



URGENT FIELD SAFETY NOTICE (FSN) – PRODUCT RECALL

Issue Date: 23 July 2026

FSN #: HHE2026003_ANRYV Connector – Potential Endotoxins Contamination

PURPOSE: Voluntary Recall Due to Potential Endotoxins Contamination

PRODUCT RANGE: ANRYV

PRODUCT REF. and LOTS #: See (Annex: Notice of Receipt ref. HHE2026003)

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

Dear Customers,

Balt Extrusion SAS has identified non-conforming bacterial endotoxin test results during routine quality control testing performed on sampled ANRYV connectors.

Following the opening of internal non-conformance investigations and an assessment of manufacturing records, Balt Extrusion SAS determined that two production lots of the ANRYV connector did not meet the established endotoxin acceptance criteria. As routine quality control testing is performed on a sampling basis, Balt Extrusion SAS cannot exclude the presence of non-conforming devices within the affected production lots.

The identified non-conformance relates exclusively to bacterial endotoxin test results obtained during routine quality control testing. The investigation is ongoing to determine the root cause, and appropriate corrective and preventive actions are being implemented to prevent recurrence.

The potential risk associated with the use of a non-conforming ANRYV connector is exposure to bacterial endotoxins, which may lead to an inflammatory reaction.

To date, Balt Extrusion SAS has not received any complaints, vigilance reports or post-market surveillance data indicating patient injury or adverse events related to this issue.

In accordance with our commitment to product quality, customer satisfaction and patient safety, Balt Extrusion SAS has decided to voluntarily recall the affected ANRYV connector lots, as well as all product kits containing ANRYV connectors from these lots as a precautionary measure.

This voluntary recall applies only to the product references and lot numbers listed in this Field Safety Notice. Products not included in the scope of this communication are not affected by this action.

Balt Extrusion SAS continues to monitor product quality through its quality management system and post-market surveillance activities. We sincerely apologize for any inconvenience this action may cause and thank you for your cooperation and continued trust.



Procedure to be applied by distributors and subsidiaries:

- Sent the FSN to your customers/end users and your local competent authority
- Collect the "Notice of Receipt" from your customers/end users
- Fulfill the "Notice of Receipt" (refer to the annex pages) then return it to Balt Extrusion SAS via FSCA_QA@baltgroup.com
- Stop the distribution of the ANRYV references and lots concerned by this recall
- Put in quarantine the ANRYV references and lots concerned by this recall
- Collect and return the quarantined products to Balt Extrusion SAS through the usual "RMA" (Return Materials Authorization) procedure by contacting our Customer Service department.
- Keep Balt Extrusion SAS informed of the status of products concerned by this recall.
- 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.
- Fulfill the "Notice of Receipt" (refer to the annex pages) then return it to Balt Extrusion SAS via FSCA_QA@baltgroup.com
- Stop the use of the ANRYV references and lots concerned by this recall
- Put in quarantine the ANRYV references and lots concerned by this recall
- Collect and return the quarantined products to Balt Extrusion SAS through the usual "RMA" (Return Materials Authorization) procedure by contacting our Customer Service department.
- Keep Balt Extrusion SAS informed of the status of products concerned by this recall.
- Contact BALT Extrusion for any additional information.

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



Annex: Notice of Receipt ref. HHE2026003

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*	HHE2026003
FSN Date*	23/07/2026
Product/ Device name*	ANRYV
Product Code(s) and Lot Numbers	See Annex (Annex: Notice of Receipt ref. HHE2026003)

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 10 rue de la Croix Vigneron 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.	<i>Distributor/Importer to complete or enter N/A</i>
☐	We confirm that, after verification of our stock and the stocks of our users, we declare having no physical ANRYV product(s) concerned by this recall procedure listed within the Annex (Annex: Notice of Receipt ref. HHE2026003)	N/A
☐	We declare as having physical ANRYV product concerned by this recall listed within the Annex (Annex: Notice of Receipt ref. HHE2026003). We have indicated the lot number, model/size and volume of ANRYV product(s) concerned by this recall and will	<i>Distributor/Importer to enter quantity and date on page 5</i>



	return the affected units to Balt Extrusion SAS.	
☐	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.	<i>Complete page 5</i>
Print Name*		<i>Distributor/Importer print name here</i>
Signature*		<i>Distributor/Importer sign Here</i>
Date *		



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(Quality Department) / E-MAIL: FSCA_QA@baltgroup.com

We hereby acknowledge the receipt of the recall notice reference "HHE2026-003", and we undertake to implement the actions mentioned therein.

Model Reference	Affected Lots Numbers	Expiry Date	Quantity To Be Returned to Balt Extrusion SAS
ANRYV	00611242	28/05/2030	
ANRYV	00611248	28/05/2030	
LEO35X18	00638324	28/12/2030	
LEO35X18	00645478	28/02/2031	
LEO35X25	00638449	28/12/2030	
LEO35X25	00638501	28/12/2030	
LEO35X25	00644652	28/02/2031	
LEO35X25	00645903	28/02/2031	
LEO35X25	00648949	28/03/2031	
LEO35X30	00641782	28/01/2031	
LEO35X30	00648954	28/04/2031	
LEO35X35	00633163	28/11/2030	
LEO35X35	00638329	28/12/2030	
LEO35X35	00640610	28/01/2031	
LEO35X35	00645585	28/02/2031	
LEO35X50	00633357	28/11/2030	
LEO35X50	00646864	28/03/2031	
LEO40X15	00639818	28/01/2031	
LEO40X20	00638293	28/12/2030	
LEO40X20	00640637	28/01/2031	
LEO40X20	00649542	28/03/2031	
LEO40X25	00640831	28/01/2031	
LEO40X25	00646075	28/02/2031	
LEO40X30	00639961	28/01/2031	
LEO40X30	00652079	28/04/2031	
LEO40X35	00645061	28/02/2031	
LEO40X35	00650616	28/04/2031	
LEO45X20	00638682	28/12/2030	
LEO45X20	00650473	28/04/2031	
LEO45X25	00639891	28/01/2031	
LEO45X25	00643348	28/02/2031	
LEO45X25	00646869	28/03/2031	
LEO45X25	00648964	28/03/2031	
LEO45X30	00638124	28/12/2030	

LEO45X30	00639819	28/01/2031	
LEO45X30	00643012	28/02/2031	
LEO45X30	00648969	28/03/2031	
LEO45X40	00638339	28/12/2030	
LEO45X50	00640169	28/01/2031	
LEO45X50	00648975	28/03/2031	
LEO45X75	00640688	28/01/2031	
LEO45X75	00642504	28/01/2031	
LEO55X25	00632942	28/10/2030	
LEO55X30	00639496	28/01/2031	
LEO55X35	00634316	28/11/2030	
LEO55X35	00644632	28/02/2031	
LEO55X50	00633957	28/11/2030	
LEO55X50	00643321	28/02/2031	
LEO55X50	00646598	28/03/2031	
LEO55X50	00651442	28/04/2031	
LEO55X60	00634913	28/11/2030	
LEO55X75	00639251	28/01/2031	
SCOPERNIC10	00643117	28/02/2031	
SCOPERNIC15	00643128	28/03/2031	
SCOPERNIC20	00643137	28/02/2031	
SCOPERNIC30	00647597	28/03/2031	
SCOPERNIC30	00649232	28/04/2031	
SCOPERNIC30	00652661	28/04/2031	
SECLIPSE12	00643160	28/03/2031	
SECLIPSE12	00652707	28/05/2031	
SECLIPSE15	00640157	28/01/2031	
SECLIPSE15	00640161	28/01/2031	
SECLIPSE15	00643164	28/02/2031	
SECLIPSE15	00643169	28/02/2031	
SECLIPSE15	00645802	28/02/2031	
SECLIPSE15	00656818	28/05/2031	
SECLIPSE20	00640165	28/01/2031	
SECLIPSE7	00643146	28/03/2031	
SECLIPSE7	00649236	28/04/2031	
SECLIPSE9	00643151	28/02/2031	
SECLIPSE9	00643155	28/03/2031	
SECLIPSE9	00647604	28/03/2031	
SECLIPSE9	00651660	28/04/2031	