

## URGENT FIELD SAFETY NOTICE (FSN) / PRODUCTS RECALL

Issue Date: 24 FEBRUARY 2021

**FSN #: 20210224\_SILK Vista Baby\_Missing Spring**

**PURPOSE:** Missing Silk Vista Baby pusher's distal spring

**PRODUCT RANGE (INTENDED USE):** SILK Vista Baby (flow-diverter for treatment of intracranial aneurysms)

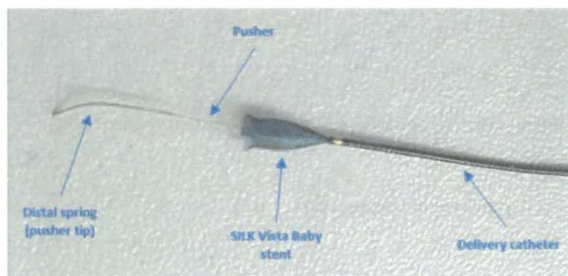
**PRODUCT REF:** SILK\_V\_3,25X25

**LOTS #:** 00387748

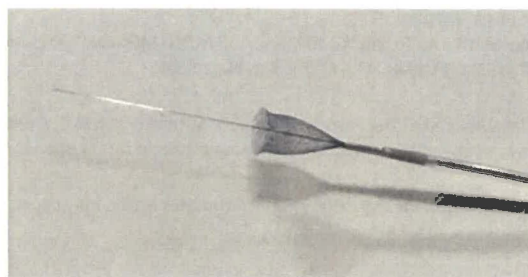
**Who may be affected:** Distributors, Safety Officers, Vigilance Coordinators, and Head of Neuroradiology Department in Healthcare Centers

Dear Partners,

During the post-marketing surveillance program, Balt Extrusion received complaints related to manufacturing lot 00387748 of reference SILK\_V\_3,25X25 where the radiopaque distal spring of SILK Vista Baby pusher was not visible on X-ray during the procedure.



Correct Configuration



Missing distal spring

In each reported complaint, the procedure was completed successfully, and no patient injury was observed. However, this issue is not detectable before the use of device in-vivo; Use of the device without a radiopaque distal spring may lead to a vessel damage/ rupture or may affect deployment. Thus, this failure mode could result in a permanent impairment or life-threatening injury for the patient.

The investigation revealed that the cause of these complaints was an isolated human error where the distal spring was never mounted on the pusher during our manufacturing process. Confirmation testing performed on our remaining inventory has concluded that the scope of this issue is limited to the lot subject to this FSN.

**To prevent any further issue during use, BALT Extrusion has decided to recall from the market the units of the affected lot number.**

**Procedure to be applied by distributors:**

- Inform your clients and your local competent authority about this notice;
- Identify and locate the SILK Vista Baby products concerned by this recall procedure;
- Collect and put in quarantine the SILK Vista Baby products concerned by this recall procedure and then return them to BALT Extrusion through the usual "RMA" (Return Material Authorization) procedure by contacting our customer service;
- Keep informed BALT Extrusion about the status of every unit of SILK Vista Baby product concerned by this recall procedure;
- Fulfill the receipt (cf. annex) then return it to BALT Extrusion via the indicated contact;
- Contact BALT Extrusion for any additional information.



**Procedure to be applied by the hospital staff:**

- Inform, within your hospital, the safety officers, the vigilance coordinators, and the neuroradiology department staff, as well as any other person if deemed necessary;
- Identify and locate the SILK Vista Baby products concerned by this recall procedure;
- Collect and put in quarantine the SILK Vista Baby products concerned by this recall procedure and then return them to your local distributor as per its return procedure;
- Keep informed your local distributor about the status of every unit of SILK Vista Baby product concerned by this recall procedure;
- Contact 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](mailto:claim@balt.fr)

BALT EXTRUSION

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), German competent authority (FIDMD) and Dutch Competent Authority (IH) have been beforehand informed about this field safety notice.

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

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**Annex: Notice Receipt ref. # 20210224\_SILK Visa Baby\_Missing Spring**

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

*We hereby acknowledge the receipt of the field safety notice reference "20210224\_SILK Vista Baby\_Missing spring" and we undertake to implement the actions therein mentioned.*

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

- We confirm that, after verification of our stock and the stocks of our users, we declare having no product SILK Vista Baby ref. SILK\_V\_3,25X25 lot #00387748 concerned by this recall procedure.
- If not, please, indicate the volume of SILK Vista Baby product(s) concerned by this recall procedure:

Product reference	Lot number	Quantity to be returned to BALT Extrusion (distributor <u>and</u> hospital(s) stocks)
SILK_V_3,25X25	00387748	

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