URGENT FIELD SAFETY NOTICE (FSN) – PRODUCT RECALL

Issue Date: 11 October 2023

FSN #: 20231011_HYBRID Wrong Device in Pouch
PURPOSE: Incorrect device reference inside the pouch
PRODUCT RANGE: HYBRID and SONIC
PRODUCT REF. and LOTS #:

Reference	Lot Number	UDI-DI
HYBRID1214D	**00506800**	**03700481334430**
HYBRID007D	**00506369**	**03700481334331**
HYBRID008D	**00521942**	**03700481334379**
HYBRID008J	**00520501**	**03700481334386**
HYBRID1214DA	**00514715**	**03700781338261**
HYBRID007J	**00520500**	**03700481334355**
HYBRID1214D	**00506801**	**03700481334430**
SONIC1.2F15/HYBRID007D-KIT	**00524096**	**00840303702092**
SONIC1.2F25/HYBRID007D-KIT	**00513093**	**00840303702108**
SONIC1.2F15/HYBRID007D-KIT	**00513550**	**00840303702092**

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

Dear partners,

During the post-market surveillance program, Balt Extrusion SAS received two (2) complaints related to friction during the use of HYBRID guidewire with MAGIC microcatheters. The investigation of the returned products confirmed that the products' dimensions do not match the specifications: the outer diameter of the HYBRID guidewires inside the pouch does not correspond to the outer diameter mentioned on the labels.

In each reported complaint, the procedure was completed successfully with no patient injury. However, the issue is not detectable before the use of the guidewire.

The use of the wrong size of HYBRID guidewire could damage the microcatheter resulting in the worst-case to permanent impairment (e.g., neurologic deficit) for the patient.

The investigation revealed that the root cause of these complaints was an isolated human error in production. Confirmation testing is being performed on our remaining inventory to confirm the scope of this issue is limited to the lot subject to this FSN.

To prevent any further issues during use, BALT Extrusion has decided to voluntarily recall from the market the units of the affected lot numbers (detailed above) pending the completion of the ongoing investigations.

Procedure to be applied by distributors:

- Inform your customers and your local competent authority about this notice (outside EEA, UK, Switzerland, and Turkey).
- Complete and return the "Notice Receipt form" below (Appendix section) as soon as possible to the e-mail address: 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 the above-mentioned references and lots (see above for details) 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.
  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 BALT Extrusion SAS Quality Department or your local distributor.

Contact:

Quality Department
✉ : claim@baltgroup.com
BALT EXTRUSION SAS
10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY - France
☎: +[redacted]

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

[redacted]

Vice-President Global Quality

Appendix: Notice Receipt ref. # FSN202310 11 _ HYBRID Wrong Device in Pouch

RETURN THE FULFFILED RECEIPT BY: FAX: [redacted] **/ MAIL**: BALT EXTRUSION SAS 10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY (Quality Department) / **E-MAIL:** claim@baltgroup.com

Please check the two boxes below:

☐ ***We confirm that I have received and read this Field Safety Notice (FSN #: 20231011)***
☐ ***We 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:	

☐ ***We confirm that, after verification of our internal and customers' (incl. end-users) inventory stock, we declare having no products from the below references concerned by this recall procedure.***

☐ ***If not, please indicate the volume of products units available and not available for return to BALT Extrusion SAS per this recall procedure:***

Product reference	Lot Number	QTY available for return to BALT Extrusion SAS (distributor and end-user(s) inventory stock)	QTY not available for return to BALT Extrusion SAS (distributor and end-user(s) inventory stock)
HYBRID1214D	00506800		
HYBRID007D	00506369		
HYBRID008D	00521942		
HYBRID008J	00520501		

HYBRID1214DA	**00514715**		
HYBRID007J	**00520500**		
HYBRID1214D	**00506801**		
SONIC1.2F15/ HYBRID007D- KIT	**00524096**		
SONIC1.2F25/ HYBRID007D-KIT	**00513093**		
SONIC1.2F15/ HYBRID007D-KIT	**00513550**		

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