

<**References: 92705305 & 92289212-FA**>

3 June 2021

**Cover letter for Distributors – Urgent Field Safety Notices
INGENIO™ Family DR EL Pacemakers and CRT-Ps (92705305-FA)
And
Hydrogen Induced Accelerated Battery Depletion (92289212-FA)**

Dear «Users_Name»,

Please find attached:

- Distributor Acknowledgement Form and,
- Customer package document being issued by Boston Scientific.

You are kindly requested to follow the below instructions:

- 1- Please read the two (2) Field Safety Notices.
- 2- Please notify all of your Customers that have received Model 3120 and 3300 Programmers. While the programmer is not affected by these advisories, programmer locations are being used to identify locations where patients may be followed.
 - a. Send the packages to your Customers via courier company, email or hand delivery. Keep evidence of delivery.
 - b. Retain all returned Acknowledgement Forms from your Customers.
- 3- After confirming all customers have been provided with their Customer package, complete and sign the attached Distributor Acknowledgement Form. Return the form to Boston Scientific via email at «Customer_Service_Fax_Number» by **25 June 2021**.

The BSC website has the **Device Lookup Tool, with all two advisories**. Available in multiple language;
Link: <https://www.bostonscientific.com/en-US/pprc/device-lookup-tool/device-lookup-tool-eu-en.html>

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice, unless per local regulation, this task is to be performed by you as a Distributor.

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

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



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

Attachment: - Distributor's Acknowledgement Form
- Field Safety Notices



Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_name»

Distributor's Acknowledgement Form – Field Safety Notices:

**INGENIO™ Family DR EL Pacemakers and CRT-Ps
And
Hydrogen Induced Accelerated Battery Depletion**

92705305 & 92289212-FAs

**I acknowledge receipt of the
Boston Scientific Field Safety Notices
dated 3 June 2021 for the
INGENIO™ Family DR EL Pacemakers and CRT-Ps
And
Hydrogen Induced Accelerated Battery Depletion
and will disseminate this information to our customers.**

NAME* _____ **TITLE** _____

Telephone _____ Email _____

Distributor' SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy