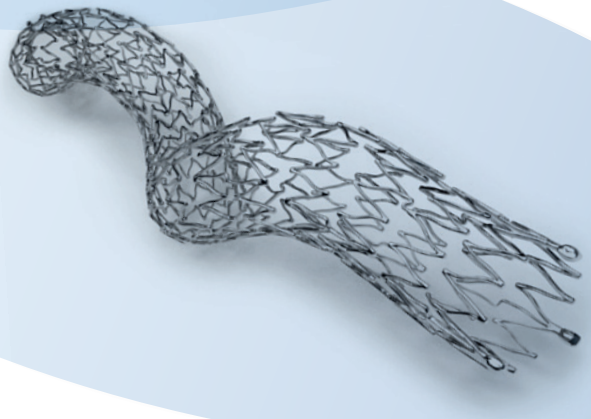
BioMimics 3D

The Swirling Flow® Stent

MIMICS 2

Three-Year Results



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MIMICS 2 Three-Year Results

Summary

MIMICS-2 is a prospective, single-arm, multicenter clinical study conducted under FDA-approved Investigational Device Exemption to evaluate the safety and effectiveness of the BioMimics 3D Vascular Stent System in the treatment of patients with symptomatic atherosclerotic disease of the femoropopliteal artery.

Baseline Demographics & Lesion Characteristics		N=271 Subjects
Age	Mean years ± SD (N)	68.4 ± 9.5 (271)
Risk factor	Diabetes Mellitus	45.4% (123/271)
Rutherford category	2/3/4	99.6% (270/271)
Lesion location	Mid/Distal	88.5% (239/270)
Lesion length	Mean ±SD (mm)	81.2 ± 38.4 (269/271)
Total occlusion	%	30.0 (81/270)
Lesion calcification	Moderate / Severe	45.9 (124/270)
BioMimics 3D Stents*	# Stents / N	305 / 271
Stented Segment**	Mean ± SD (mm)	112.3 ± 36.3 (269/271)

Study Principal Investigators:
Timothy M. Sullivan, MD
Minneapolis, MN, USA

Thomas Zeller, MD
Bad Krozingen, Germany

Masato Nakamura, MD
Tokyo, Japan

43 investigational sites enrolled 271 subjects:
US: 31 sites N =162
Germany: 6 sites N =78
Japan: 6 sites N =31

- **Duration of follow-up:** 3 years.
- Independent committee adjudication of clinical events.
- Core laboratories: Duplex ultrasound; angiography and X-ray.

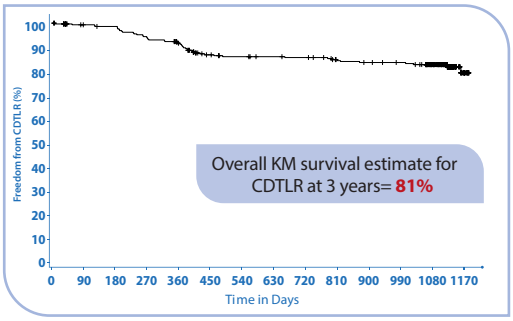
Results

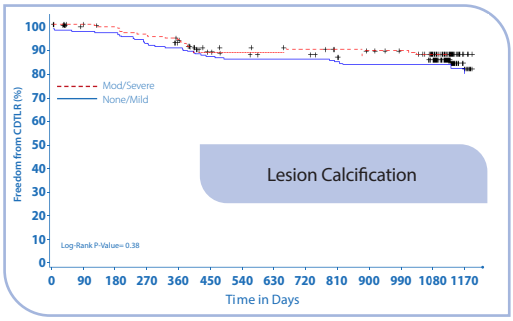
Overview of 3 Year Results from MIMICS-2

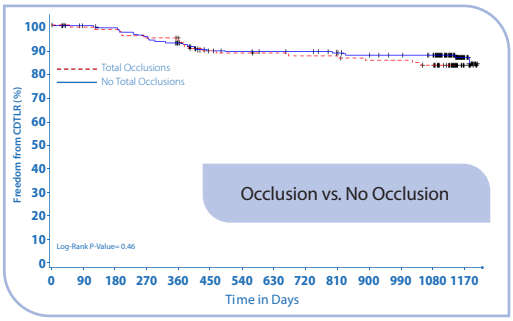
Primary Safety Endpoint***	30 days	99.6%
Stent fracture/Core Lab review	Maintained out to 3 years	0%
KM freedom from loss of primary patency	12 months	83%
KM freedom from CDTLR****	12 months	89%
	2 Years	84%
	3 Years	81%

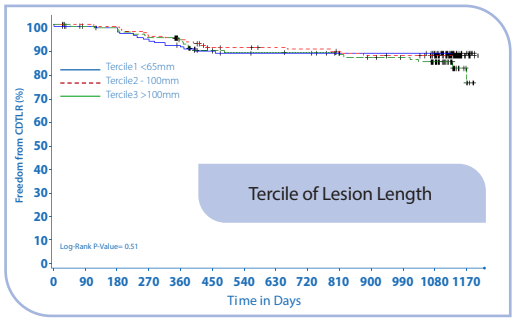
Rigorous, high quality data shows continuing benefit at
3 years

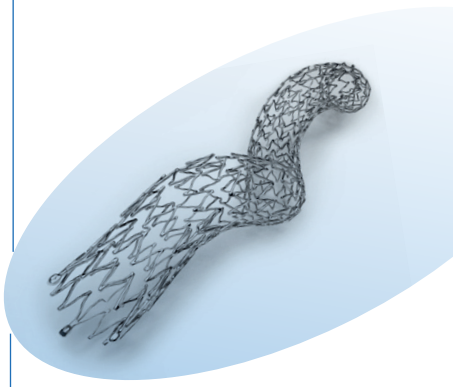
Continuing benefit at 3 years even in challenging cases











* Investigator-reported

** CoreLab-reported

*** Major Adverse Events comprising death, major amputation on index limb or CDTLR through Day 30.

****Core Lab adjudicated, clinically-driven TLR with objective evidence. Subjects are censored at their last known follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.[1]

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Conclusions

MIMICS-2 shows continuing benefit of the BioMimics 3D Vascular Stent System at 3 Years, even in challenging cases:

- Reproducible, rigorous, high quality data from US, Japan and Europe.
- 81% freedom from CDTLR at 3 years.
- Comparable outcomes to DES/DCB despite more challenging lesions and without the need for lesion preparation.
- Providing ease-of-use simplicity and long-term benefits.
- Core Lab X-ray imaging review confirmed 0% stent fracture .

The BioMimics 3D Vascular Stent System reduces the burden of re-intervention for the patient and the health care system.[1,2]

The MIMICS Clinical Program: An evolving database of the safety and effectiveness of the BioMimics 3D Vascular Stent System.

Gathering clinical evidence from a "real world" patient population from single de novo to complex, long and severely calcified lesions.

1750+
patients and growing

MIMICS *FIH*	MIMICS *RCT*	MIMICS *2*	MIMICS 3D	MIMICS 3D *USA*	MIMICS *et seq*
N = 10 1 site Germany	N = 50 8 sites Germany	N = 271 43 sites USA/Japan/Germany	N = 507 23 sites Pan European	N = c. 500 c. 40 sites USA	N = c. 400 Multiple sites Europe
• First in Human • FU - 1 year • Completed	• Randomized controlled trial • FU - 2 years • Completed	• IDE Registry • FU - 3 years • Completed	• Prospective Registry • FU - 3 years • 2 years complete	• Prospective Registry • FU - 3 years • Enrolment ongoing	• Physician initiated prospective and retrospective registries • Enrolment ongoing

MIMICS *RCT*
A randomized study comparing safety and effectiveness of the BioMimics 3D Vascular Stent System to a straight stent control. Freedom from loss of primary patency through 2 years for BioMimics 3D Vascular Stent System was superior (P = 0.05) to straight control stents (72% vs 55%). There were no stent fractures at 2 years for patients treated with the BioMimics 3D Vascular Stent System.[3]

MIMICS *2*
A multicenter, international (USA, Japan and Germany) IDE study. At 3 years follow-up BioMimics 3D demonstrated continuing benefit with CDTLR showing comparable outcomes to DES/DCB. Core Lab X-ray imaging review confirmed 0% stent fracture in any MIMICS-2 subject treated with BioMimics. MIMICS-2 represents a more challenging patient population. than in DES/DCB pivotal trials.[4,5].

MIMICS 3D
A prospective observational registry evaluating the BioMimics 3D Vascular Stent System in a real-world clinical population with a dedicated subgroup analysis of device performance as a complementary treatment in procedures involving drug-coated balloons. MIMICS-3D enrolled 507 patients across 23 clinical sites in Europe.

MIMICS 3D *USA*
A prospective, multicenter observational study evaluating the safety, effectiveness and device performance of the BioMimics 3D Vascular Stent System within a real-world clinical population of patients undergoing femoropopliteal intervention. MIMICS-3D USA will enrol a minimum of 500 patients in up to 40 sites across the United States.

1. Data on file at Veryan Medical
2. Kearns BMJ 2016
3. Zeller T et al; Circ Cardiovasc Interv. 2016;9
4. Kenneth Rosenfield et al :N Engl J Med 2015;373:145-53. DOI: 10.1056/NEJMoa1406235
5. Michael D. Dake et al : Circ Cardiovasc Interv. 2011;4:495-504

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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.

For additional information please contact your local representative.

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