«Hospital_Name»
«Users_Name» - «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

April 2018

Dear «Users_Name»,

Boston Scientific is committed to continuous improvement of our products.

In September 2017, we distributed updates to the Physician's Lead Manual (PLM) for the INGEVITY™ MRI[1] extendable/retractable (active fixation) pacing lead to French implanting centers as a Field Safety Notice. Based on subsequent discussions, other European Competent Authorities have requested that we distribute the same PLM update to all European centers as a Field Safety Notice. This approach is intended to capture physician attention of these PLM changes to encourage the best use of the product.

Please note the following about the attached September 2017 letter:

- The PLM referenced in the letter is distributed in France and the PLM distributed in your country is available online at www.BostonScientific-eLabeling.com.
- The product performance information in Appendix B remains accurate and the latest performance information is available online at www.BostonScientific.com/ppr.

If you have additional questions regarding this information, please contact your Boston Scientific representative or Technical Services.

Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

[1] Magnetic Resonance Imaging

Urgent Field Safety Notice

September 2017

Subject: Important Medical Device Information – INGEVITY™ MRI active fixation pacing lead manual - Ref. 92160868-FA

Dear Doctor,

Boston Scientific is committed to continuous improvement of our products. Based on recent updates to the Physician's Lead Manual[1] (PLM) for the INGEVITY™ MRI[2] (INGEVITY) extendable/retractable (active fixation) pacing lead, the French National Security Agency of Medicines and Health Products (ANSM) has requested that Boston Scientific communicate directly to pacing lead implanters[3] in France. This letter is intended to ensure your awareness of these PLM updates and the potential outcomes if instructions are not observed. Appendix A highlights the specific changes made to the PLM.

It is important to emphasize that patient safety risk associated with the INGEVITY lead remains unchanged and that the PLM updates provide further clarification of existing instructions. The updates to the INGEVITY PLM have been incorporated to share best practices and optimize product use/handling.

Background

Boston Scientific has received complaints of helix deployment difficulty (e.g., inability to extend or retract the helix) with the INGEVITY active fixation lead during surgical implantation. This behaviour is highly detectable and can be resolved without any adverse health consequences.

Helix deployment difficulties are attributed to severe bending due to challenging anatomy, proximal bending during activation of the terminal pin, and/or rapid rotation of the terminal pin (e.g., rotating terminal pin faster than one turn per second). Typically, this behaviour is overcome using techniques described in the existing INGEVITY PLM or by implanting a new INGEVITY lead. If the lead's terminal pin is rotated in excess of the maximum number of thirty (30) turns, an acute conductor coil break may result.

Based on detailed laboratory analysis of returned INGEVITY leads associated with reported helix deployment difficulty, Boston Scientific has confirmed all conductor coil breaks observed to date have occurred acutely during surgical implantation or revision procedures. No latent INGEVITY coil breaks have occurred due to helix deployment difficulty; however, in some cases the break was not identified until the pocket was closed due to delayed PG testing, which has led to a revision procedure. Additionally, the existing INGEVITY PLM provides instructions for evaluating functional performance after a lead has been surgically positioned. The existing instructions include verifying electrical performance using a pacing system analyser (PSA) before attaching the lead to the pulse generator, and performing additional testing once the lead is attached to the pulse generator. These steps are important to demonstrate lead integrity before pocket closure. If compromised integrity is detected the lead can be removed and replaced during the procedure. Boston Scientific has updated the INGEVITY PLM to provide further clarification of these existing instructions.

[1] Physician Lead Manual part number (358659-061) available online at www.BostonScientific-eLabeling.com
[2] Magnetic Resonance Imaging
[3] Implantable pacemakers, defibrillators

Physician Lead Manual Updates
The updates apply to the INGEVITY MRI Physician's Lead Manual for Extendable/Retractable Fixation part number 358659-061. All Boston Scientific PLMs, including INGEVITY's, are available online at www.BostonScientific-eLabeling.com. The INGEVITY PLM updates do not change the way the lead is used, but rather provide further clarification of existing instructions and heighten awareness of what may occur if existing helix-related instructions are not followed. These updates are highlighted in Appendix A.

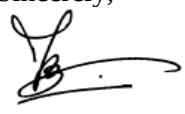
Performance
The INGEVITY lead-related complication-free rate (from implant to three months) was 97.6% in the clinical studies[4]. Boston Scientific's experience with over 330,000 INGEVITY Active Fixation leads worldwide (including more than 30,000 implanted in France) with more than 4.2 million implant-months:

- Helix deployment difficulty has been observed; however, complaints have reached a steady state in Europe and France at approximately 1%.
- The overall complication rate, acute and chronic, is comparable to other leads

Significant analysis of the performance of the INGEVITY active fixation pacing lead has shown that the clinical consequences associated with helix deployment difficulty during implant procedures are consistent with patient safety and risk expectations. The frequency of this behaviour is reduced if PLM instructions are followed. The potential risk to patient safety from helix deployment difficulty is very low and within the design risk analysis, as it occurs during an implant or revision procedure when remedial action can be implemented.

Additional Information
Boston Scientific values physician feedback regarding INGEVITY lead handling and, as described above, has incorporated applicable updates to our INGEVITY PLM to share best practices and optimize product use/handling. If you have additional questions regarding this information or would like to report clinical events, please contact your Boston Scientific representative or Technical Services.

Sincerely,



Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

[4] Clinical Summary INGEVITY Study 358487-023 and Clinical Summary Samurai Study 358487-024 available online at www.BostonScientific-eLabeling.com

Appendix A: Summary of INGEVITY Active Fixation Physician Lead Manual Updates

Table 1 provides the added clarification wording to the Physician's Lead Manual for INGEVITY MRI Active Fixation lead models. The updated wording is highlighted in yellow. These updates do not change the way the lead is used, but rather provide further clarification of existing instructions and to heighten physician awareness of what may occur if existing instructions are not followed.

Table 1: Updates to INGEVITY MRI Active Fixation Physician's Lead Manual

Location in *Physician's Lead Manual*	Labeling Updates
Information for Use: Precautions AND Implantation: Handling the Fixation Helix	**Do not overextend or over-retract the helix**. Do not overextend or over-retract the helix. The lead conductor coil or fixation mechanism can be damaged or broken if you continue to rotate the terminal pin once the helix is fully extended or retracted.
Information for Use: Precautions AND Implantation: Handling the Fixation Helix and Lead Fixation	**Avoid creating sharp bends while extending or retracting helix**. Avoid creating sharp bends in the lead terminal or lead body while extending or retracting the helix. Sharp bends can increase the risk of breaking the conductor coil or fixation mechanism during helix extension and retraction.
Information for Use: Precautions AND Implantation: Lead Fixation and Repositioning the Lead	**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 5 Specifications (Nominal) on page 29). Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.
Implantation / Handling the Fixation Helix section	NOTE: The expected number of turns and the recommended maximum number of turns to extend or retract the helix are provided in the specifications (Table 5 Specifications (Nominal) on page 29). Any curves introduced into the stylet could increase the number of turns needed to extend or retract the helix.
Implantation / Lead Fixation section	NOTE: The number of turns to extend or retract the helix may vary based on patient anatomy and implant conditions. Maintain a straight trajectory coming out of the patient anatomy to the extent feasible.
Implantation / Evaluating Lead Performance	Verify electrical performance of the lead using a pacing system analyzer (PSA) before attaching the lead to the pulse generator. Verifying electrical performance will confirm lead integrity. (Note: This is also proposed for the tined fixation manual.)
Implantation / Electrical Performance	• A discontinuous signal may indicate a lead conductor coil break, fracture or an otherwise damaged lead, or an insulation break that would necessitate lead replacement.
Specifications / Specifications table (Note this CAUTION statement was previously included in the manual and was added to this section of the PLM)	Recommended maximum number of rotations to extend/retract the helix **CAUTION:** Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.

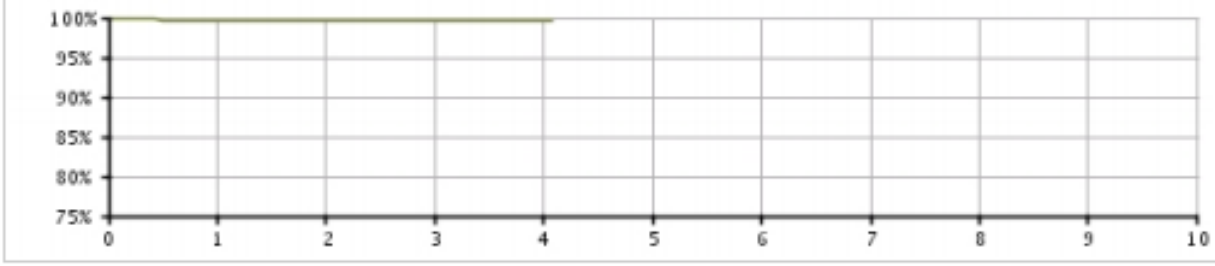
Appendix B: INGEVITY Active Fixation Performance

U.S. Summary

U.S. Registered Implants: 102,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 99,000

U.S. Chronic Lead Complications: 194
U.S. Malfunctions:14
Without Compromised Therapy:6
With Compromised Therapy:8

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8
Non Advisory Population	99.67 (-0.1/+0.0)	99.67 (-0.1/+0.0)	99.67 (-0.1/+0.0)	99.67 (-0.1/+0.0)	99.67 @ 49 mo. (-0.1/+0.0)	–	–	–
Registered Implants: 102000								
Effective Sample Size	11835	928	817	313	235	–	–	–

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