VeGa™

MRI Active Pacing Leads

FEATURING INNOVATIVE SILGLIDE® TECHNOLOGY

Streamline the implant procedure

MicroPort™ CRM

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VeGa™

A unique combination of flexibility, *slide* and control [1,2]

Silicone + *Silglide®*

Silicone lead body for flexibility
Innovative Silglide® coating for enhanced slide.[1]

6F *lead body*

More Length Choice

→ 45 cm → 52 cm → 58 cm

Precision Tip

High X-ray visibility allows for fast and precise lead placement.[3]

Proven Safety

Vega builds on the reliability and experience of the **Beflex** lead generation with a 99.9% implant survival rate after 6 years.[4]

MRI *Conditional*

Allowing patients to safely undergo MRI scans and benefit from AutoMRI mode.[5,6]

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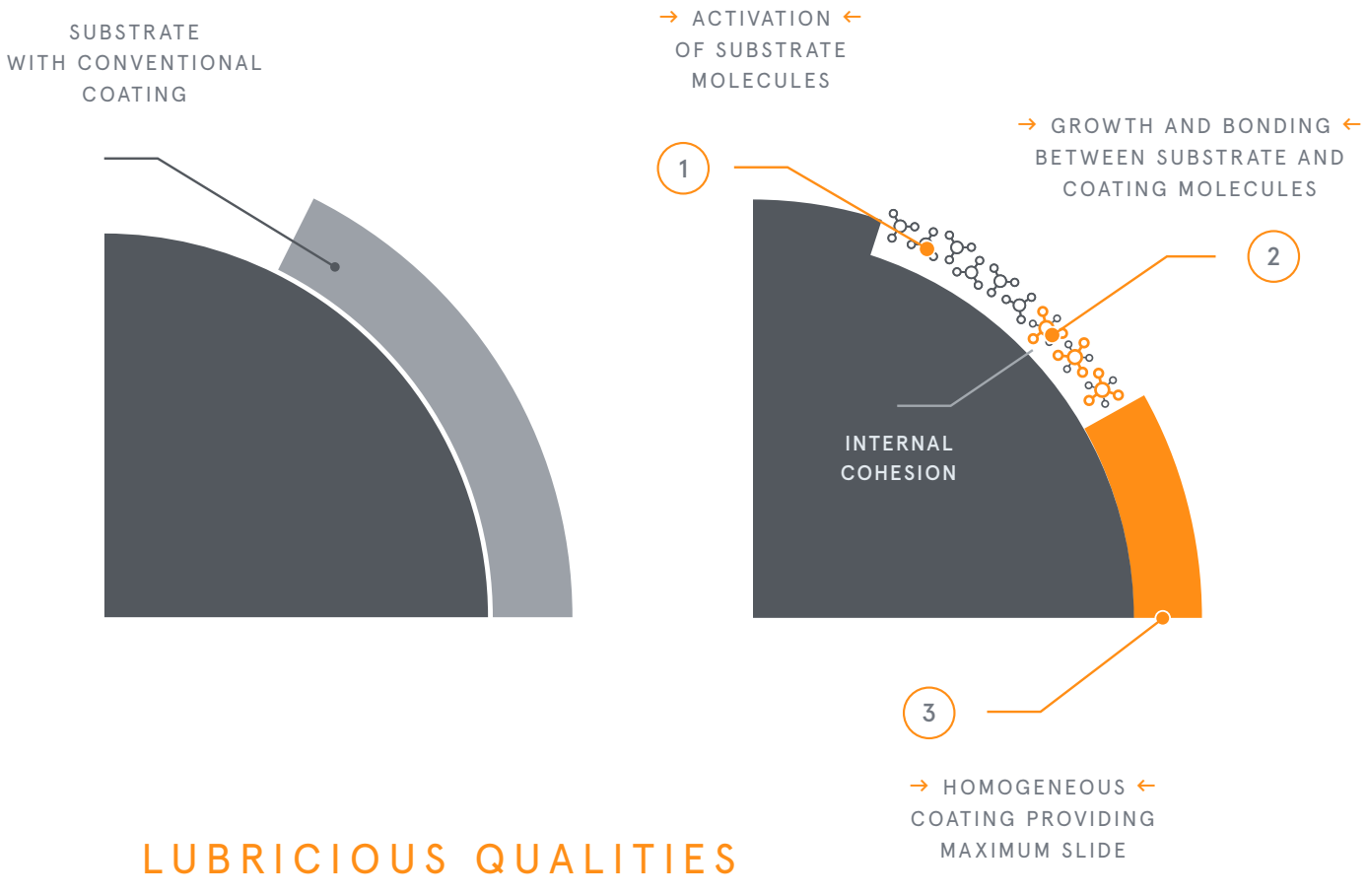
Silglide® + Silicone

The combination of the Silicone body with *Silglide*® coating offers natural flexibility with enhanced gliding for smoother implants[1]

Silglide® is a surface enhancement that treats the silicone tubing of the lead using a vacuum plasma polymerization deposition process.

CONVENTIONAL COATING

PLASMA POLYMERIZATION COATING PROCESS



LUBRICIOUS QUALITIES OF *SILGLIDE®*

- → Facilitates insertion
- → Enables swift advancement through the veins
- → Reduces surface friction
- → Facilitates placement of multiple leads

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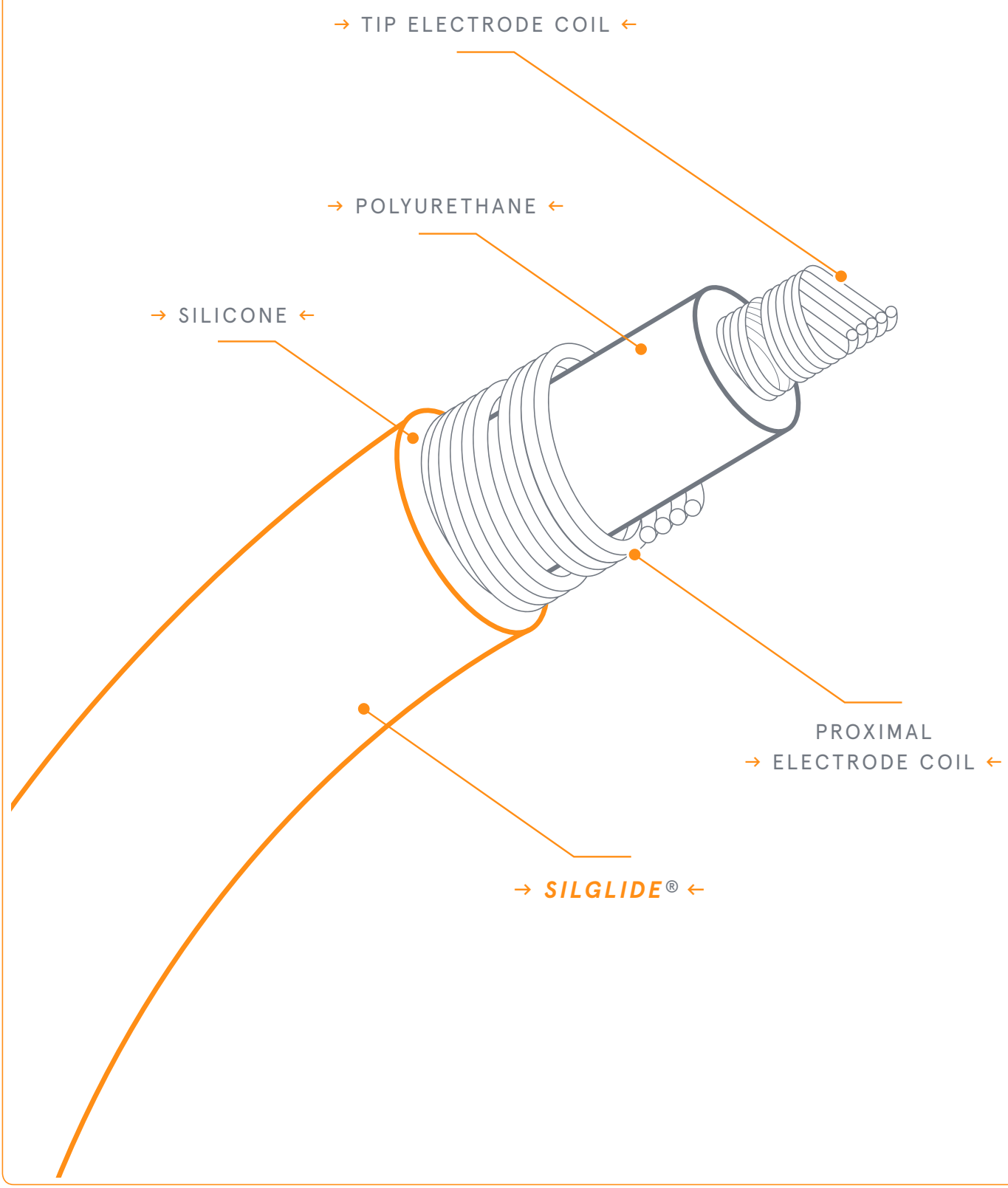
BODY TECHNOLOGY

Bipolar coaxial Internal conductor structure

- → High X-ray visibility[3]
- → Maximum torque response[2]
- → Polyurethane internal insulator
  - *Smooth helix extension and retraction*[7]
  - *Internal coil friction reduction*


→ TIP ELECTRODE COIL ←
→ POLYURETHANE ←
→ SILICONE ←
PROXIMAL
→ ELECTRODE COIL ←
→ SILGLIDE® ←

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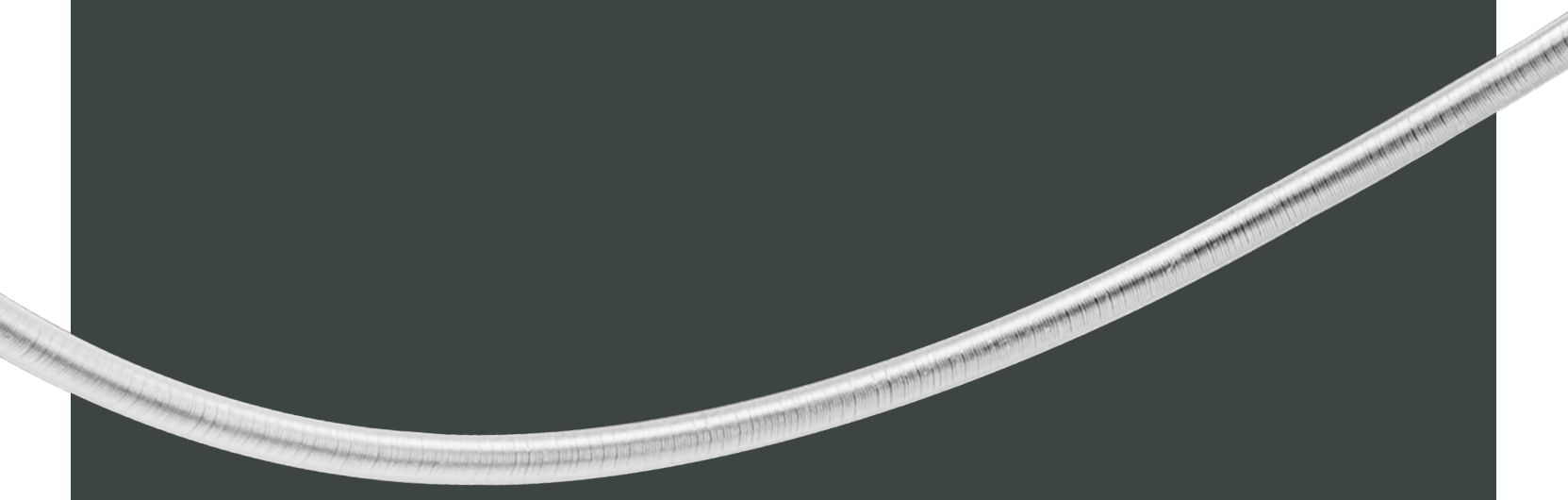
TIP TECHNOLOGY

Reduced 4 mm² pacing surface

- → Increases pacing efficiency[8]
- → Improves sensing detection[8]
- → Reduces polarization[8]



→ STEROID COLLAR ←

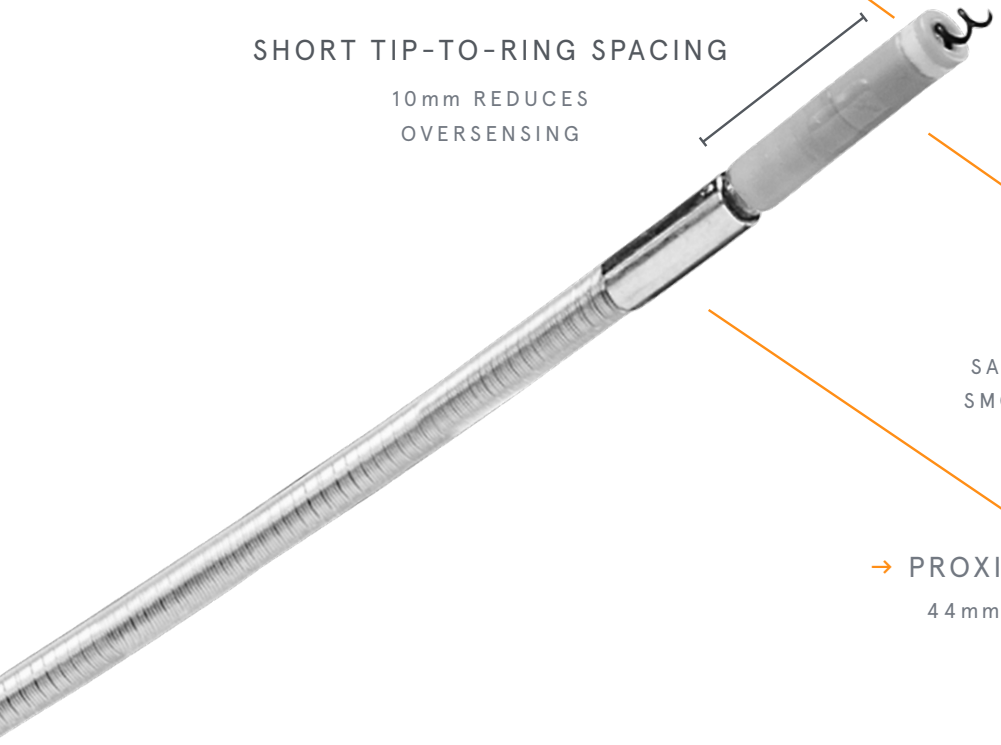
310 µg DSP*
REDUCES TISSUE INFLAMMATION
LOWERS ACUTE/CHRONIC THRESHOLDS

→ 1.5 mm ACTIVE HELIX ←

REDUCES PERFORATION RISK [8]
4mm² Pt-Ir TiN COATED ELECTRODE

SHORT TIP-TO-RING SPACING

10mm REDUCES
OVERSENSING



→ PEEK** HOUSING ←

SAFE HELIX PROTECTION ENSURES
SMOOTH EXTENSION/RETRACTION [6]

→ PROXIMAL ELECTRODE ←

44mm² Pt-Ir ELECTRODE

** Dexamethasone Sodium Phosphate*
***Polyether ether ketone*

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PRECISION TIP

ENGINEERED FOR
EXCELLENT X-RAY VISIBILITY[3]

—

VERY FAST LEAD TIP POSITIONING
CONFIRMED BY THE EVALUATION
OF MORE THAN 200 IMPLANTS[10]

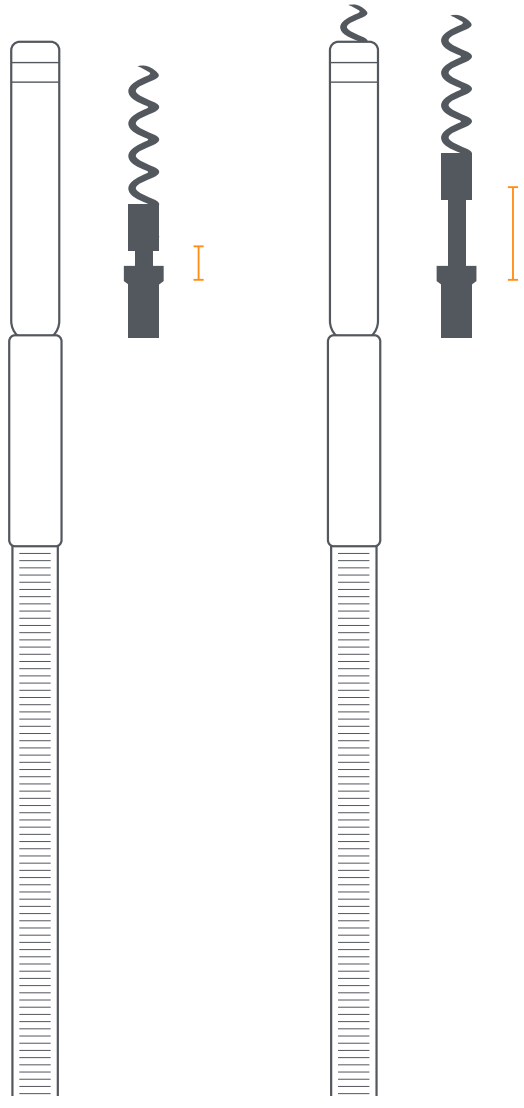
—

VERY GOOD MANEUVERABILITY
IN THE CHAMBER[2]

Pleasure-S Clinical Study

X-RAY VISIBILITY

PIN-DRIVEN SCREW
WITH X-RAY MARKER
FOR CLEAR VISIBILITY
OF HELIX EXTENSION[3]



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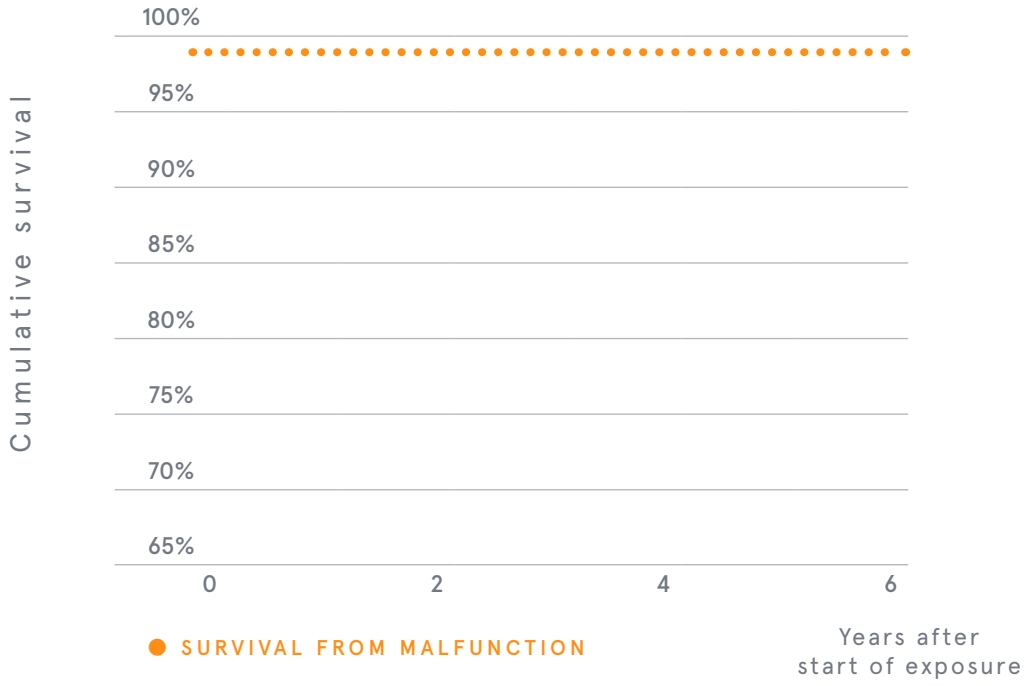
SAFETY & SECURITY

Building on the reliability and experience of the Beflex lead generation with a

99.9%

IMPLANT SURVIVAL RATE
AFTER 6 YEARS.[4]

PRODUCT PERFORMANCE - BEFLEX RF45D/RF46D *



CUMULATIVE SURVIVAL FROM MALFUNCTION WITH 95% CONFIDENCE INTERVAL AS A FUNCTION OF YEARS AFTER IMPLANT

	01	02	03	04	05	06
Implant survival rate (%)	**99.97**	**99.94**	**99.91**	**99.91**	**99.86**	**99.86**
Upper confidence interval (+)	0.01%	0.02%	0.03%	0.03%	0.05%	0.05%
Lower confidence interval (-)	0.02%	0.03%	0.04%	0.04%	0.07%	0.07%

** Cut-off date 31/12/15*

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Technical Specifications

CHARACTERISTICS			VEGA R45	VEGA R52	VEGA R58
LENGTH			45 cm	52 cm	58 cm
MRI CONDITIONAL[5]			✓	✓	✓
CONNECTOR	IS-1 BI (3.2 mm)		✓	✓	✓
	Serial number identification		45DRG	52DRG	58DRG
FIXATION	Pin driven Retractable Screw		✓	✓	✓
	Screw length		1.5 mm	1.5 mm	1.5 mm
	X-ray markers		✓	✓	✓
	Max number of turns to fully Extend / retract the screw	Straight Stylet	8	9	10
		J-Stylet	14	15	16
INTRODUCER	1 lead		7 F		
	1 lead + guidewire		9.5 F		
DISTAL ELECTRODE	Shape		Active screw		
	Material		Pt / Ir + TiN coating		
	Pacing surface		4 mm²		
	Steroid		310 µg of DSP*		
PROXIMAL ELECTRODE	Material		Pt / Ir		
	Surface		44 mm²		
	Inter-electrode distance		10 mm		
LEAD BODY	Diameter		6 F (2 mm)		
	Insulation		Silicone tubing with Silglide® surface treatment		
	Conductors		MP35N®		
	Internal coil		4 wires (max resistance 50 Ohm)		
	External coil		4 wires (max resistance 100 Ohm)		
ORDER CODES	Lead		TLD040C	TLD041C	TLD042C
	Stylet kit		RLK40C	RLK41C	RLK42C

** Dexamethasone Sodium Phosphate*

REFERENCES

1. Applied membrane technology AMT brochure "USP Class 6 Medical implantable Grade coating" available at www.appliedmembranetech.com.
2. During Pleasure-S Clinical Study, "97% of clinical evaluation investigators concluded that BEFLEX leads had either "equal", "better" or "the best" maneuverability in the ventricle when compared to other similar models used; 94% of clinical evaluation investigators concluded that BEFLEX leads had either "equal", "better" or "the best" maneuverability in the atrium when compared to other similar models used". SORIN data on file.
3. During Pleasure-S Clinical Study, "95% of clinical evaluation investigators concluded that BEFLEX leads had either "equal", "better" or "the best" X-ray Markers visibility in the atrium when compared to other similar models used; 94% of clinical evaluation investigators concluded that BEFLEX leads had either "equal", "better" or "the best" X-ray Markers visibility in the ventricle when compared to other similar models used". SORIN data on file.
4. Product performance report, P46, May 2016, available at www.crm.microport.com
5. When implanted with KORA 100 and KORA 250 (DR & SR) pacemakers under their intended conditions of use. More details can be found in the MRI solutions manual (KORA 100: ref U201, KORA 250: ref U641).
6. Savouré A, Mechulan A, Burban M, Olivier A, and Lazarus A. The Kora Pacemaker is Safe and Effective for Magnetic Resonance Imaging. Clin Med Insights Cardiol. 2015; 9: 85–90.
7. During Pleasure-S Clinical Study, "94% of investigators concluded that BEFLEX leads had either "equal", "better" or "the best" ease of extension/retraction of helix in the ventricle". Sorin data on file.
8. Kenneth A. Ellenbogen, Bruce L. Wilkoff, G. Neal Kay, Chu Pak Lau, Angelo Auricchio. Clinical Cardiac Pacing, Defibrillation and Resynchronization Therapy. Elsevier Health Sciences; 5th Edition; March 2016.
9. Product performance report 2016 shows that in more than 60,000 leads implanted worldwide only 1 perforation and 1 lead dislodgment occurred as chronic lead complications.
10. During Pleasure-S Clinical Study, "94% of investigators concluded that BEFLEX leads had either "equal", "better" or "the best" lead placement time in both the atrium and the ventricle". Sorin data on file.

Refer to VEGA implant manual (ref. U921) furnished with the lead for complete instructions for intended use and relevant warnings, precautions, side effects, and contraindications.

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