URGENT FIELD SAFETY NOTICE (FSN) – PRODUCT RECALL

Issue Date: 19 July 2024

FSN #: 20240719_SILK VISTA BABY Wrong Size
PURPOSE: Wrong SILK VISTA BABY flow diverter length
PRODUCT RANGE: SILK VISA BABY
PRODUCT REF. and LOTS #:

Reference	Lot Number	UDI-DI
SILK_V 2,75x15	**00567127**	**03700481337974**
SILK_V 2,75x20	**00567540**	**03700481337981**

<u>Who may be affected</u>: Distributors, safety Officers, Pharmacists, Vigilance Coordinators, Interventional Neuroradiology and Neurosurgery Departments.

Dear Customers,

The purpose of this letter is to advise affected customers that Balt Extrusion SAS is recalling two (2) lots of the SILK VISTA BABY devices due to the possibility of an inaccuracy between actual and labeled stent length:
- 20mm for the SILK_V 2,75x15 instead of 15mm.
- 15mm for SILK_V 2,75x20 instead of 20mm.

In June 2024, a complaint was reported to Balt Extrusion SAS from Italy, concerning a SILK_V 2,75x15 Lot 00567127, indicating that based on the description of incident the physician felt that the stent may have been longer than the 15mm length specified on the label.

No patient injury was associated with the procedure involving the suspected implanted flow diverter, and the patient is currently in good health. Furthermore, to date no further complaints have been reported to Balt with the same issue.

A thorough investigation was carried out to confirm whether the product had the right length, determine the cause and identify possible other affected units and lots. This included an exhaustive review of internal factors such as the manufacturing processes and lot history records, along with detailed evaluation of the information provided by the hospital, including review of CT scan images and careful review of the physician feedback.

From these investigations we were not able to formally confirm the alleged device length discrepancy complaint raised by the physician. However, considering potential clinical risk associated with potential inaccurate flow diverter length when compared to the labeled length (e.g. risk of stent displacement or migration), Balt Extrusion SAS has decided, out of an abundance of caution, to recall two (2) batches of SILK VISTA BABY. This decision reflects our commitment to maintaining patient safety and ensuring the quality of our products.

<u>Procedure to be applied by distributors and subsidiaries</u>:

- Inform your customers and your local competent authority about this notice (outside EEA, UK, Switzerland, and Turkey).
- Return to Balt Extrusion SAS the applicable products and lots from the provided list.
    - Fulfill the “Notice of Receipt” (refer to the annex on page 3) then return it to Balt Extrusion SAS via FSCA_QA@baltgroup.com
    - Collect and put in quarantine the SILK VISTA BABY concerned by this recall and then return them to Balt Extrusion SAS through the usual “RMA” (Return Materials Authorization) procedure by contacting our Customer Service department.
    - Keep Balt Extrusion SAS informed of the status of products concerned by this recall.

- 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 the above-mentioned references and lots (see above for details) or any other person if deemed necessary.
- Return to Balt Extrusion SAS the applicable products and lots from the provided list.
    - Fulfill the "Notice of Receipt" (refer to the annex on page 3) then return it to Balt Extrusion SAS via FSCA_QA@baltgroup.com .
    - Collect and put in quarantine the SILK VISTA BABY concerned by this recall and then return them to Balt Extrusion SAS through the usual "RMA" (Return Materials Authorization) procedure by contacting our Customer Service department.
    - Keep Balt Extrusion SAS informed of the status of products concerned by this recall.
- Contact BALT Extrusion SAS for any additional information.

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

Contact:

Quality Department
✉ : FSCA_QA@baltgroup.com
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 apologize for any inconvenience that this action may cause, and we thank you for your cooperation.

Thomas COLSON
VP, Global Quality

Claus Freyinger
VP, Global Regulatory, Clinical, Medical Affairs

Appendix: Notice Receipt ref. # 20240719_SILK VISTA BABY Wrong Size

RETURN THE FULFFILED 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:** FSCA_QA@baltgroup.com

Please check the two boxes below:

☐ ***We confirm that I have received and read this Field Safety Notice (FSN #: 20240719)***
☐ ***We hereby acknowledge that all required personnel or customers have been notified of this Field Safety Notice,***

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

☐ ***We confirm that, after verification of our internal and customers' (incl. end-users) inventory stock, we declare having no products from the below references concerned by this recall procedure.***

☐ ***If not, please indicate the volume of products units available and not available for return to BALT Extrusion SAS per this recall procedure:***

Product reference	Lot Number	QTY available for return to BALT Extrusion SAS (distributor and end-user(s) inventory stock)
SILK_V 2,75x15	**00567127**	
SILK_V 2,75x20	**00567540**	

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