

LEAD-FIM Clinical Study Results

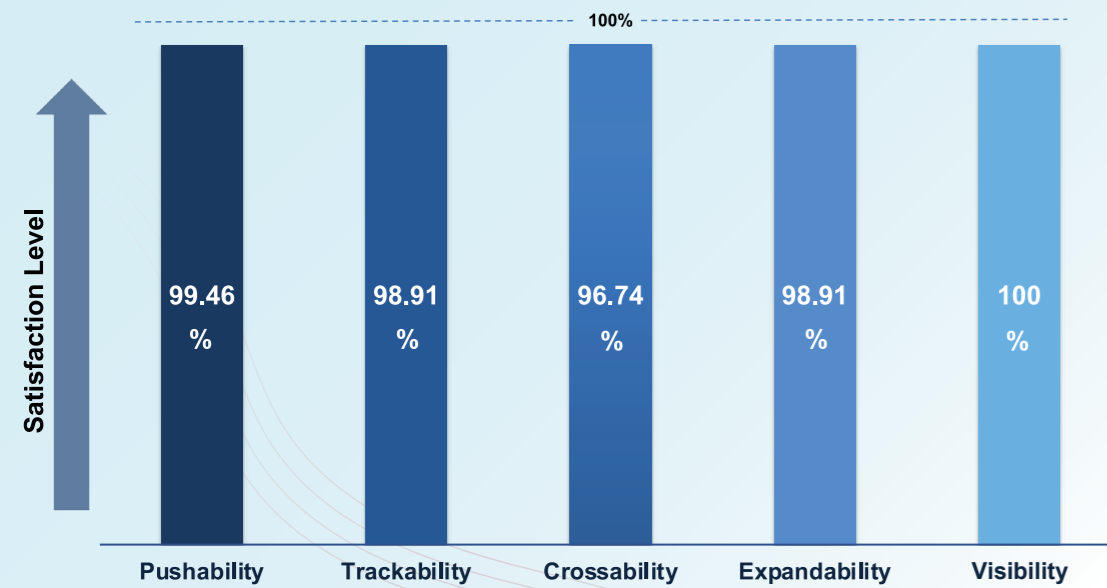
Primary Endpoint – Procedural Success Rate

Overall Procedural Success Rate is **96.7%**

[Residual stenosis $\leq 30\%$ within the stent post-implantation, no Major Adverse Cardiac Events (MACE) during hospitalization (7 days post-operation)]

Evaluation of Device performance

The device received excellent feedback from the LEAD-FIM study.



Key Parameter Information Table

During surgery, use the pulse settings in the table below. When the IVL catheter is connected, the device will automatically recognize the balloon specifications and adjust the pulse settings accordingly.

Treatment frequency	1 pulse per second
Maximum number of pulses in a single treatment cycle of continuous firing	10 pulses
Maximum number of pulses per catheter	80 pulses (8 treatment cycles)
Continuous Firing	Press and hold the button on the handheld trigger or step and hold the foot pedal
Single Firing	Press the handheld trigger or step on the foot pedal once

Specifications

Balloon Diameter (mm)	Balloon Length (mm)		Guiding Catheter	Guidewire Size
	12	15		
2.00	IVL-C20012	IVL-C20015	5F	0.014"
2.25	IVL-C22512	IVL-C22515		
2.50	IVL-C25012	IVL-C25015		
2.75	IVL-C27512	IVL-C27515		
3.00	IVL-C30012	IVL-C30015		
3.25	IVL-C32512	IVL-C32515		
3.50	IVL-C35012	IVL-C35015		
3.75	IVL-C37512	IVL-C37515		
4.00	IVL-C40012	IVL-C40015		

Balloon Compliance

Pressure (atm)	Balloon Diameter (mm)									
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	
6 (TP)	1.98	2.23	2.48	2.73	2.97	3.22	3.47	3.72	3.96	
8 (NP)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	
10	2.02	2.27	2.52	2.77	3.03	3.28	3.53	3.78	4.04	
12	2.03	2.29	2.54	2.80	3.06	3.31	3.56	3.81	4.07	
14	2.05	2.30	2.56	2.82	3.09	3.33	3.59	3.84	4.11	
16	2.07	2.32	2.58	2.84	3.12	3.36	3.62	3.87	4.15	
18	2.09	2.34	2.60	2.86	3.15	3.39	3.65	3.90	4.19	
20 (RBP)	2.10	2.36	2.62	2.89	3.18	3.42	3.68	3.93	4.22	

TP: Treatment pressure; NP: Nominal pressure; RBP: Rated burst pressure

*Do not exceed the rated burst pressure (RBP) when using

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CAUTION: The law restricts these devices to sale by or on the order of a physician and these products are intended for the use by or under the direction of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Data on file at Biosensors International for any sustained claims in this document.

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SoniCracker™

Crack the Code for Calcium

Coronary Intravascular Lithotripsy System



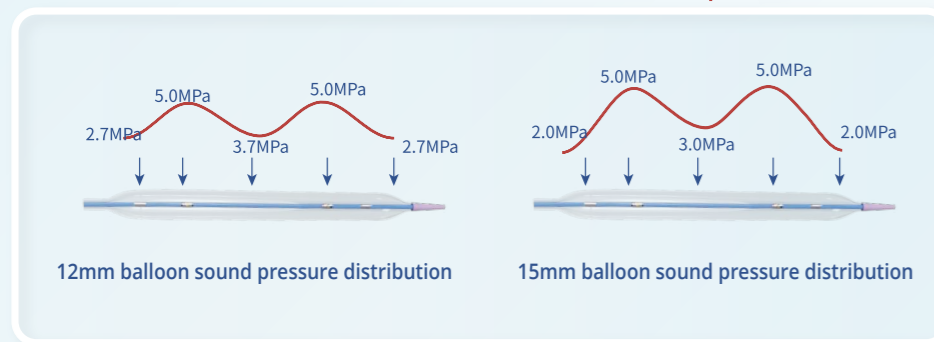
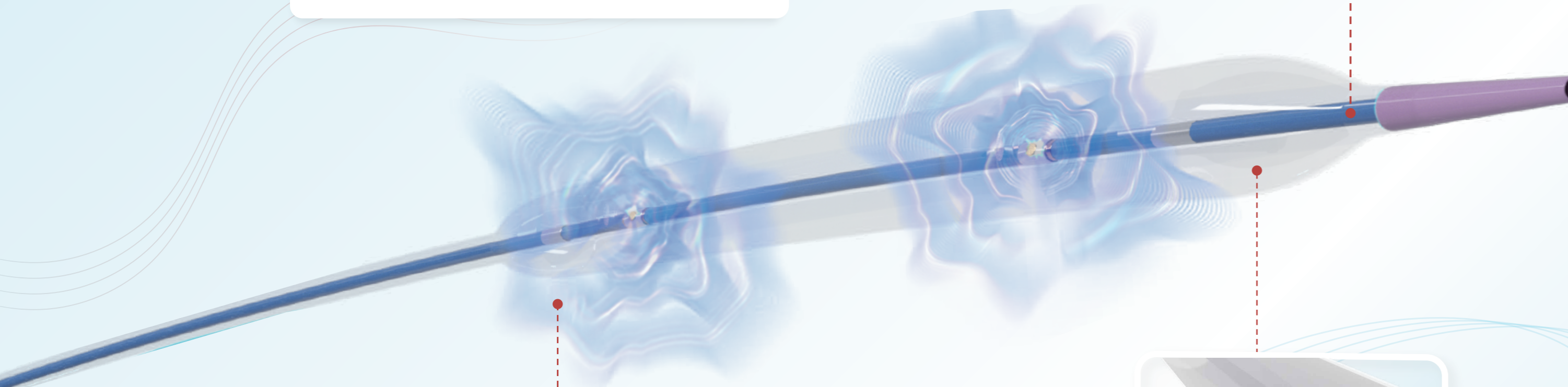
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Saving Lives Through Innovation

Breaking Through Calcified Lesions

Excellent Operational Performance

The optimised outer diameter of the tip and multi-section tube design make it suitable for 5F guiding catheters, making it easier to reach and pass through lesions

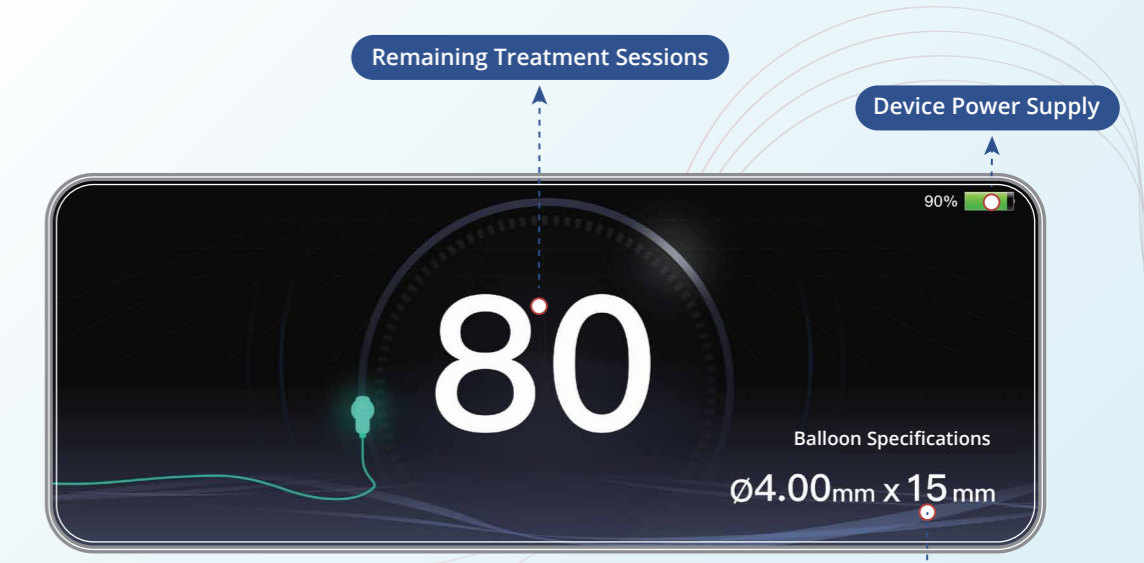
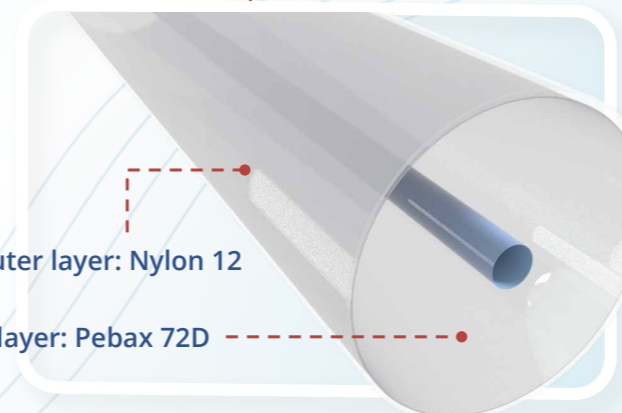


Superb Treatment Efficiency

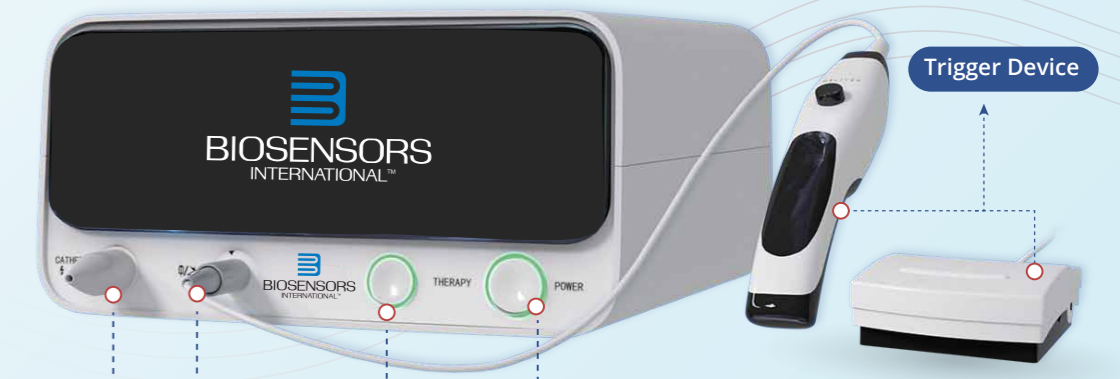
Patented electrode design ensures minimum treatment energy $\geq 3\text{MPa}$, making 15mm balloon length possible

Optimized Balloon Material

Dual-layer balloon design, taking into account both flexibility and high pressure resistance of RBP 20atm



HD Screen



Balloon Catheter Interface

Trigger Interface

Therapy Button

Power Button

Trigger Device

New intravascular lithotripsy therapy device design

- Lightweight and portable device, desktop structure design improves stability
- High definition large-screen design, key information is clearly displayed
- 2 trigger modes - handheld trigger or foot pedal