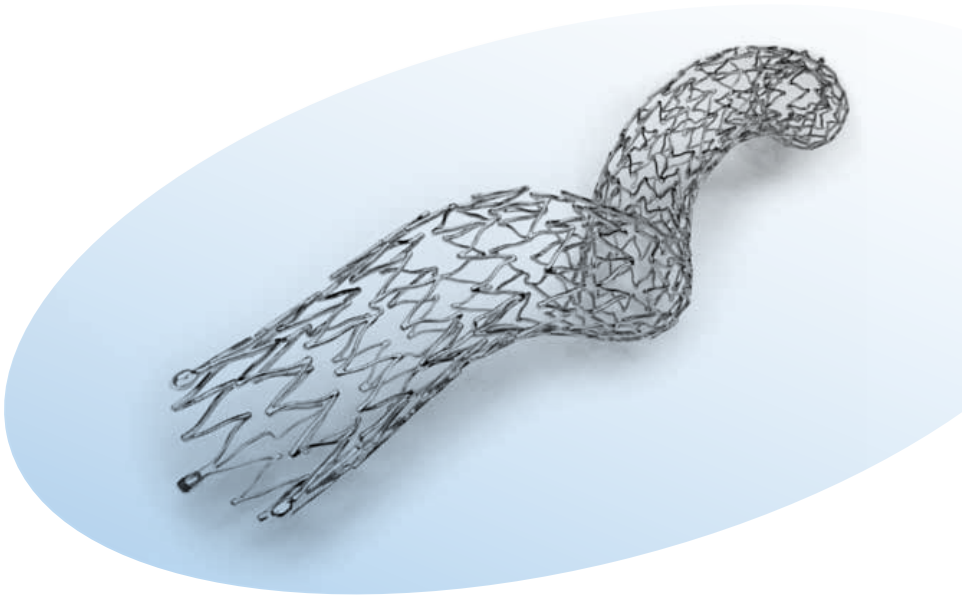
Technical Specifications

BioMimics 3D Delivery System	
Catheter design	Over-the-wire
Working length	113 cm
Shaft profile	6Fr / 2.0 mm
Sheath compatibility	6Fr (minimum ID of 2.2 mm)
Radiopaque markers	Radiopaque atraumatic system
	Distal outer sheath
	Tantalum proximal system marker
Guidewire compatibility	0.035"

BioMimics 3D Stent	
Stent material	Nickel-titanium alloy: nitinol
Radiopaque markers material	Tantalum
Radiopaque markers number and location	3 distal and 3 proximal
Radiopacity	Excellent[1]
Fracture resistance	Excellent[1]
MRI compatibility	MRI conditional

Ordering information

Quick order reference	Catalog number	Stent diameter (mm)	Reference vessel diameter (mm)	Stent length (mm)	Sheath compatibility*: Fr/Minimum ID (mm)	Guidewire compatibility (mm)
5x60	142122-01	5	4.0	60	6 / 2.2	0.035
5x80	142122-05	5	4.0	80	6 / 2.2	0.035
5x100	142122-09	5	4.0	100	6 / 2.2	0.035
5x125	142122-13	5	4.0	125	6 / 2.2	0.035
5x150	144700-05	5	4.0	150	6 / 2.2	0.035
6x60	142122-02	6	4.0-5.0	60	6 / 2.2	0.035
6x80	142122-06	6	4.0-5.0	80	6 / 2.2	0.035
6x100	142122-10	6	4.0-5.0	100	6 / 2.2	0.035
6x125	142122-14	6	4.0-5.0	125	6 / 2.2	0.035
6x150	144700-12	6	4.0-5.0	150	6 / 2.2	0.035
7x60	142122-03	7	5.0-6.0	60	6 / 2.2	0.035
7x80	142122-07	7	5.0-6.0	80	6 / 2.2	0.035
7x100	142122-11	7	5.0-6.0	100	6 / 2.2	0.035
7x125	142122-15	7	5.0-6.0	125	6 / 2.2	0.035
7x150	144700-19	7	5.0-6.0	150	6 / 2.2	0.035



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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 to infection, contamination and non-performance.
- DO NOT re-sterilize the BioMimics 3D Vascular Stent System.

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 SDS tip contacts the outer sheath marker 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 (labeled) 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.

* Evaluated with 6Fr Cordis® Brite Tip and 6Fr Terumo® Radifocus Introducer II sheath introducers
1. Data on file at Veryan Medical

For additional information please contact your local representative.

FOR SALES
T (844) 864 2001
E ussales@veryanmed.com
W veryanmed.com

FOR ORDERS & CUSTOMER SERVICE
T (844) 864 2001
E us-customerservice@veryanmed.com
W veryanmed.com

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