

«SOLD\_TO\_NAME»  
«Physician\_name» - «Department»  
«SOLD\_TO\_STREET»  
«SOLD\_TO\_POSTAL\_CODE» «SOLD\_TO\_CITY»  
«SOLD\_TO\_COUNTRY»

Xx November 2016

### **Boston Scientific FSCA on INGEVITY™ MRI endocardial pacing leads**

Dear «Physician\_name»,

Our records indicate that you have been supplied with product(s) impacted by this advisory population.

This package includes the following documents:

- Notification letter
- Verification form
- Affected product list affected by the action

Please read the letter carefully.

Then complete and sign the enclosed Verification Form and return it to your local Boston Scientific Office at «Customer\_Service\_Fax\_Number» before mentioned date on the form.

Please pass this notice to any health professional within your organization that needs to be aware of this notification.

We regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure patient safety.

Should you have any questions or require further assistance regarding this matter, please do not hesitate to contact your local Sales Representative.

Yours sincerely,

...  
Quality Department  
Boston Scientific International S.A.

November 2016

Dear Doctor,

This letter provides important product performance information regarding a population of fifteen (15) Boston Scientific INGEVITY™ MRI endocardial pacing leads. There is a possibility that the polyurethane boot at the terminal end of the lead was not securely connected to the lead body. Investigation determined that manufacturing equipment may not have applied adequate adhesive between the terminal boot and lead body. These leads were sold in Belgium, Germany, Italy, Netherlands, the United Kingdom, and the United States.

**Clinical Considerations**

Implant status of leads is not reported to Boston Scientific in all geographies. Boston Scientific therefore is unable to determine how many of the 15 leads have been implanted. However, no adverse events associated with this population have been reported. When the terminal of an affected lead is successfully connected to the pulse generator, normal chronic lead performance is expected. However, damage may occur to the terminal boot during lead or pulse generator replacement. Additional considerations at the time of system revision are contained in recommendations below.

**Recommendations**

- 1- If an affected lead (Table 1) has not been implanted, please return to Boston Scientific (do not implant).
- 2- If an affected lead (Table 1) has been implanted, Boston Scientific recommends normal follow-up monitoring, either in clinic or via the LATITUDE remote Patient Management System.
- 3- If an affected lead terminal is to be removed from a lead port (during pulse generator or lead replacement):
  - a. When the lead under revision is a ventricular lead for a pacemaker dependent patient, ensure access to a temporary backup pacemaker.
  - b. Visually inspect terminal boot integrity. Confirm the boot is not loose or damaged.
  - c. Perform standard electrical lead tests using a Pacing System Analyzer prior to inserting into a new pulse generator.
  - d. Insert and connect the lead terminal to the pulse generator in accordance with instructions for use.
  - e. Perform electrical lead tests using the pulse generator (per instructions for use).
- 4- If there is evidence that either the integrity of the terminal boot or the electrical performance of the lead is compromised, consider placement of a new lead.

## Affected Population

**Table 1:** Affected INGEVITY™ MRI endocardial pacing leads (by sold to country and model/serial number)

Country	Model/Serial Number
Belgium	7736/631322
	7741/636545
Germany	7741/641593
Italy	7736/632188
	7742/584869
Netherlands	7742/631202
United Kingdom	7732/488740
	7740/610662
	7741/563539
	7741/628198
	7741/656713
	7741/656904
United States	7742/572200
	7740/633464
	7741/657588

No other Boston Scientific INGEVITY leads or other lead families are affected.

### Further information

We recognize the impact of this communication on you and your patient, and want to reassure you that patient safety remains our primary concern. If you have any questions or feel that an implanted lead system is not performing as expected, please contact your local Boston Scientific representative or Technical Services.

Sincerely,

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Quality Department  
Boston Scientific International S.A.