INSIGHT-LBBA Study Shows Proven Lead Performance of INGEVITY™+ for LBBAP

The INSIGHT (ConductIoN System pacInG witH IngeviTy+ for Left Bundle Branch Area (**INSIGHT-LBBA**) study is an investigator-initiated retrospective multicenter registry to assess use of the INGEVITY+ 6Fr stylet driven pacing lead for LBBAP.[1]

Study Design

- All LBBAP implant attempts using 59cm INGEVITY+ leads via a Site Selective Pacing Catheter (SSPC) were collected in the registry.
- Procedure success was site-reported and defined as capture of left septal tissue or the left sided conduction system.

Median Follow up
9.9 months

Study Size
1122

8
US Centers

Outcomes

Pacing Capture Thresholds at 3 months

98.8% of LBBA thresholds were less than or equal to 2V at 0.4ms

Procedural Success Rate

LBBAP was achieved in 95.6% of cases (1073/1122), 90.6% on the first lead attempt (1017/1122)

Lead-Related Complication-Free Rate

97.7% of LBBAP INGEVITY+ pacing leads were complication-free at 3 months and 97.2% were still complication free at 24 months

1.07
Average number of leads used for each LBBAP implant attempt.

100%
Boston Scientific Site Selective Pacing Catheters **(SSPC)** used in **ALL** implants.

ZERO
Distal tip intracardiac conductor fractures in 1122 leads (median follow-up time 9.9 months).

Results from INGEVITY+ leads in this study suggest that acute implant safety and post implant electrical performance are similar to lumenless leads.[1]

INGEVITY+ for LBBAP

Designed for long-term reliability, expanded to a new application

With **over 4 years of commercial data at 99.5% survivability** and **rigorous R&D testing**, the 6Fr INGEVITY+ pacing leads are proven for longevity in this new application.

Silicone Flexible Neck

The overmolded design is **resistant** to conductor fractures providing flexibility with smooth transitions.[2]

Low stress coils for high fatigue performance

Similar to RV traditional locations, INGEVITY+ demonstrated **zero conductor fractures** in rigorous fatigue testing for LBBA use conditions.[3]

Proven Insulation Materials

>15 years for PTFE
>20 years for ETFE
>20 years for 55D Polyurethane

Multiple Insulation layers

Only pacing lead designed with at least **3 layers of insulation** between conductors[2]

References

1. INSIGHT Friedman DJ, Shadrin I, Goldbarg S, et al. Performance of an active fixation stylet-driven lead in left bundle branch area pacing: Results from INSIGHT-LBBA. *Heart Rhythm*. Published February 4, 2025.
2. Boston Scientific data on file: ELN 402204
3. Boston Scientific data on file: ELN 184951-413, 415, 434, 436, 12941008

SSPC1, SSPC2, SSPC3, SSPC4 Delivery Catheter

INDICATIONS FOR USE

The Delivery Catheter is indicated for the introduction of various types of catheters and pacing or defibrillator leads.

CONTRAINDICATIONS

- Obstructed or inadequate vasculature for venous access

WARNINGS

- Do not advance Deliver Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not advance a lead or catheter through the Delivery Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not remove the Deliver Catheter or a lead or catheter placed through the Deliver Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not resterilize or reuse. Structural integrity and/or function may be impaired by cleaning, resterilisation, or reuse.
- Do not expose the device to the MR Environment

PRECAUTIONS

- The Delivery Catheter should be used by interventionalists experienced in performing cardiovascular procedures.
- Do not use if package is open or damaged.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories.
- Upon removal from package, inspect device to ensure no damage has occurred during shipping.
- Do not expose to solvents.
- Use in conjunction with fluoroscopic guidance and proper anti-coagulation agents.
- Ensure the catheter is thoroughly flushed and free of air prior to use.
- Care should be taken during the procedure to ensure that the hemostatic valve is not damaged and that the side port remains closed to reduce potential for air ingress or blood loss.

COMPLICATIONS

Possible complications include, but are not limited to, the following: exposure to x-ray radiation, adverse or allergic reactions to contrast agents, infection, hematoma, pneumothorax, embolization, vessel thrombosis, dissection, acute occlusion, clot formation, hemorrhage, vessel rupture, arrhythmia or heart block, hemodynamic changes, myocardial infarction, perforation of the heart, cardiac tamponade, stroke, and death.

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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INGEVITY™+ Pace/Sense Lead
INDICATIONS This Boston Scientific lead is indicated for use as follows: • Intended for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator. In addition, pacing and sensing in the
left bundle branch area is indicated with a single or dual chamber pacemaker as an alternative to the right ventricle.

CONTRAINDICATIONS Use of this Boston Scientific lead is contraindicated for the following patients: • Patients with a hypersensitivity to dexamethasone acetate • Patients with mechanical tricuspid heart valves.
WARNINGS: General • Labeling knowledge. Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. • Backup defibrillation protection.Always have external defibrillation equipment available during implant and electrophysiologic testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death. • Resuscitation availability.
Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. • Lead fracture. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Clinical Considerations • His Bundle Pacing. These leads have not been evaluated for safety and performance in His bundle pacing; therefore, they are not intended for implantation in the His bundle. Evidence indicates that there is increased risk with His bundle pacing, compared to conventional pacing, including increased implantation procedure duration, elevated pacing threshold, increased occurrence
of lead dislodgment and sensing issues, and more rapid battery depletion.1 • Excessive flexing. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgment. • Do not kink leads. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Implanted Related • Do not implant in MRI site Zone III. Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology2. Some of the accessories packaged with pulse generators and leads, including the torque wrench and stylet wires, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas. • Ensure position on interventricular septum. Prior to fixation when implanting in the left bundle branch area, ensure the lead is positioned on the interventricular septum, not on the ventricular free wall. If the lead is not positioned on the interventricular septum, rotating the lead body could result in perforation and/or effusion.
• Lead body rotation mechanism. The lead body rotation mechanism is only used for placement of the lead within the interventricular septum, not to anchor the distal tip of the lead to the endocardial surface of the right atrium or right ventricle. • Avoid perforation of interventricular septum when rotating lead body. To avoid perforation of the septum, monitor the location of the lead tip in the interventricular septum when rotating the lead body. • Helix entanglement. Acute lead repositioning in and/or removal from the interventricular septum may cause the helix to become entangled and may result in lead component separation or deformation, and/or damage to the endocardium, valve, or vein. To reduce
this risk, re-orient the catheter to the position used for the original implant prior to repositioning the lead. Consider lead abandonment as an alternative. • Avoid excessive force. Avoid excessive forward force and/or torque on the lead and/ or catheter since these can damage the lead and/or cause tissue damage, such as cardiac perforation. Monitor electrical performance since abnormal values can indicate damage and/or tissue trauma. Post-Implant • Magnetic ResonanceImaging (MRI) exposure. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements of the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as a complete list of MRI-related Warnings and Precautions. • Diathermy. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. • Chronic removal of lead. In a chronic situation, exercise caution if a lead must be removed from the interventricular septum since the helix may become deformed and/or entangled which could result in lead component separation and/or damage to the endocardium, valve, or vein. Monitor the condition of the helix and lead during an attempt to remove the lead. Consider lead abandonment as an alternative.
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PRECAUTIONS:
Handling For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow-up testing. Handling • Do not immerse in fluid. Do not wipe or immerse the tip electrode in fluid. Such treatment will reduce the amount of steroid available when the lead is implanted. • Chronic repositioning. Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted. • Protect from surface contamination. The lead uses silicone rubber which can attract particulate matter, and therefore, must
always be protected from surface contamination. • No mineral oil on lead tip. Mineral oil should never come in contact with the helix. Mineral oil on the helix may inhibit tissue ingrowth and conduction. Implantation • Do not over extend or over-retract the helix. Do not overextend or over-retract the helix. Exceeding the recommended maximum number of turns indicated in the specifications (Table 7 Specifications on page 36) may damage the conductor coil or fixation mechanism. • Terminal pin maximum number of turns. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications (Table 7 Specifications on page 36).
Continuing to rotate the terminal pin can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise. • Maximum lead body rotations. Do not exceed the recommended maximum number of fixation/positioning attempts and lead body rotations indicated in the specifications (Table 7 Specifications on page 36) during fixation/positioning attempts in the interventricular septum. Exceeding the recommended maximum number may damage the lead body and/or helix. It is recommended to replace the lead after 3 fixation/positioning attempts. • Helix pre-extension. If the helix is pre-extended prior to insertion into a lead delivery
catheter, carefully insert the lead into the catheter to avoid damage to the helix. • Ensure a pre-extended helix remains within catheter. Whether the helix is preextended prior to or after insertion into the catheter, ensure the helix does not extend beyond the end of the catheter until the fixation step to prevent damage to the tissue and/or lead. • Prevent dislodgment. To prevent dislodgment, avoid rotating the terminal pin counterclockwise after fixating the lead.

POTENTIAL ADVERSE EVENTS: Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: Acute or chronic septal perforation; Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Arteriovenous (AV) fistula; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation;
Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Coronary artery injury/acute coronary syndrome/myocardial infarction; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to pace; Inappropriate
therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Prolonged exposure to fluoroscopic radiation; Prolonged procedure time; Pulse generator and/or lead migration; Renal failure from contrast media used during lead placement; Syncope; Tachyarrhythmias, which include accelerration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Trapped/damaged lead fixation helix (including unretrieved device fragment);Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).
Transient procedural adverse events are expected in some patients. These include, but are not limited to, discomfort, pain, and other systemic symptoms that might be related to medications or other interventions performed during implant.

If adverse events occur, invasive corrective action and/or modification or removal of the pulse generator and/or lead may be needed.
For a list of potential adverse events associated with MRI scanning, refer to the ImageReadyTM MR Conditional Pacing System or Defibrillation System MRI Technical Guide.
Any serious incident that occurs in relation to this device should be reported to Boston Scientific using the information on the back cover and to the relevant local regulatory authority.

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CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling

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