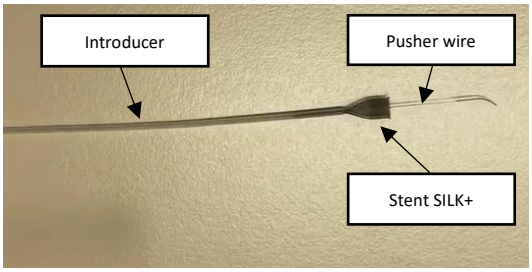
FIELD SAFETY NOTICE (FSN) / PRODUCTS RECALL

Issue Date: 22 JAN 2019

FSN #: 20190122_INTROSILK+
PURPOSE: Wrong introducer size for stent SILK+
PRODUCT RANGE: SILK+ (stent flow-diverter for interventional neuradiology)
PRODUCT REF: SILK4,0x20
LOTS #: 00327114 and 00327700
Who may be affected: Distributors, Safety Officers, Vigilance Coordinators and Head of Neuroradiology Department in Healthcare Centers

Dear Customers,

During Balt Extrusion's post-marketing surveillance program, Balt Extrusion received a total of 4 complaints related to the use of a **wrong introducer size for stents SILK+**. A larger introducer was inadvertently placed in the **2 lot numbers #00327114 and #00327700 reference SILK4,0x20**.



No patient injury was observed for the 4 complaints above-mentioned. Generally, the use of a introducer, with a larger lumen, implies the detachment of the stent from its pusher wire within the introducer or else, its blocking within the delivery catheter; in this configuration, the stent cannot be deployed into the patient and the system shall be replaced.

To prevent any further issue during use, BALT Extrusion has decided to recall from the market the units of the 2 affected lot numbers.

Procedure to be applied by distributors:

- Inform your clients and your local competent authority about this notice;
- Identify and locate the SILK+ products concerned by this recall procedure;
- Collect and put in quarantine the SILK+ products concerned by this recall procedure and then return them to BALT Extrusion through the usual "RMA" (Return Material Authorization) procedure by contacting our sales administration department;
- Keep informed BALT Extrusion about the status of every unit of SILK+ 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+ products concerned by this recall procedure;
- Collect and put in quarantine the SILK+ 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+ product concerned by this recall procedure;
- Contact your local distributor for any additional information.

BALT EXTRUSION SAS
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10 rue de la Croix Vigneron
95160 Montmorency • France
www.balt.fr

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
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 beforehand informed about this field safety notice.

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

Sophie REHAULT
Quality and Regulatory Affairs Director
Vigilance Coordinator

Annex: Notice Receipt ref. # 20190122_INTROSILK+

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

We hereby acknowledge the receipt of the notice reference "20190122_INTROSILK+" and we undertake to implement the actions therein mentioned.

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

☐ We confirm that, after verification of our stock and the stocks of our users, we declare having no product concerned by this recall procedure.

☐ If not, please, indicate the volume of SILK+ product(s) concerned by this recall procedure:

Product reference	Lot number	Quantity to return (distributor and hospitals)
SILK4,0X20	**00327114**	
SILK4,0X20	**00327700**	

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