

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

Issue Date: 21 MAY 2020

FSN #: 20200521\_SPIF\_MIX-UP

PURPOSE: Packaging Mix-up between 2 SPIF coils references

PRODUCT RANGE (INTENDED USE): SPIF+ (flow-coil for embolization of vascular malformations of the vasculature)

PRODUCT REF: SPIF 2,5X5P10 and SPIF 2,5X20P10

LOTS #: 00391846 (SPIF 2,5X5P10) and 00390815 (SPIF 2,5X20P10)

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

Dear Customers,

During the post-marketing surveillance program, Balt Extrusion received one (1) complaint related to the following issue:

- Flow-coil ref. SPIF 2,5X5P10 (length 5cm) / lot # 00391846 has been labeled under the ref. SPIF 2,5X20P10 (length 20cm) / lot # 00390815 (box and pouch);
- And on the opposite: flow-coil ref. SPIF 2,5X20P10 (length 20cm) / lot # 00390815 has been labeled under the ref. SPIF 2,5X5P10 (length 5cm) / lot # 00391846 (box and pouch).



Ref. SPIF 2,5X5P10 (length 5cm) / lot # 00391846 has been labeled under the ref. SPIF 2,5X20P10 (length 20cm) / lot # 00390815



Ref. SPIF 2,5X20P10 (length 20cm) / lot # 00390815 has been labeled under the ref. SPIF 2,5X5P10 (length 5cm) / lot # 00391846

No patient injury was observed for the complaint above-mentioned. However, the issue is not assuredly detectable before use and the inadvertent injection of the inadequate sized SPIF coil could represent a risk of adverse event such as: improper AVM occlusion, coil migration and/or vessel occlusion.

**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 SPIF products concerned by this recall procedure;
- Collect and put in quarantine the SPIF 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 SPIF 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 SPIF products concerned by this recall procedure;
- Collect and put in quarantine the SPIF 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 SPIF 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)

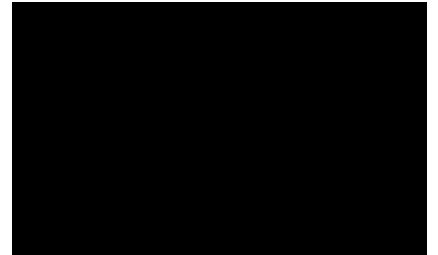
BALT EXTRUSION

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 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.



**Annex: Notice Receipt ref. # 20200521\_SPIF\_MIX-UP**

**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 notice reference "20200521\_SPIF\_MIX-UP" and we undertake to implement the actions therein mentioned.*

<b>NAME:</b>	
<b>TITLE:</b>	
<b>COMPANY:</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 concerned by this recall procedure.
- If not, please, indicate the volume of SPIF 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)
SPIF 2,5X5P10	00391846	
SPIF 2,5X20P10	00390815	

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