FIELD SAFETY NOTICE (FSN)

Issue Date: 12 APRIL 2021

FSN #: 20210412_SILK VISTA_MRI INFORMATION ERROR
PURPOSE: Incorrect MRI information for stent flow-diverter SILK Vista
PRODUCT RANGE: SILK VISTA (stent flow-diverter for interventional neuroradiology)
PRODUCT REF: ALL REFERENCES *(SILK_V_3,50X15/ SILK_V_3,50X20/ SILK_V_3,50X25/ SILK_V_3,50X30/ SILK_V_3,50X35/ SILK_V_3,50X40/ SILK_V_3,75X15/ SILK_V_3,75X20/ SILK_V_3,75X25/ SILK_V_3,75X30/ SILK_V_4,00X15/ SILK_V_4,00X20/ SILK_V_4,00X25/ SILK_V_4,00X30/ SILK_V_4,25X15/ SILK_V_4,25X20/ SILK_V_4,25X25/ SILK_V_4,25X30/ SILK_V_4,50X15/ SILK_V_4,50X20/ SILK_V_4,50X25/ SILK_V_4,50X30/ SILK_V_4,75X15/ SILK_V_4,75X20/ SILK_V_4,75X25/ SILK_V_4,75X30)*
LOTS #: ALL LOTS
Who may be affected: Distributors, Safety Officers, Pharmacists, Vigilance Coordinators, and Head of Neuroradiology Department in Healthcare Centers.

Dear Customers,

During the post-marketing surveillance program, Balt Extrusion SAS received a customer complaint about an error in the MRI information regarding the Silk Vista stent. Indeed, a physician noticed in the Instruction For Use (IFU) that the SAR (Specific Absorption Rate) value for the Silk Vista is incorrect 0.5W/kg at 1.5 Tesla and 0.6W/kg at 3 Tesla. This level makes the use of MRI impossible, as in normal imaging conditions, the SAR exceeds those values.

As the end-user follows the exact MRI information described in the IFU, the MRI exam is not possible to perform.

The investigations revealed that the root cause is related to a recopying error in the MRI Safety and Compatibility Information section of the SILK Vista's IFU (in section 7bis in both the IFUs MDE046 ind.14 and MDE056 ind.4).

The following directions should be applied to MRI exam related to SILK Vista products:

Non-clinical testing has demonstrated "flow diverter" SILK VISTA stent range is "MR Conditional" in accordance with the ASTM F2503-13 standard [1] definitions.
A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Patient implanted with one stent only and with uncompromised thermoregulation,
- Horizontal bore MRI system with a static magnetic field of 1.5 Tesla or 3 Tesla,
- Gradient magnetic fields lower or equal to 19T/m,
- $B_0 * |dB_0/dr|$ product lower or equal to $48T^2/m$,
- RF whole body transmit/receive coil use only,
- Whole body averaged SAR (Specific Absorption Rate) limited to Normal operating mode (WB-SAR ≤2W/kg),
- During non-clinical testing, the "Flow diverter" SILK VISTA stent produced a maximal temperature rise of 4.6 ± 1.0°C at 1.5T for a measured WB-SAR of 2.15 ± 0.81 W/kg and a maximal temperature rise of 3.5 ± 1.0 °C at 3T for a measured WB-SAR of 2.15 ± 0.88 W/kg both after 15 minutes of continuous scanning,
- MR image quality may be compromised if the imaging area of interest is in the exact same area of the implant.

[1] ASTM F2503 - 13, 2013, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment," ASTM International, West Conshohocken, PA, 2013. DOI: 10.1520/F2503-13

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There is no device failure but a mistake in the product IFU. The error is likely to be recognized by the user while reviewing the IFU as reported in the complaint. The user can recognize the discrepancy.

The instructions for use will be updated accordingly.

Please note that no product return or rework is required as a result of this notification.

Procedure to be applied by distributors and subsidiaries:

- Inform your customers and your local competent authority (outside EEA, UK, Switzerland and Turkey) about this notice.
- Complete and return the "Notice Receipt form" below (Appendix section) as soon as possible to the e-mail address: Claim@balt.fr.
- Contact BALT Extrusion SAS for any additional information.

Procedure to be applied by the hospital staff:

- Communicate this information to staff within the hospital that may use SILK Vista stents or use MRI imaging for SILK Vista treated patients and any other person if deemed necessary.
- Complete and return the "Notice Receipt form" below (Appendix section) as soon as possible to the e-mail address: Claim@balt.fr.
  By returning the completed Notice Receipt form by e-mail or mail, you acknowledge that you have read and understood this Field Safety Notice.
- Contact Balt Extrusion SAS or your local distributor for any additional information.

Should you require any additional information about this field safety notice, do not hesitate to contact our Quality Department or your local distributor.

Contact:
Quality Department
✉ : claim@balt.fr
BALT EXTRUSION SAS
10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY - France
☎: +33.1.39.89.46.41 / Fax: +33.1.34.17.03.46

We confirm that the French competent authority ANSM has been informed beforehand about this field safety notice.

We apologize for any inconvenience that this action may cause, and we thank you for your cooperation.

Paul Ruthenbeck-Chiaramonte
Quality Director
Vigilance Coordinator Deputy

Appendix: Notice Receipt ref. # FSN #: 20210412_SILK VISTA_MRI INFORMATION ERROR

RETURN THE COMPLETED RECEIPT BY: FAX: +33.1.34.17.03.46 / MAIL: BALT EXTRUSION SAS 10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY (Quality Department) / **E-MAIL:** claim@balt.fr

Please check the two boxes below:

☐ ***I confirm that I have received and read this Field Safety Notice (FSN #: 20210412_SILK VISTA_MRI INFORMATION ERROR) and acknowledge the updated MRI Safety and Compatibility recommendation for Silk Vista products.***

☐ ***I hereby acknowledge that all required personnel or customers have been notified of this MRI Safety and Compatibility recommendation,***

NAME:	
TITLE:	
COMPANY/ HOSPITAL:	
LOCATION:	
CONTACT (E-MAIL AND/OR PHONE):	
DATE:	
SIGNATURE:	

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