



Safety and effectiveness of a 6-French MRI conditional pacemaker lead: Prospective INGEVITY plus Active Fixation Pace/Sense Lead Clinical Study in Korea



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Korean Heart Rhythm Society

COI Disclosure

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Disclosure

Relationships with commercial interests:

- Grants/Research Support: Samjin, Yuhan, Medtronic, Abbott and Boston Scientific
- Consulting Fees: Samjin, Yuhan, Huino and Medtronic
- Other: no



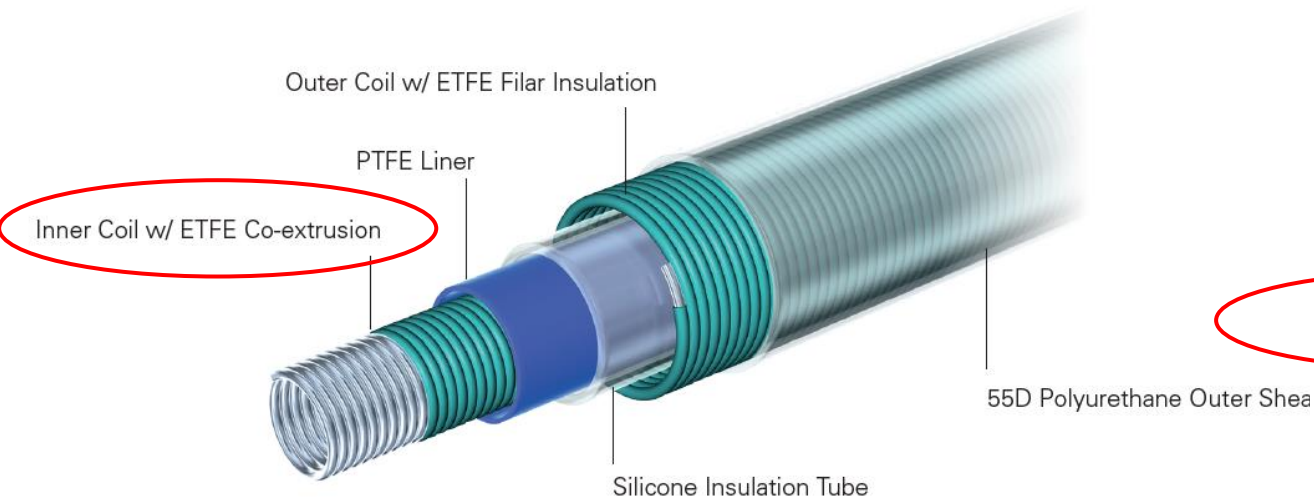
Background:

- Boston Scientific INGEVITY Plus pacing lead (Boston Scientific., Marlborough, MA, USA) has been upgraded from INGEVITY lead.
- The performance of the INGEVITY Plus pacing lead had not been reported.
- The INGEVITY Plus study is an investigator-initiated study evaluating the acute and chronic safety and effectiveness of these leads, and lead handling experiences.

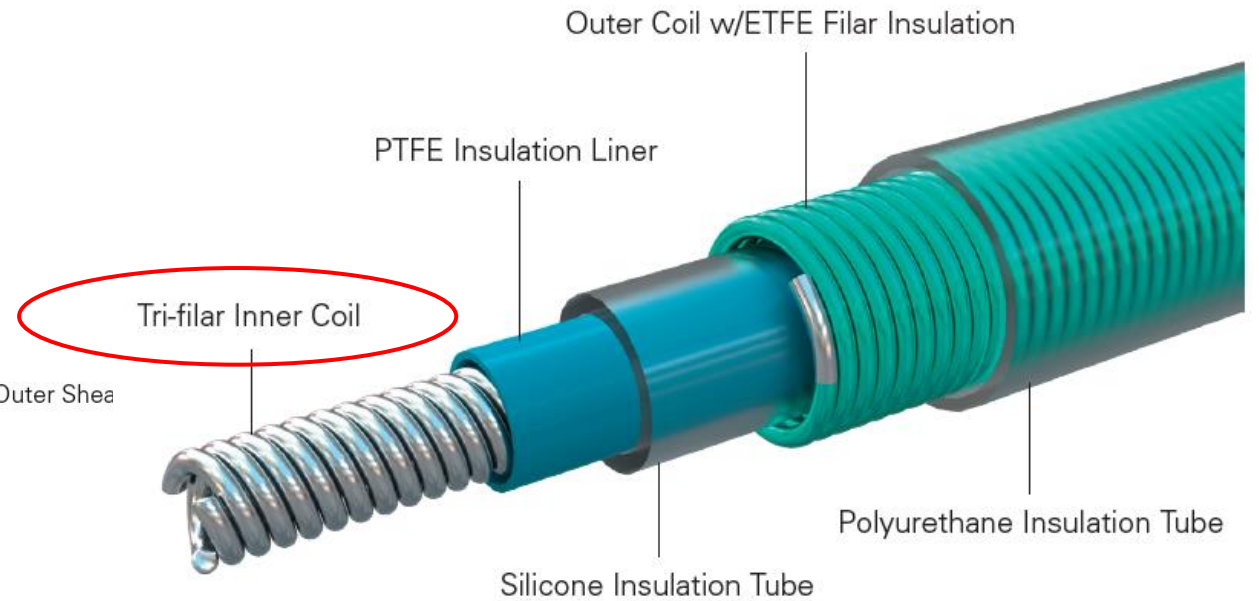


Figure 1. Lead design

INGEVITY lead



INGEVITY+ lead



- A unifilar inner coil has lower torque transfer than a similarly designed multifilar coil.

Methods:

- Consecutive patients were included in **9 institutions** in Korea,
- Class I or Class II indication for pacemaker implantation.
- 401 leads (201 right ventricular active fixation leads, and 200 right atrial active fixation leads) were implanted or attempted in **200 subjects**.



Methods: Clinical evaluation

- The **safety and effectiveness** of the INGEVITY+ active fixation pacemaker leads **during a 3-month follow-up**
- **Safety**
 - lead-related complication-free rate
 - Lead-related complications: adverse events resulting in permanent loss of pacing therapy, invasive intervention, injury, or death
- **Clinical effectiveness**
 - pacing and sensing performance



Methods: Implant feedback

- To understand the implanting physicians' experience with this new lead,

Rate the radiopacity quality of the extendable/retractable helix markers
Rate Handling and Maneuverability of the stylet and lead used
Rate overall Handling Performance of the Lead
Rate the overall the number of turns to fully extract the helix (Screw)
Rate the overall the number of turns to fully retract the helix (Screw)
The Lead is easy to pass through Small vessels and/or vessels with multiple leads



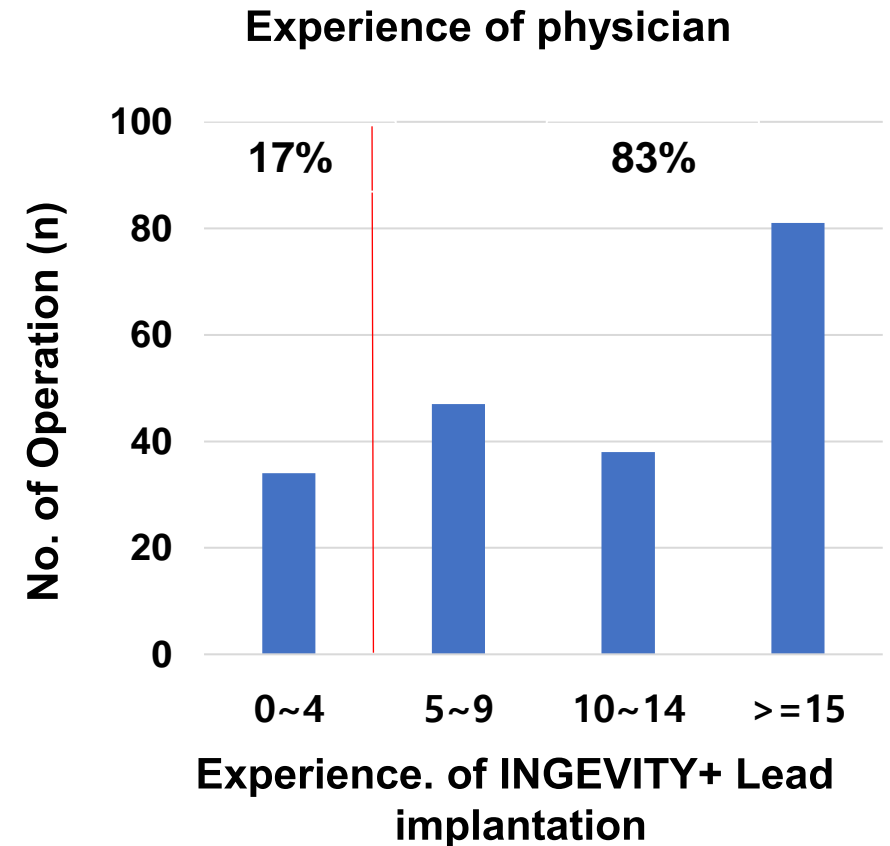
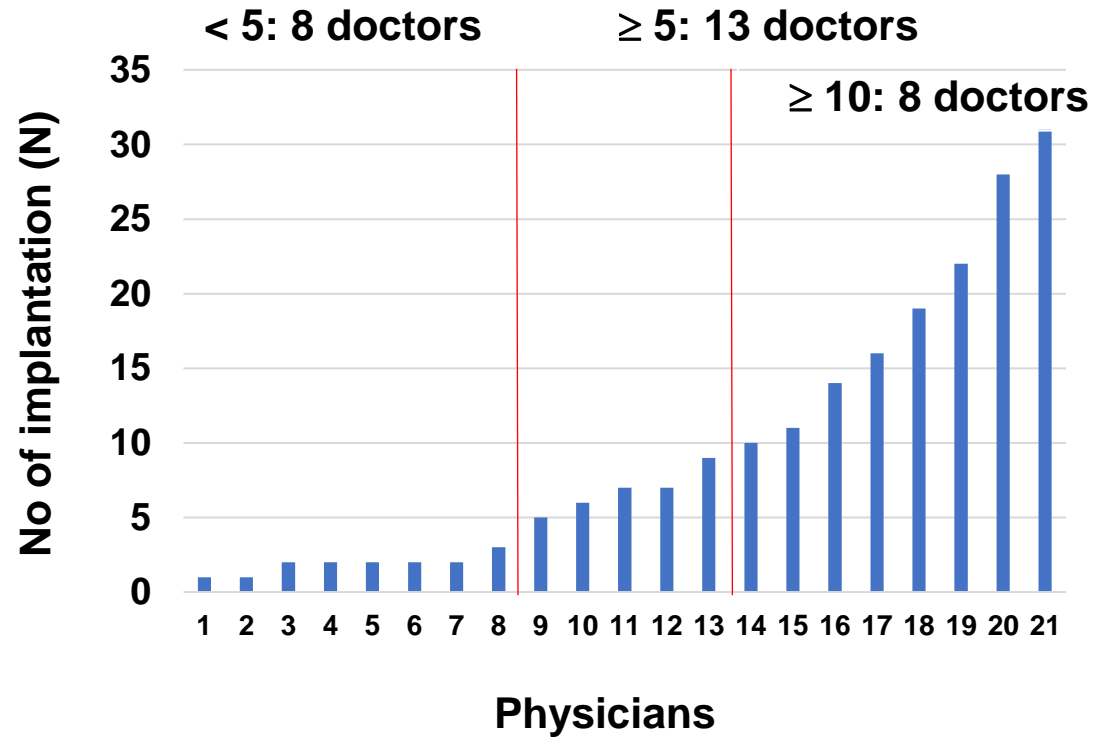
Result: Demographics of study subjects

- The mean age was 70.2 ± 9.1 years, with 43.5% being male

Variables	
Age at implant (years)	70.2 ± 9.1
Male	87 (43.5)
BMI	24.2 ± 3.9
Height	159.3 ± 14.8
Weight	62.4 ± 12.7
Smoking, current	22 (11.0)
Drinking, current	21 (10.5)
Indication of PM implantation* [N (%)]	
Sinus node dysfunction	81 (40.5)
Atrioventricular block	78 (39.0)
Both	34 (17.0)
Other	7 (3.5)
Associated diseases and risk factors* [N (%)]	
Hypertension	126 (63.0)
Diabetes	61 (30.7)
Myocardial infarction	12 (6.1)
Valvular heart disease	11 (5.6)
Heart failure	14 (7.1)
Peripheral artery occlusive disease	9 (4.5)
Cerebrovascular disease	18 (9.0)
Dyslipidemia	94 (47.2)



Result: Implantation



- During the implantation procedure, **one patient** required the change of RA lead (**0.25%**) due to lead screw failure.

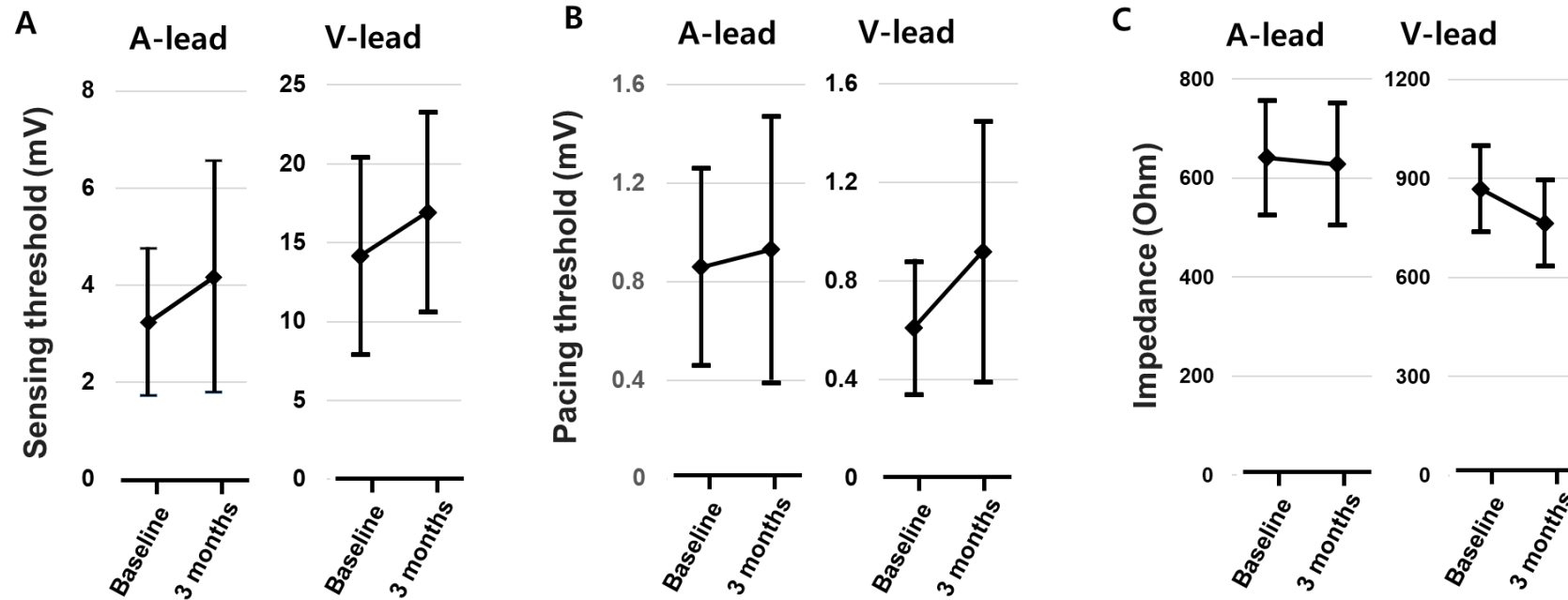


Safety: Lead-related complication-free rate

- The INGEVITY study passed the predefined safety endpoints with a lead related **complication free rate at 3 months of 100%**.
- **Dislodgments occurred in no subjects**, for an overall dislodgement rate of 0%. Zero perforation (0.0%) and zero pericardial effusions (0.0%) occurred in the study.



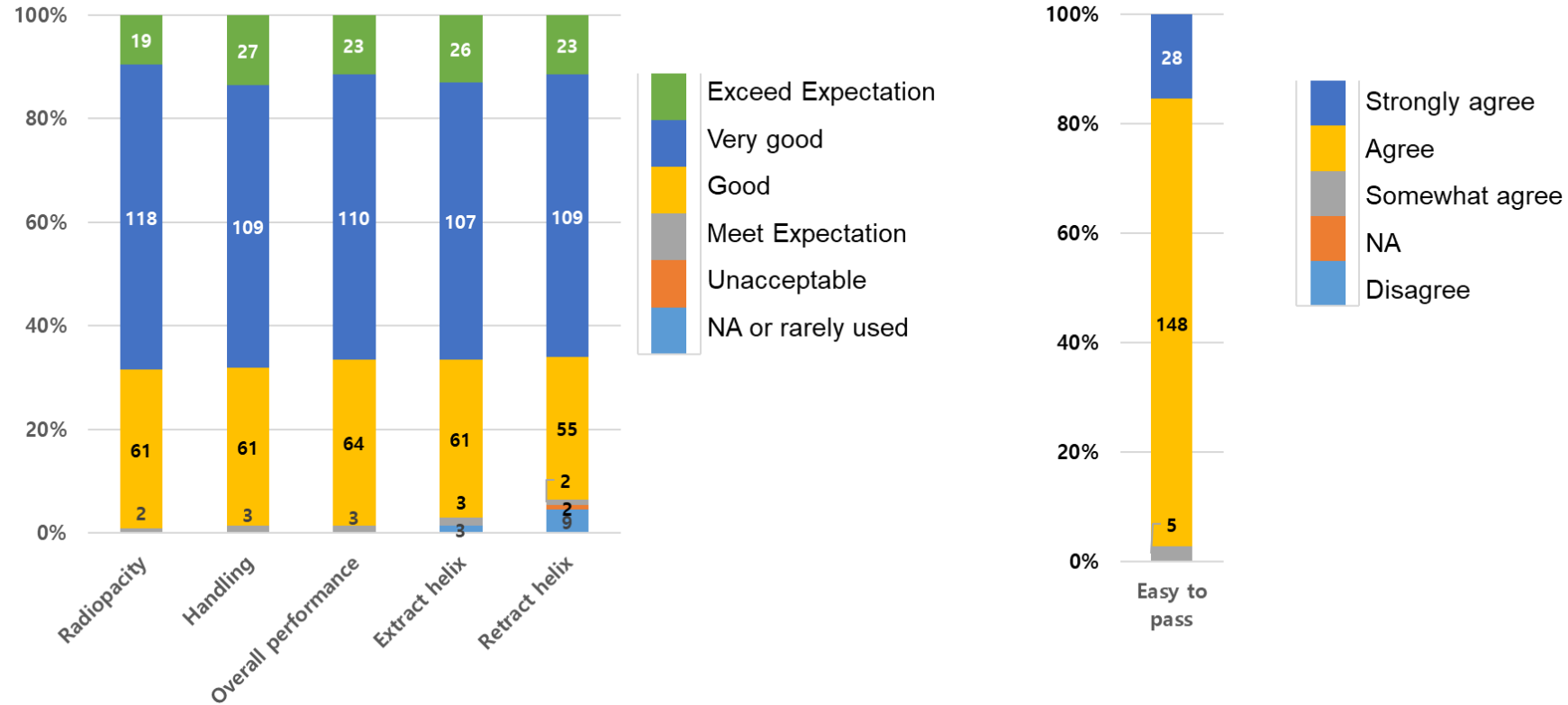
Clinical effectiveness: The change of lead profiles



- A total of **92.4% of atrial leads** had amplitudes greater than 1.5 V and **96.5% of ventricular leads** had amplitudes greater than 5 V at 24 months.
- A total of **95.7% of RA leads** and **99.5% of RV leads** had thresholds less than 1.5 V at 3 months.
- A total of **99.8% had impedances** between 300 and 1,300 ohms.



Lead handling questionnaire



- The radiopacity quality of the extendable/retractable helix markers, the handling and maneuverability of the stylet and lead, and overall handling performance of the lead was very good or exceeded expectations in 68.5%, 68%, and 66.5%, respectively.
- 88% of operators agree or strongly agree that the leads were easy to pass through small vessels or vessels with multiple leads.



Discussion

Lead-related complication free rate
 INGEVITY + lead (0-3mon) – 100%
 INGEVITY lead (0-3mon)- 98.4%^a

Other MRI leads - 96.3-97.0%
 Non MRI Leads – 97.3-97.9%

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

Worldwide Confirmed Malfunctions		59		Worldwide
Worldwide Distribution		364,000		
0.0162%		With Compromised Therapy	Without Compromised Therapy	Total
Conductor				
Extracardiac fracture (41)		6	16	22
Other				
Non-patterned, other		19	18	37
Grand Total		25	34	59

U.S. Chronic Lead Complications

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation	
INGEVITY+ Positive Fixation 7840/7841/7842	173,000	67	58	245	47	15	9	1	12	0	2	0.26%
		0.04%	0.03%	0.14%								

U.S. Acute Lead Observations

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation	
INGEVITY+ Positive Fixation 7840/7841/7842	246,000	285	33	644	130	36	38	3	22	0	5	0.49%
		0.12%	0.01%	0.26%								



a. Nielsen JC, *Pacing Clin Electrophysiol.* 2017;40:1121-1128.

Study limitations:

- The study design was **observational, single arm**, and the results can only be compared with historical control groups.
- **High-volume implanting pacemaker centers with experienced principal investigators and operators** were selected for participation in this study.
- Therefore, the present results of this clinical study may be different in other settings with less experienced operators and lower volume of overall procedures.



Conclusion:

- The clinical performance of the INGEVITY Plus pacing lead demonstrated **a high lead-related complication-free rate** over 3 months of follow-up and excellent electrical characteristics with very good lead-handling experiences.



Thank you for your attention!

