

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country»

<Reference: 92984351-FA>

2 March 2023

Urgent Field Safety Notice - Important Medical Device Information Habib™ EndoHPB Bipolar Radiofrequency Catheter IFU Generator Setting

Dear «Users_Name»,

This Field Safety Notice provides important information about the use of the Habib EndoHPB Catheter when used with the ERBE VIO® 3 Generator. **Habib EndoHPB Catheter users should cease use with the ERBE VIO 3 Generator immediately** due to the potential for delivery of excessive energy leading to thermal injury or tissue damage as a result of the inaccurate setting currently provided in the Habib EndoHPB Catheter's Instructions for Use ("IFU"). Boston Scientific recommends that patients who have been treated using the Habib EndoHPB Catheter with the ERBE VIO 3 Generator continue with their regular or routine check-ups and follow-up care.

This Field Safety Notice affects only the UPN(s) and lot(s) listed below. No other UPNs or lots are impacted by this Field Safety Notice.

Product Description	UPN #	GTIN	Lot/Batch #	Expiration Date
Habib™ EndoHPB Bipolar Radiofrequency Catheter	M00500070	08714729981909	All	All

Boston Scientific is not removing any Habib EndoHPB Catheter devices from the field. Devices remain available for use, as the current Habib EndoHPB Catheter IFU identifies ten (10) other generators in which the Habib EndoHPB Catheter IFU lists correct settings. This generator information is presented in the table below.

Generator	Recommended Generator Settings
<ul style="list-style-type: none">ERBE ICC200™ERBE ICC300™ERBE ICC350™	Bipolar Mode Coagulation mode Power Setting: 7-10 Watts (Low-High) 90 seconds
<ul style="list-style-type: none">ERBE VIO™ 200 (D/S)ERBE VIO™ 300 (D/S)	Soft Coag Mode Effect 8 Power Setting: 7-10 Watts (Low-High) 90 seconds

Generator	Recommended Generator Settings
Genii™ GI 4000	Bipolar Mode Power setting: 22-32 Watts (Low-High) 120 seconds
KLS MARTIN MAXIUM™	Micro Coag Mode Power Setting: 9-12 Watts (Low-High) 90 seconds
Olympus ESG-100	Soft Coag Mode Power Setting: Level 22-32 (Low-High) 120 seconds
RITA 1500	Power Setting: 7-10 Watts (Low-High) 90 seconds
RITA 1500X	Power setting: 7-10 Watts (Low-High) 90 seconds

The most serious adverse health consequence reasonably foreseeable to occur associated with use of the Habib EndoHPB Catheter with the ERBE VIO 3 Generator with the setting currently listed in the IFU is anticipated to be thermal injury to the surrounding vessels. To date, there has been one event reported to Boston Scientific associated with thermal injury to surrounding vessels potentially leading to thrombosis and death involving use of the Habib EndoHPB Catheter with the ERBE VIO 3 Generator.

The most common adverse health consequence reasonably foreseeable to occur associated with the use of the Habib EndoHPB Catheter with the ERBE VIO 3 Generator with the setting currently listed in the IFU is tissue damage or thermal injury. To date, there has been one event reported to Boston Scientific associated with tissue damage.

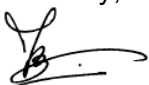
Instructions:

- 1- **Habib EndoHPB Catheter users should cease use with the ERBE VIO 3 Generator immediately.**
- 2- Please read carefully the Field Safety Notice letter and immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.
- 3- Please complete the attached Acknowledgement Form even if you do not have any affected product.
- 4- When completed, please **return the Acknowledgement Form to your Boston Scientific office** for the attention of «**Customer_Service_Fax_Number**» **on or before 22 March 2023.**
- 5- Please pass on this notice to any healthcare professional from your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

Patient safety remains our highest priority and we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information, please contact your local Boston Scientific sales representative.

Sincerely,



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

Attachment: - Acknowledgement Form



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

«Sold_to» - «Hospital_Name» - «City» - «Country»

Acknowledgement Form – Field Safety Notice

Habib™ EndoHPB Bipolar Radiofrequency Catheter IFU Generator Setting
92984351-FA

By signing this form, I confirm that

**I have read and understood
the Boston Scientific Field Safety Notice**

dated 2 March 2023 for

Habib™ EndoHPB Bipolar Radiofrequency Catheter IFU Generator Setting

NAME* _____ **Title** _____

Telephone _____ **Email** _____

SIGNATURE* _____ **DATE*** _____

* Required field

dd/mm/yyyy