

BeFlex® 主动固定螺旋电极导线

固定方式	可伸缩螺旋	
鞘管	1 电极导线	7 F
	1 电极导线 + 1 导引钢丝	9.5 F
远端电极	形状	主动螺旋
	材料	Pt / Ir + TiN 涂层
	起搏表面积	4 mm ²
	激素	310 µg DSP*
	X 影像标记	是
	螺旋机制	连接杆驱动
近端电极	材料	Pt / Ir
	表面积	44 mm ²
	电极间距	10 mm
导线体	绝缘层	硅橡胶
	导体	MP35N
	内线圈	4 根电缆 (最大阻抗 50 Ω)
	外线圈	4 根电缆 (最大阻抗 100 Ω)
	直径	6 F
	长度/型号	52 cm / RF45D 58 cm / RF46D
连接头	类型	IS-1 BI

* 地塞米松磷酸钠

- BEFLEX电极导线 RF45D 和 RF46D 在严格的条件下，可与指定起搏器一起适用于MRI检查 (详见产品使用说明书)。
- MRI 检查前，请参阅起搏器包装中的《MRI 解决方案》，以获得完整的MRI 检查清单。

REFERENCES :

1. During Pleasure-S Clinical Study, 99% of clinical evaluation investigators concluded that BEFLEX leads had either "equal", "better" or "the best" x-ray visibility of the lead body in the atrium when compared to other similar models typically used by investigators; 97% of investigators concluded that BEFLEX leads had either "equal", "better" or "the best" maneuverability in the ventricle; 95% of investigators concluded that BEFLEX leads had either "equal", "better" or "the best" overall ease of lead placement in the ventricle; 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.
2. During Pleasure-S Clinical Study, 99% of clinical evaluation investigators concluded that BEFLEX leads had either "equal", "better" or "the best" ease of use with recommended introducer without guidewire when implanted in the atrium when compared to other similar models typically used by investigators; 91% of investigators concluded that BEFLEX leads had either "equal", "better" or "the best" ease of use with recommended introducer with guidewire. Sorin data on file.
3. During Pleasure-S Clinical Study, 97% of clinical evaluation investigators concluded that BEFLEX leads had either "equal", "better" or "the best" lead advancement through the vein in the atrium when compared to other similar models typically used by investigators; 96% of investigators concluded that BEFLEX leads had either "equal", "better" or "the best" lead tip positioning in the ventricle; 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. Sorin data on file.
4. During Pleasure-S Clinical Study, it has been demonstrated that the BEFLEX leads provided low acute pacing thresholds and satisfying impedance values in both chambers. The amplitudes, impedance values and thresholds were stable during the onemonth follow up. In the clinical evaluation, the sponsor noted that the preliminary clinical data has provided sufficient proof that the Beflex lead is safe and effective for its intended use. Sorin data on file.
5. Sorin Group Product Performance Report Ed. Nov 2009 shows that in more than 16000 leads with the same length depth (Stelix and Stelix II models) commercially implanted since 1999, only 1 displacement occurred and no perforations occurred.
6. During Pleasure-S Clinical Study, electrical performances were stable and clinically acceptable in all patients as expected. Sorin data on file.

详细规格参数请参考产品使用说明书
注册证号：国械注进 20183120454

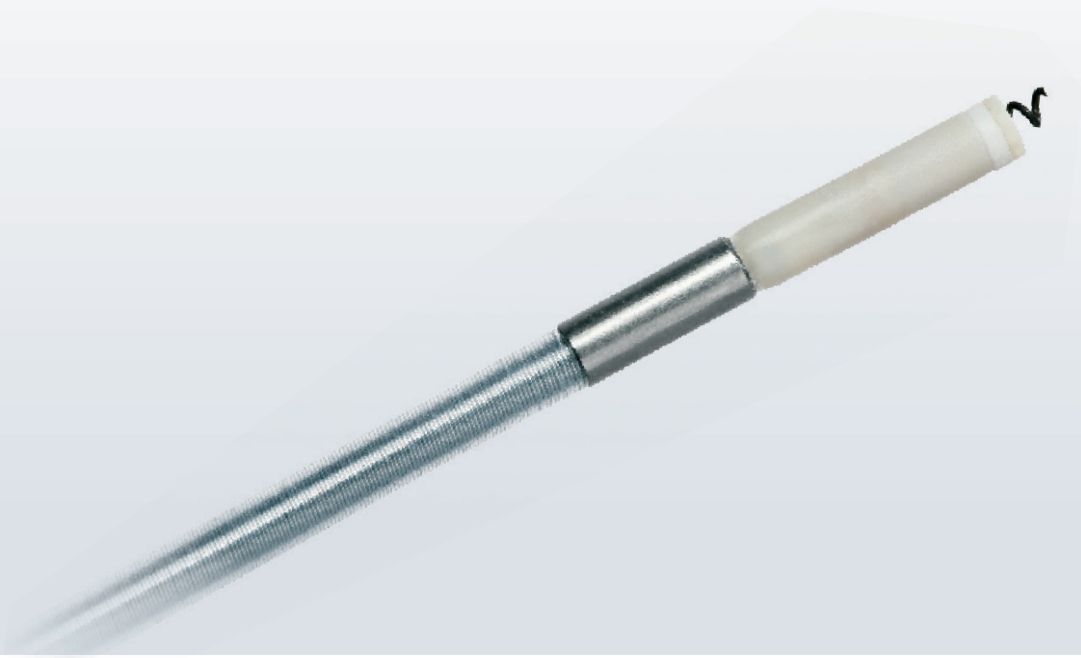


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MK-BEFLEX-001

BeFlex®



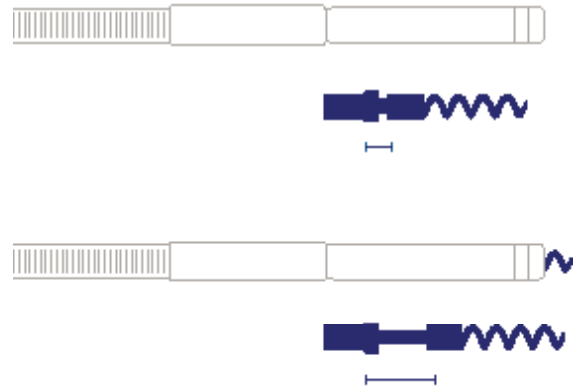
EASY, FAST and SAFE

主动固定螺旋电极导线 (磁共振条件安全)

BeFlex® 主动固定螺旋电极导线

EASY¹

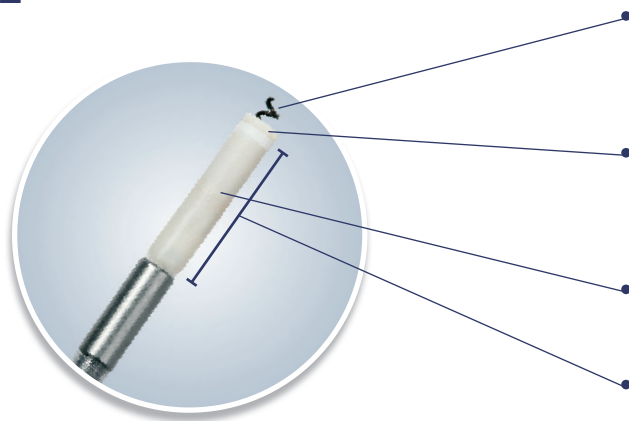
- ◆ **6F导线体, 适用于7F穿刺鞘:**易于通过较小血管以及在同一穿刺点插入两根BEFLEX电极导线²
- ◆ **同轴设计:**导线体在X光影像下有更好的可视性
- ◆ **X光标记:**用于判断螺旋头端旋出
- ◆ **可靠的螺旋机制:**易于将螺旋头端旋出/旋回
- ◆ **多种钢丝和蝶形扳手:**帮助更易植入



FAST³

- ◆ **高通过性:**顺滑的硅胶绝缘层在血管中通过性能优异
- ◆ **高定位性:**超过200例临床结果显示导线头端定位性能优异
- ◆ **高操控性:**在心腔中操控性能优异

SAFE⁴



- 1.5 mm主动固定螺旋确保头端固定稳定,且减少穿孔风险⁵, 4 mm² Pt-Ir TiN涂层电极增加起搏效率,减少极化作用
- 310 µg DSP*激素缓释减少组织炎症反应,降低急性/长期起搏阈值
* 地塞米松磷酸钠
- PEEK *外壳确保螺旋顺滑的伸出/旋回,同时保护螺旋
* 聚醚醚酮
- 头端电极-环电极的10 mm短距离提高感知特异性和减少过感知

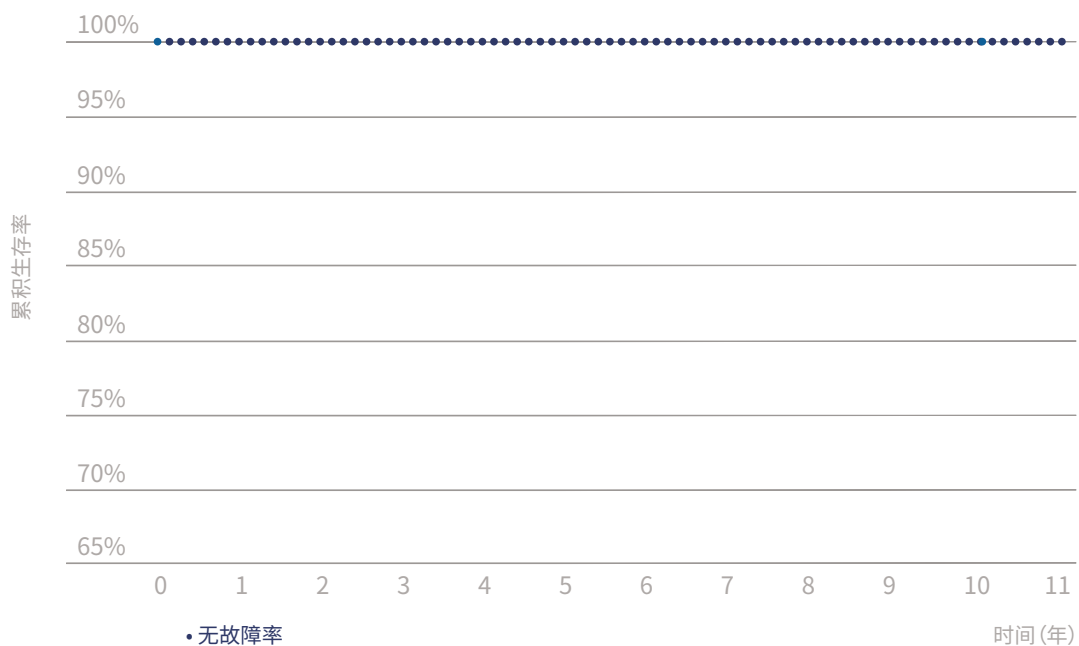
经临床评估,卓越的电学性能⁶包括

- ◆ 降低起搏阈值
- ◆ 提高感知特异性
- ◆ 高阻抗增加装置寿命

BeFlex® 主动固定螺旋电极导线



年度性能报告 *



无故障累积生存率 (95%置信区间)

	01	02	03	04	05	06	07	08	09	10	11 (年)
生存率 (%)	99.95	99.91	99.87	99.84	99.81	99.79	99.77	99.76	99.73	99.73	99.73
置信区间上限 (+)%	0.01	0.02	0.02	0.02	0.02	0.03	0.03	0.03	0.04	0.04	0.04
置信区间下限 (-)%	0.01	0.02	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05	0.05

*2021产品性能年度报告