

## 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, and Head 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. No patient injury was observed for the complaint above-mentioned.

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.

The investigation revealed that the 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](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 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](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 BALT Extrusion SAS 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 apologize for any inconvenience that this action may cause, and we thank you for your cooperation.



**Thomas COLSON**  
Vice-President Global Quality

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

**RETURN THE FULFILLED RECEIPT BY: FAX: +33.1.34.17.03.46 / MAIL: BALT EXTRUSION SAS 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:*

- 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,*

<b>NAME:</b>	
<b>TITLE:</b>	
<b>COMPANY/ HOSPITAL:</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 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 <u>available</u> for return to BALT Extrusion SAS (distributor <u>and</u> end-user(s) inventory stock)	QTY <u>not available</u> for return to BALT Extrusion SAS (distributor <u>and</u> end-user(s) inventory stock)
HYBRID1214D	00506800		
HYBRID007D	00506369		
HYBRID008D	00521942		
HYBRID008J	00520501		

<b>HYBRID1214DA</b>	<b>00514715</b>		
<b>HYBRID007J</b>	<b>00520500</b>		
<b>HYBRID1214D</b>	<b>00506801</b>		
<b>SONIC1.2F15/ HYBRID007D- KIT</b>	<b>00520506</b>		
<b>SONIC1.2F25/ HYBRID007D-KIT</b>	<b>00513093</b>		
<b>SONIC1.2F15/ HYBRID007D-KIT</b>	<b>00513550</b>		

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