URGENT FIELD SAFETY NOTICE (FSN) – PRODUCT RECALL

Issue Date: 31 October 2025

FSN #: HHE2025-013_HYBRID007D straight guidewire – Frictions with microcatheter
PURPOSE: Frictions between HYBRID straight guidewire and microcatheter
PRODUCT RANGE: HYBRID
PRODUCT REF. and LOTS #:

Reference	Lot Number	Quantity Impacted	UDI-DI
HYBRID007D	**00535219**	**101**	**03700481334331**

<u>Who may be affected</u>: Distributors, safety Officers, Pharmacists, Vigilance Coordinators, Interventional Neuroradiology and Neurosurgery Departments.

Dear Customers,

The purpose of this letter is to advise affected customers that Balt Extrusion is recalling one (1) lot of the HYBRID straight guidewire device due to the possibility of friction during guidewire navigation in the microcatheter.

In October 2025, complaints were reported to Balt Extrusion from Germany, concerning HYBRID007D Lot 00535219, indicating, based on the description of the incident, the physician felt resistance and an increased guidewire friction inside the microcatheter.

No patient injury was associated with the procedure involving the use of the guidewire. In total, to date twelve (12) complaints have been reported to Balt for the same issue (friction) on twelve (12) units of the same reference and lot number. No patient was associated with these complaints. The patients are reported to be in good health.

A thorough investigation will be carried out to find the root cause of this failure and to identify possible other affected units and lots. This includes a review of internal factors such as the manufacturing processes and lot history records, along with detailed evaluation of the information provided by the hospital, including careful analysis of the returned products and of the physician feedback.

Considering the potential clinical risks associated (e.g., extension of procedure that could lead to vessel injury), Balt Extrusion has decided to recall this batch of HYBRID. This decision reflects our commitment to maintaining the highest standards of patient safety and product quality.

Procedure to be applied by distributors and subsidiaries:

- Inform your customers and your local competent authority about this notice.
- Return to Balt Extrusion the applicable products and lots from the provided list.
    - Fulfill the "Notice of Receipt" (refer to the annex pages) then return it to Balt Extrusion via FSCA_QA@baltgroup.com
    - Collect and put in quarantine the HYBRID concerned by this recall and then return them to Balt Extrusion through the usual "RMA" (Return Materials Authorization) procedure by contacting our Customer Service department.
    - Keep Balt Extrusion informed of the status of products concerned by this recall.
    - Contact BALT Extrusion 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.
- Return to Balt Extrusion the applicable products and lots from the provided list.
    - Fulfill the "Notice of Receipt" (refer to the annex pages) then return it to Balt Extrusion via FSCA_QA@baltgroup.com .
    - Collect and put in quarantine the HYBRID concerned by this recall and then return them to Balt Extrusion through the usual "RMA" (Return Materials Authorization) procedure by contacting our Customer Service department.
    - Keep Balt Extrusion informed of the status of products concerned by this recall.
- Contact BALT Extrusion for any additional information.
- Should you require any additional information about this field safety notice, do not hesitate to contact BALT Extrusion Quality Department or your local distributor.

Contact:

Quality Department
✉ : FSCA_QA@baltgroup.com
BALT EXTRUSION SAS
10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY - France
☎: +33.1.39.89.46.41

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

Thomas COLSON
VP, Global Quality

Claus Freyinger
VP, Global Regulatory, Clinical, Medical Affairs

Annex: Notice of Receipt ref. HHE2025-013

RETURN THE COMPLETED RECEIPT BY: MAIL: 10 Rue de la Croix Vigneron, 95160 Montmorency, France (Quality Department) / **E-MAIL:** FSCA_QA@baltgroup.com

Mandatory fields are marked with *

1. Field Safety Notice (FSN) information	
FSN Reference number*	HHE2025-013
FSN Date*	31 OCTOBER 2025
Product/ Device name*	HYBRID
Product Code(s) and Lot Numbers	HYBRID007D Lot 00535219

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	FSCA_QA@baltgroup.com
Postal Address	Balt Extrusion SAS Rue du Fonds des Aulnes, 95160 Montmorency - FRANCE
Deadline for returning the Distributor/Importer reply form*	14 Business Days

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	We confirm that, after verification of our stock and the stocks of our users, we declare having no physical HYBRID product(s) concerned by this recall procedure listed within Section 1 (Field Safety Notice (FSN) information)	N/A
☐	We declare as having physical HYBRID product concerned by this recall listed within Section 1 (Field Safety Notice (FSN) information). We have indicated the lot number, model/size and volume of HYBRID	Distributor/Importer to enter quantity and date on page **5**

	product(s) concerned by this recall and will return the affected units to Balt Extrusion.	
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Complete page **5**
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

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We hereby acknowledge the receipt of the recall notice reference "HHE2025-013", and we undertake to implement the actions mentioned therein.

Affected Lot Number	Model Number	Quantity To Be Returned to Balt Extrusion
00535219	HYBRID007D	

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