URGENT: FIELD SAFETY NOTICE

Issue Date: 04 JANUARY 2023

FSN #: 3014162263-12/23/23-001-R
PRODUCT: Optima Coil System
PURPOSE: Discoloration along delivery pusher component

Who may be affected: Distribution/subsidiary agents and hospital staff including safety officers, purchasing agents, pharmacists, neuroradiology staff, and physicians including but not limited to endovascular neurosurgeons and interventional neurologists.

Dear Partners,

The purpose of this letter is to advise you that Balt USA is initiating a Field Safety Corrective Action (FSCA) for specific lots of the Optima Coil System due to discoloration along the delivery system pusher component. Since the product was launched, Balt USA has received three (3) complaints related to this issue, however, no patient harm has occurred. For precautionary reasons, Balt USA has decided to recall the affected Optima Coil System lots. The affected subassembly product lots were manufactured between July 8, 2020, and March 8, 2021. Refer to Attachment 1 for the list of affected finished good lots.

Reason for the FSCA:
On November 20, 2023, Balt USA became aware of a situation where discoloration along the delivery system pusher component of the Optima Coil System was identified during in-house inspection of released finished good products. Discoloration was observed on the outside of the PET jacket along the hypotube component.

Risk to Health:
The discolored appearance on the pusher component was found on certain Optima Coil System products. The discoloration present on the outside of the PET jacket of the delivery pusher can result in negative patient reaction where the discolored area may lead to any of the following:

- Allergic reaction.
- Foreign emboli.
- Pyrogenic response.
- Adverse response to device materials.
- Chemical aseptic meningitis.
- Difficulty or excessive forces in advancing or retracting the delivery pusher.

Procedure to be applied by the hospital staff:

- Stop or cease use of the affected product.
- Inform your hospital staff, such as safety officers, pharmacists, purchasing agent, head of neuroradiology and the neuroradiology staff, physicians including but not limited to endovascular neurosurgeons and interventional neurologists, as well as any other person if deemed necessary.
- Identify and locate the Optima Coil System products concerned by this field safety notice (FSN).
- Collect and put in quarantine the Optima Coil System products concerned by this FSN, then return them to Balt USA through the usual "RGA" (Return Goods Authorization) procedure by contacting Balt USA's Customer Service department.
- Keep informed by Balt USA about the status of every unit of Optima Coil System products concerned by this recall procedure.
- Fulfill the "Notice of receipt" (refer to annex on pages 3 and 4), then return it to Balt USA via the indicated contact.
- Contact Balt USA for any additional information.

Procedure to be applied by distributors/subsidiaries:

- Stop or cease processing of the affected recall product.
- Inform your customers about this notice.
- Identify and locate the Optima Coil System products concerned by this FSN.
- Collect and put in quarantine the Optima Coil System products concerned by this FSN and then return them to your local distributor as per their return procedure.
- Keep informed by Balt USA about the status of every unit of Optima Coil System product concerned by this FSN.
- Fulfill the "Notice of receipt" (refer to annex on pages 3 and 4), then return it to Balt USA via the indicated contact.

BALT USA
T: +1 949.788.1443
F: +1 949.788.1444
29 Parker
Irvine, CA 92618 • USA
www.baltgroup.com

- Contact Balt USA for any additional information.

Any serious incidents experienced in conjunction with or as a result of the affected product may be reported to the manufacturer and Competent Authority in the Member State where the incident occurred.

Should you require any additional information, do not hesitate to contact Balt USA's Quality Department.

Contact:
Quality Department
✉ : QA@baltgroup.com
Balt USA, LLC
29 Parker | Irvine CA, 92618 | USA
☎: +1 949.788.1443 | Fax: +1 949.788.1444

Patient safety is of the utmost concern. We apologize for this inconvenience and thank you for your cooperation in this regard.

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Annex: Notice of Receipt Ref. # 3014162263-12/23/23-001-R

RETURN THE COMPLETED RECEIPT BY: FAX: +1 949.788.1444 / MAIL: 29 PARKER | IRVINE CA, 92618 | USA (Quality Department) / **E-MAIL:** QA@baltgroup.com

1. Field Safety Notice (FSN) information	
FSN Reference number*	3014162263-12/23/23-001-R
FSN Date*	03 January 2024
Product/ Device name*	Optima Coil System
Product Code(s) and Lot Numbers	Please see **Attachment 1**

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	QA@baltgroup.com
Postal Address	29 PARKER, IRVINE, CA. 92618
Deadline for returning the Distributor/Importer reply form*	Within 72 hours of receipt

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 Optima Coil System product(s) concerned by this recall procedure listed within Attachment 1	N/A

☐	We declare as having physical Optima Coil System product concerned by this recall procedure listed within Attachment 1. We have indicated the lot number, model/size and volume of Optima Coil System product(s) concerned by this recall procedure and will return the affected units to Balt USA.	Distributor/Importer to enter quantity and date on page **5**
☐	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 *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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

We hereby acknowledge the receipt of the field safety notice reference "3014162263-12/23/23-001-R" and we have implemented the actions mentioned therein.

Affected Lot Number	Model / Size	Quantity to be returned to Balt USA

- End of document -

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