URGENT FIELD SAFETY NOTICE (FSN) / PRODUCT RECALL

Issue Date: 04 January 2022

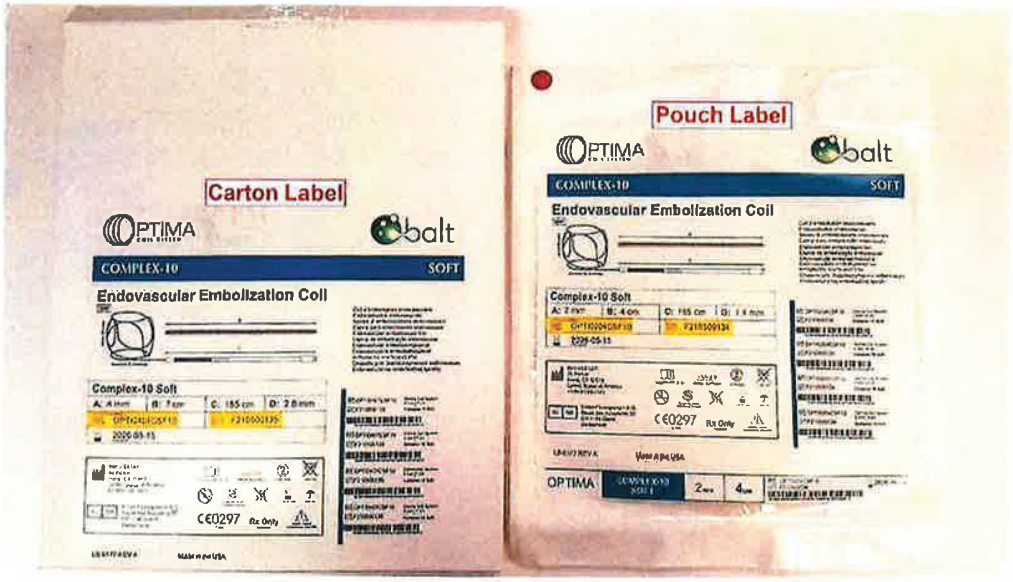
FSN #: 20220104_Optima Labeling Mix-Up
PURPOSE: Optima Labeling Mix-Up
PRODUCT RANGE (INTENDED USE): Optima Coil System (implantable embolic coil system)
PRODUCT REF: *OPTI0204CSF10 & OPTI0407CSF10*
LOTS #: F210500134 & F210500135

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

Note: BALT Extrusion SAS distributes this communication on behalf of BALT USA.

Dear Partners,

A recent field complaint has brought to our attention the existence of two (2) nonconforming lots of Optima Coil System devices.



With the way that product label reconciliation works at Balt USA, it can reasonably be assumed that there is at least one (1) other label mix-up in the field. This hazard presents a high risk to patient safety and product performance regarding the discrepant device(s) and should be returned to Balt USA for remediation.

Balt USA has not received any additional customer complaints for the affected lot numbers, however, to prevent any product misuse, Balt USA has decided to recall from the market all Optima Coil Systems from lot F210500134 & F210500135.

Note: BALT Extrusion SAS will handle the product recall on behalf of BALT USA.

BALT EXTRUSION SAS
R.C.S. Pontoise 315 633 081
T: +33 (0)1 39 89 46 41
F: +33 (0)1 34 17 03 46
10 rue de la Croix Vigneron
95160 Montmorency • France
www.balt.fr

Procedure to be applied by distributors/ subsidiaries:

- For outside EEA, inform your customers and your National Competent Authority about this notice;
- For inside EEA, inform your customers about this notice;
- Identify and locate the Optima products concerned by this recall procedure;
- Collect and put in quarantine the Optima products concerned by this recall procedure and then return them to BALT Extrusion SAS through the usual "RMA" (Return Material Authorization) procedure by contacting our customer service;
- Inform BALT Extrusion SAS about the status of every unit of Optima product concerned by this recall;
- Complete the "Notice of receipt" (cf. annex) then return it to BALT Extrusion SAS via the indicated contact;
- Contact BALT Extrusion SAS for any additional information.

Procedure to be applied by the hospital staff:

- Inform, within your hospital, Safety Officers, Pharmacists, Vigilance Coordinators, Head of Neuroradiology and the neuroradiology department staff, as well as any other person if deemed necessary;
- Identify and locate the Optima products concerned by this recall procedure;
- Collect and put in quarantine the Optima products concerned by this recall procedure and then return them to your local distributor as per its return procedure;
- Inform your local distributor or BALT Extrusion SAS about the status of every unit of Optima product concerned by this recall;
- Complete the "Notice of receipt" (cf. annex) then return it to BALT Extrusion SAS via the indicated contact;
- Contact your local distributor or BALT Extrusion SAS for any additional information.

Should you require any additional information about this Field Safety Notice (FSN), do not hesitate to contact our Quality Department or your local distributor.

Contact:
Quality Department
✉ : claim@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 this action may cause, and we thank you for your cooperation.

[redacted]

balt extrusion

Annex: Notice of Receipt ref. # 20220104_Optima Labeling Mix-Up

RETURN THE COMPLETED 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@baltgroup.com

We hereby acknowledge the receipt of the field safety notice reference "20220104_Optima Labeling Mix-Up," and we undertake to implement the actions therein mentioned.

NAME:	
TITLE:	
COMPANY/ HOSPITAL:	
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 Optima products (with lot # F210500134 or F210500135) concerned by this recall procedure.

☐ If not, please, indicate the volume of Optima product(s) (with lot # F210500134 or F210500135) by reference concerned by this recall procedure:

Carton Label Reference (Model # / Lot #)	Units to be returned to BALT Extrusion SAS (Quantity + Expiry date)
OPTI0204CSF10 / F210500134	
OPTI0407CSF10 / F210500135	

- End of document -

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