xFine™

MRI Passive Pacing Leads

WORLD'S THINNEST LEAD BODY FEATURING TWIN CONDUCTOR WIRES AND IRIS TIP TECHNOLOGY [1,2,3,4,5]

Achievable excellence x2

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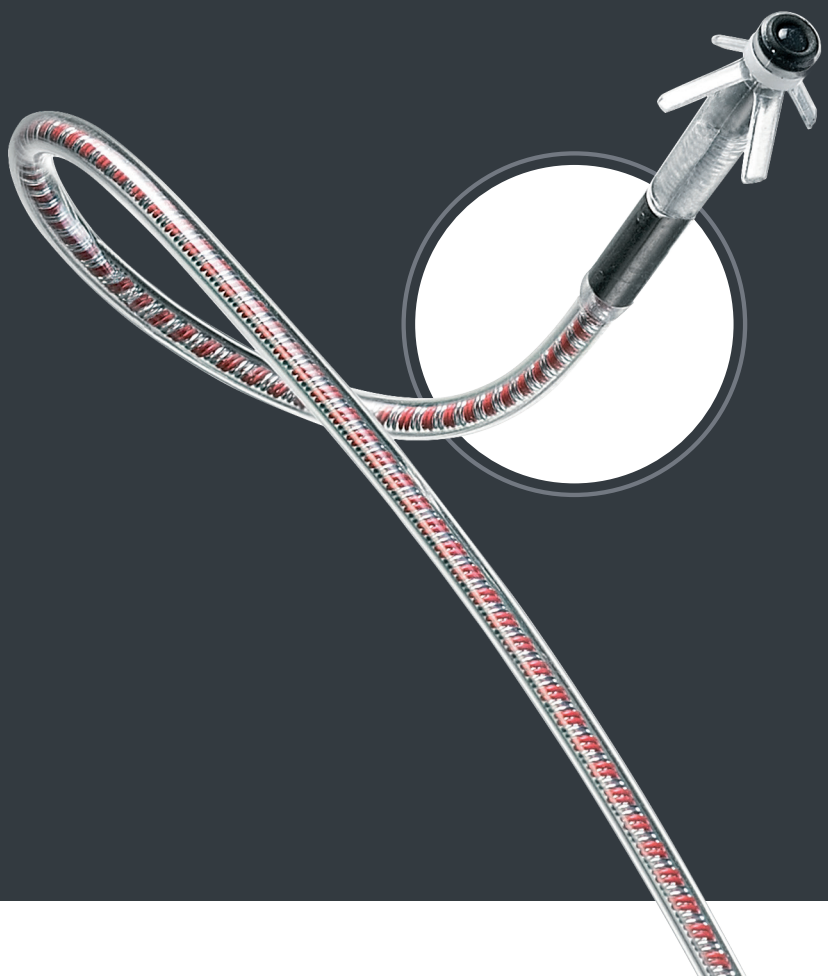
xFine™

Performance, range and reliability *all* in your hands.[6]



World's *Thinnest* Lead Body

4.8 F lead body

A Complete Portfolio

Straight → 52 cm or 58 cm
J-Shape → 45 cm or 52 cm

Dual *Safety*

Double insulation + Twin conductor wires

High *Performance*

Bi-material conductors

Iris Design™

Featuring Iris Tip technology for optimum contact with the heart

MRI Conditional[7,8]

Allowing patients to safely undergo MRI scans and benefit from AutoMRI mode

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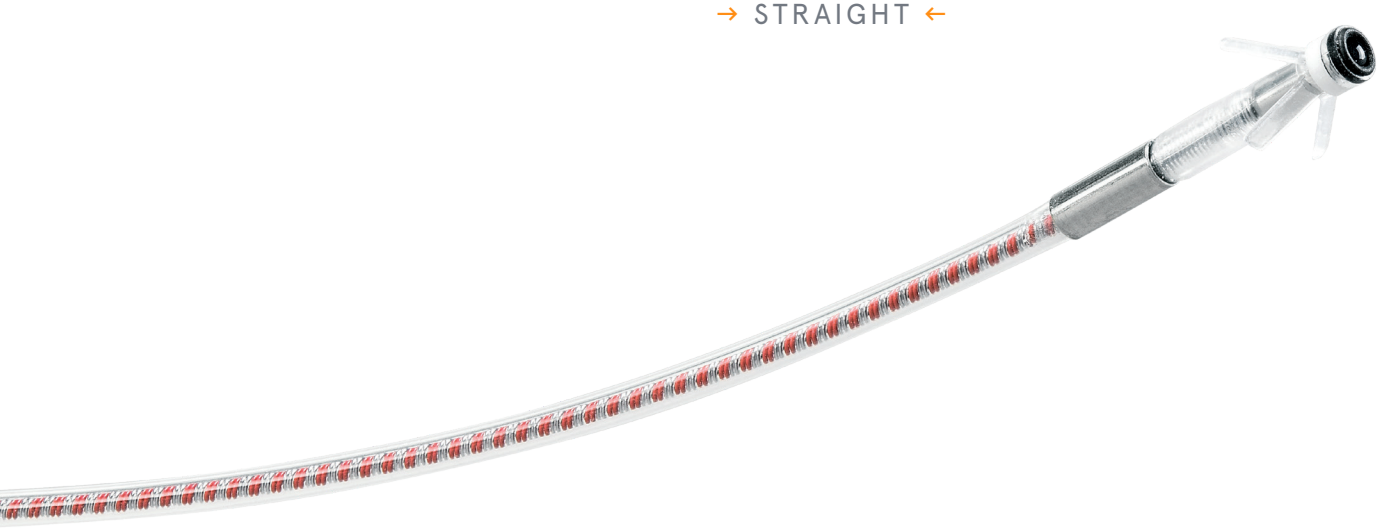
BODY TECHNOLOGY

×Fine's thin lead body is thanks to its polyurethane coating *combined* with a co-radial inner structure

- → Co-radial structure ensures enhanced ***flexibility***
- → Polyurethane coating ensures excellent ***pushability*** and enhances sliding
- → 4.8 F lead body, the world's thinnest, enhances ***maneuverability***[9]

→ STRAIGHT ←



→ J-SHAPE ←

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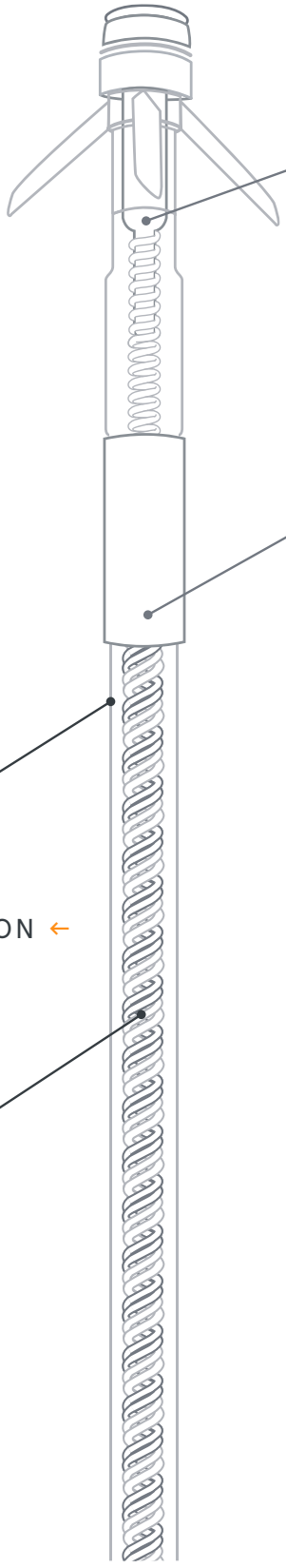

→ ***DISTAL*** ELECTRODE ←

connected with 2 wires

→ ***PROXIMAL*** ELECTRODE ←

connected with 2 wires

→ ***POLYURETHANE*** BODY INSULATION ←

Higher resistance
to abrasion

→ ***ETFE**** WIRE INSULATION ←

Each conductor wire is
insulated separately

** Ethylene Tetrafluoroethylene*

DUAL SAFETY

Two is better than one

Two independent wires are connected
to *each electrode* ensuring
greater reliability.

Dual Insulation

Co-radial technology allows for
two layers of insulation, a *ETFE* coating* for
the conductor wires
and a *polyurethane insulation*
for the lead body.

** Ethylene Tetrafluoroethylene*

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HIGH PERFORMANCE

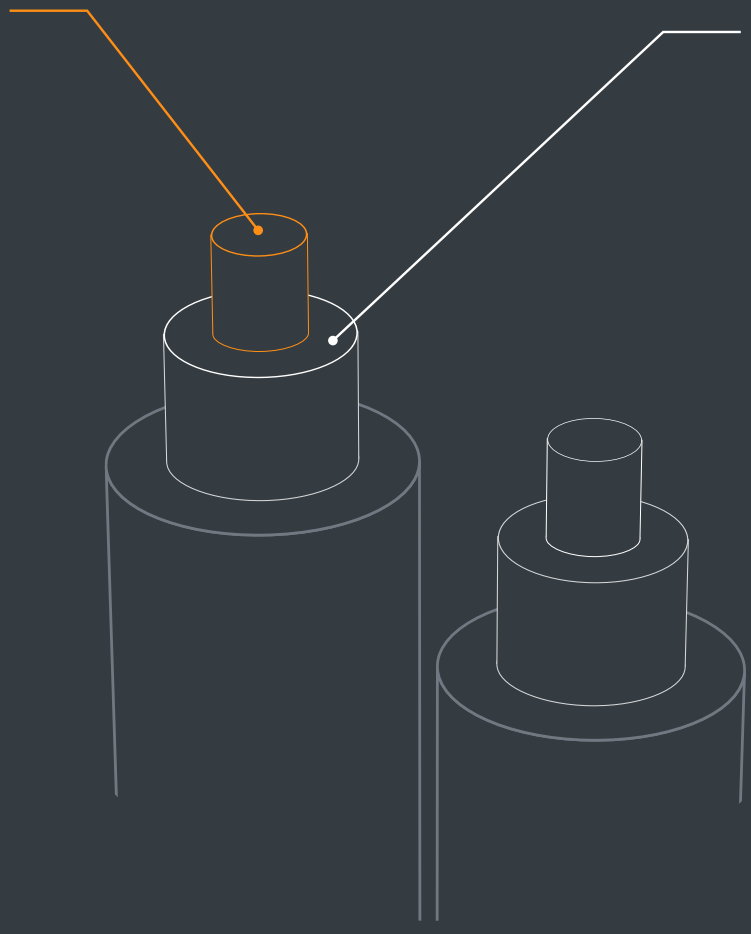
DFT®* WIRE TECHNOLOGY ALLOWS FOR A VARIETY OF PROPERTIES IN A SINGLE WIRE SYSTEM

→ SILVER CORE ←

ENSURES HIGH CONDUCTIVITY AND INCREASED ENERGY EFFICIENCY

→ MP35N® CONTOUR ←

ENSURES HIGH RESISTANCE TO CORROSION AND INCREASED MECHANICAL RESISTANCE



** Drawn Filled Tube*

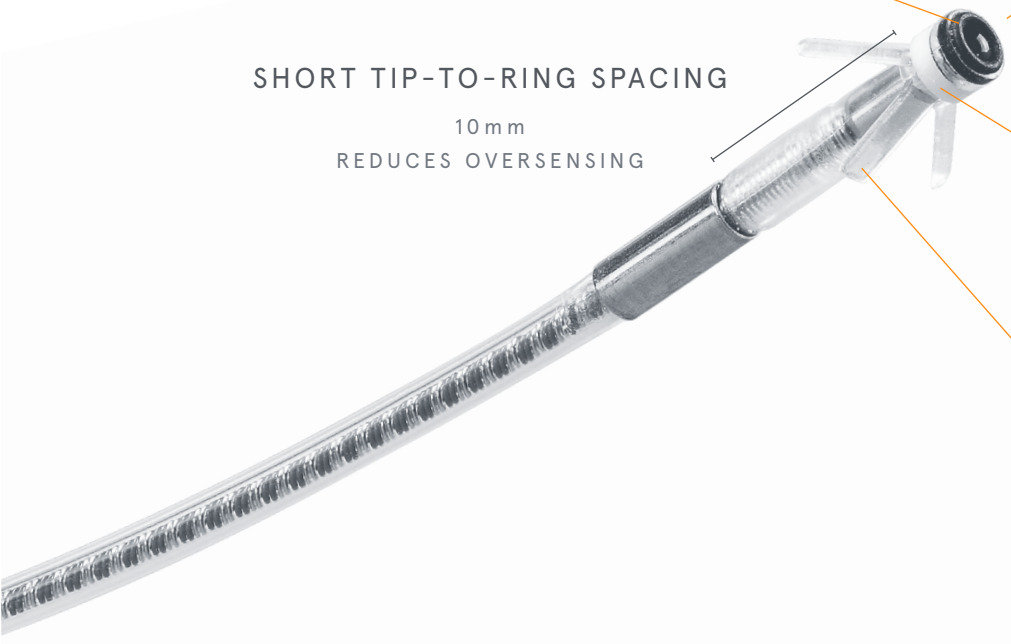
TIP TECHNOLOGY

→ CARBON ELECTRODE ←

POROUS PROPERTIES PROVIDE MAXIMUM MICROSCOPIC SURFACE FOR HIGHER PACING AND SENSING EFFICIENCY

→ IRIS DESIGN™ ←

FOR OPTIMUM CONTACT WITH THE HEART



SHORT TIP-TO-RING SPACING

10 mm
REDUCES OVERSENSING

→ STEROID COLLAR ←

REDUCES TISSUE INFLAMMATION

→ HELICAL TINES ←

FOR EASIER INTRODUCTION AND OPTIMUM RETENTION

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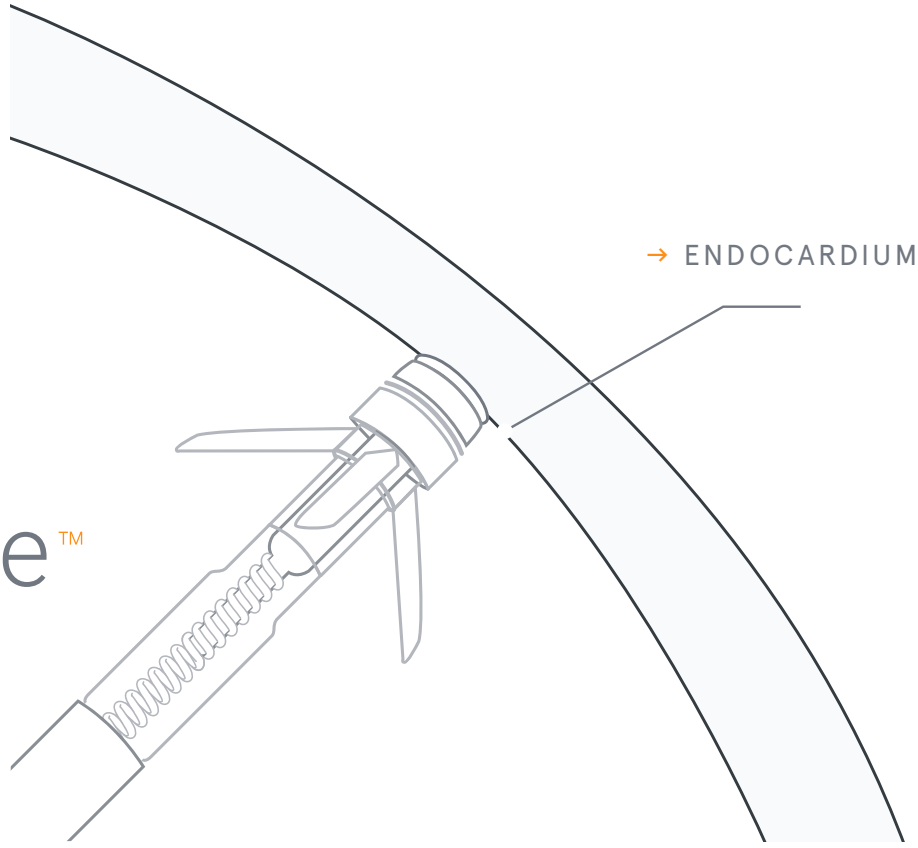

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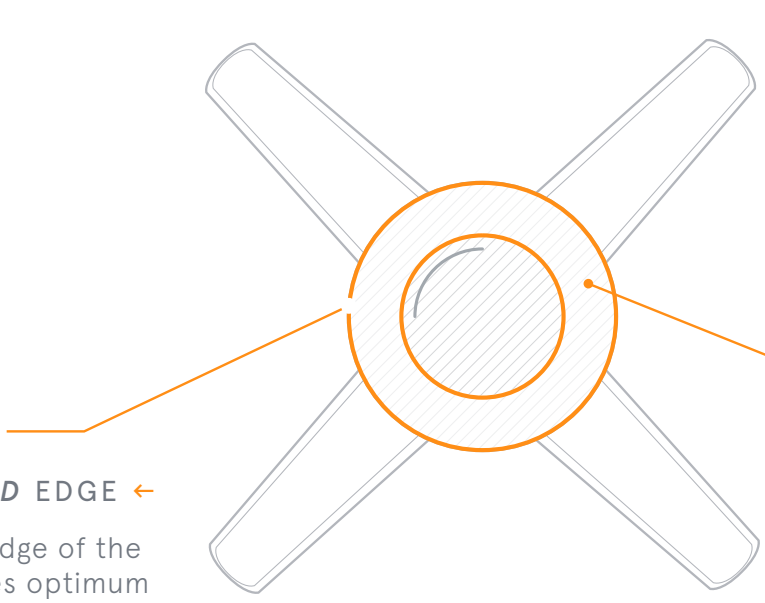

→ ***CONTACT*** AREA ←

Maximized contact surface limits risk of perforation [10]

→ ***CURVED*** EDGE ←

Curved edge of the tip ensures optimum electrical contact, regardless of the lead position

→ ***2mm² TIP*** SURFACE AREA ←

Higher impedance levels and optimal device longevity

IRIS DESIGN™

Minimum pacing surface with maximum contact

The Iris design™ of the distal electrode allows for a pacing area of just *2 mm²*. While at the same time *maximizing* the contact surface.

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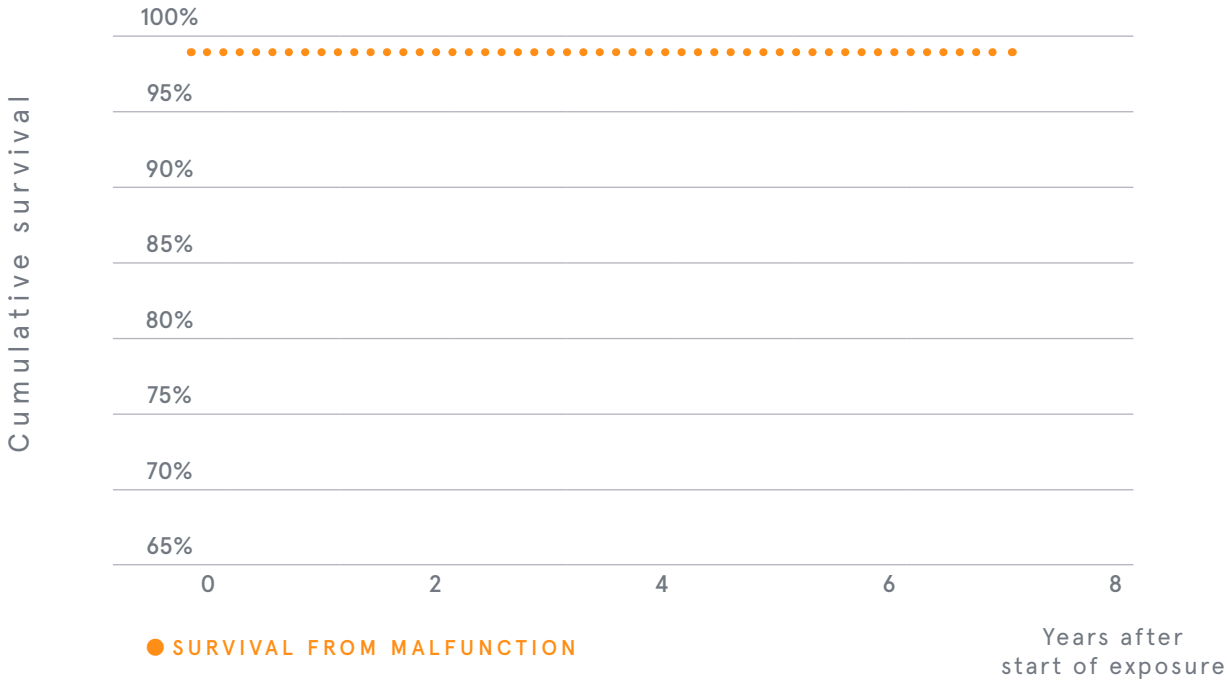
SAFETY & SECURITY

PRODUCT PERFORMANCE · XFINE TX25D/TX26D



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

	01	02	03	04	05	06	07
Survival	**99.96**	**99.95**	**99.94**	**99.94**	**99.92**	**99.92**	**99.92**
Upper confidence interval (+)	0.02%	0.02%	0.02%	0.02%	0.03%	0.03%	0.03%
Lower confidence interval (-)	0.03%	0.03%	0.04%	0.04%	0.04%	0.04%	0.04%

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

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Technical Specifications

CHARACTERISTICS		J SHAPED	STRAIGHT
MODELS		JX24D, JX25D	TX25D, TX26D
LENGTH		45 cm / 52 cm	52 cm / 58 cm
MRI CONDITIONAL*		✓	✓
CONNECTOR	IS-1	✓	✓
	Serial number identification	TJX4 / TJX5	TTX5 / TTX6
FIXATION	Tines	✓	✓
INTRODUCER	1 Lead	7 F	
	1 Lead + guidewire	9 F	
TIP ELECTRODE	Shape	Annular	
	Material	Carbon	
	Pacing surface	2 mm²	
	Steroid	310 µg of DSP**	
PROXIMAL ELECTRODE	Material	Pt / Ir	
	Surface	34 mm²	
	Inter electrode distance	10 mm	
LEAD BODY	Insulation	Outer sheath polyurethane + wires coated ETFE***	
	Conductors	Dual insulated wires, MP35N® sheath and silver core	
	Max conductors resistance	15 Ω	
	Diameter	4.8 F (1.6 mm)	

ACCESSORIES INCLUDED IN THE PACKAGE	JX24D, JX25D	TX25D, TX26D
1 xFine lead with suture sleeve	✓	✓
1 vein lifter	✓	✓
2 soft straight stylets: tapered, Ø 0.35 mm, green handle (one already pre-inserted into the lead)	✓	✓
2 firm straight stylets: tapered, Ø 0.40 mm, red handle	✓	✓

* *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)*
** *Dexamethasone Sodium Phosphate*
*** *Ethylene Tetrafluoroethylene*

Not available for distribution or sale in the USA.

REFERENCES

1. xFine implant manual U862, technical characteristics, 2016.
2. Medtronic, Capsure Sense MRI™ Surescan® 4074 p 10, 2013.
3. Boston Scientific Fineline™ II sterox physician's lead manual, p14, 2015. Boston Scientific Ingevity™ MRI Physician's lead manual, p25, 2014.
4. St Jude IsoFlex™ user's manual, p10, 2015.
5. Biotronik Solia T, JT Technical manual, p20, 2015.
6. Product performance report p54, May 2016.
7. 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).
8. 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.
9. During Pleasure-T study 90% of the investigators reported that xFine is "equal", "better" or "the best" maneuverability in the chamber when compared to other similar models used. Sorin data on file.
10. Product performance report shows that in more than 30000 leads implanted worldwide, only 1 cardiac perforation occurred.

Refer to xFine implant manual (U862) furnished with the lead for complete instructions for intended use and relevant warnings, precautions, side effects, and contraindications.

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