

## URGENT FIELD SAFETY NOTICE (FSN)

Issue Date: 26 JULY 2023

FSN #: 20230726\_FARGO\_CBV\_LABEL MIX-UP

PURPOSE: Packaging/labeling mix-up inside FARGO guiding catheter. Wrong label on FARGO pouch inside the box.

PRODUCT RANGE: FARGO and CRISTAL BALLOON (CBV)

PRODUCT REF: FRG6F115\_8MP / CBV18X40/110

LOTS #: 00468713 (FRG6F115\_8MP) / 00469479 (CBV18X40/110)

UDI-DI #: FRG6F115\_8MP (03700481333501) / CBV18X40/110 (03700481311981)

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

Dear partners,

During the post-market surveillance program, Balt Extrusion SAS received one complaint related to a labeling error on the TYVEK pouch of FRG6F115\_8MP guiding catheter ((label for Valvuloplasty Cristal Balloon CBV18X40/110 was applied).



Image 1: FRG6F115\_8MP lot 00468713 box label

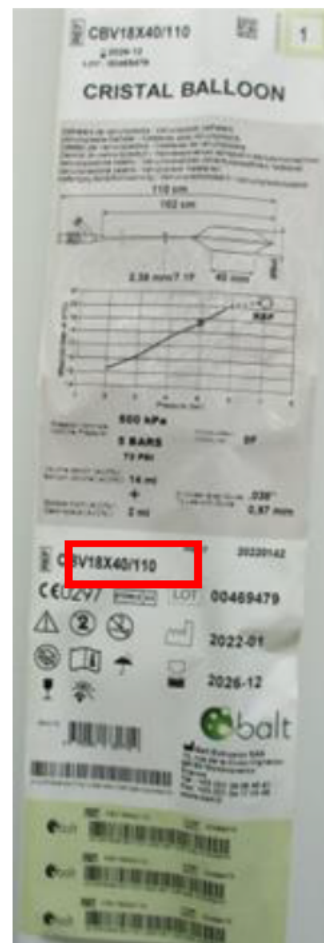


Image 2: FRG6F115\_8MP lot 00468713 pouch label



Image 3: FRG6F115\_8MP lot 00468713 HUB

No patient injury was observed for the complaint above-mentioned. Besides, this issue is necessarily detectable at the opening of the pouch since the compatible version of FRG6F115\_8MP guiding catheter is available to use with the box.

The investigations revealed that the root cause is related to human error during the manufacturing process (Labeling).

**To prevent any issue with label confusion, BALT Extrusion SAS has decided to issue this field safety corrective action with the procedures to apply.**

**Please note that no product return or rework is required because of this notification.**

**Procedure to be applied by distributors:**

- Inform your customers and your local competent authority about this notice.
- Complete and return the "Notice Receipt form" below (Appendix section) as soon as possible to the e-mail address: [Claim@baltgroup.com](mailto:Claim@baltgroup.com).
- 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 references and lots (see above for details) stents or any other person if deemed necessary.
- Complete and return the "Notice Receipt form" below (Annex section) as soon as possible to the e-mail address: [Claim@baltgroup.com](mailto:Claim@baltgroup.com).  
By returning the completed Notice Receipt form by e-mail or mail, you acknowledge that you have read and understood this Field Safety Notice.
- Contact Balt Extrusion SAS or 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@baltgroup.com](mailto:claim@baltgroup.com)

BALT EXTRUSION SAS

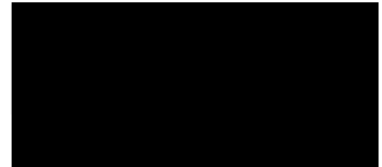
10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY - France

☎ : +33.1.39.89.46.41 / Fax: +33.1.34.17.03.46



We confirm that the French competent authority ANSM has been informed beforehand about this field safety notice.

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



**Vice-President Quality Global**

**Appendix: Notice Receipt ref. # FSN20230726\_FARGO\_CBV\_LABEL MIX-UP**

**RETURN THE FULFILLED 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](mailto:claim@baltgroup.com)**

*Please check the two boxes below:*

- I confirm that I have received and read this Field Safety Notice (FSN #: 20230726) and acknowledge the instructions provided.*
- I 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:	

**For BALT Extrusion SAS data consolidation purposes, please provide the number of units initially delivered:**

Product reference	Lot number	QTY Initially Delivered	QTY Used/Discarded
FRG6F115_8MP	00468713		
CBV18X40/110	00469479		

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