URGENT: FIELD SAFETY NOTICE – PRODUCT RECALL

Issue Date: May 13, 2025

FSN #: 3014162263-05/05/25-001-R
PRODUCT: Optima Coil Systems (implantable embolic coil system)
PURPOSE: Product recall for Radiopaque (RO) marker visibility issue

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

Dear Partners,

This voluntary recall notice is intended to inform affected customers of a defect impacting specific lots of the Optima Coil Systems, in which the distal 3 cm radiopaque (RO) marker may not be visible under fluoroscopy. At the time of this letter, only one (1) complaint related to RO marker visibility has been received globally from the affected lots. To date, Balt USA has not received any report of adverse patient harm from this or any similar complaint modality.

To prevent any patient safety or product related issues regarding the RO marker not being visible for the affected lots, Balt USA has decided to voluntarily recall the affected Optima Coil System lots which might have this same defect. The affected lots were manufactured between August 2023 and September 2023. Please refer to Attachment 1 for the list of affected finished good lots for your account.

The complaint associated with this recall did not result in any patient harm. The physician was able to identify that the RO marker was not visible under fluoroscopy by following the Optima Coil Systems IFU step, "*Continue to advance the Optima Coil into the desired site until the radiopaque marker on the delivery pusher is adjacent to the distal side of the proximal marker on the microcatheter*." The affected coil system was removed and replaced to proceed with the planned treatment for the patient. Through Balt USA's investigation, it was confirmed that the cause of this visibility issue was due to incorrect material (stainless steel instead of platinum) being utilized for the RO marker of the affected unit.

Although the reported incident resulted in no patient harm, the absence of a visible RO marker on the device could lead to clinical harms. Failure to detect the RO marker could lead to a migration of the coil or coil mass if the coil system is repositioned or retracted. Absence of a visible RO marker could also lead to an over advancement of the coil system with extreme over advancement resulting in vessel damage. Therefore, Balt USA recommends that all coils within the affected lots be returned or inspected fluoroscopically to confirm the presence of the RO marker prior to use.

As a voluntary alternative to returning the affected products, devices from the affected lots can be inspected by trained hospital personnel for the presence of the RO marker using available fluoroscopy imaging equipment prior to a clinical procedure. It is important to conduct this inspection as soon as possible. The image is achieved by taking the fluoroscopic image of the coil system within the unopened box.

1) If the image contains the RO marker, as exemplified from **Figure 1**,
    i. Complete the "Notice of Receipt" (refer to the annex on page 5 to 7) indicating the verified results.
    ii. Mark the inspected boxes with the date and time of the fluoroscopy test and the name of the person performing the test.
    iii. Return the product back to your inventory with no further action required.
    iv. Send the completed "Notice of Receipt" to Balt USA at FSCA_QA@baltgroup.com.

2) If the image does not contain the RO marker from **Figure 2** or if the RO marker is not visually discernable, contact Balt USA at FSCA_QA@baltgroup.com to process the return of the product.

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

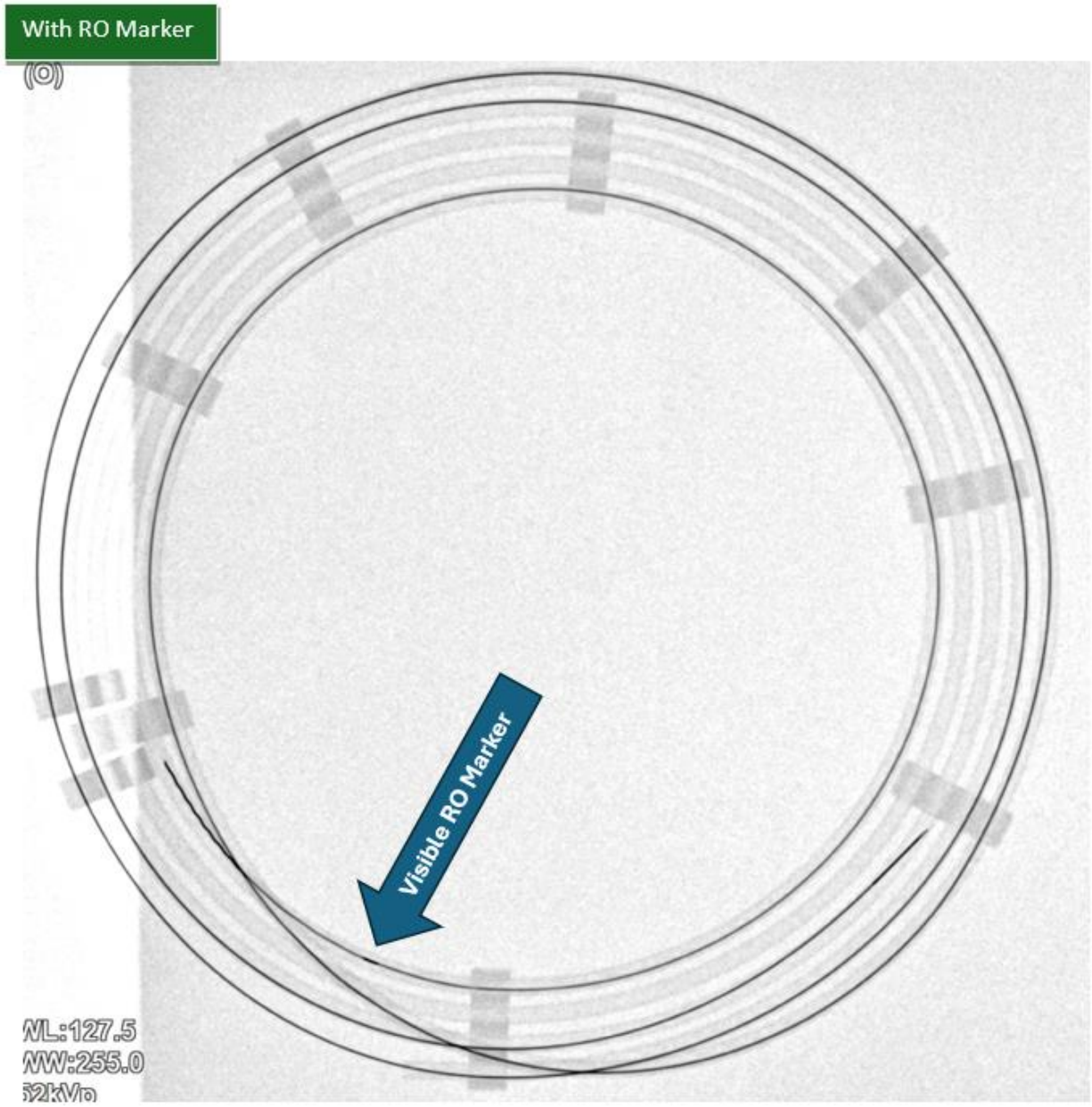

Figure 1. Representative image taken of the coil system inside of the sealed pouch in the unopened box with a visible RO marker located 3 cm from the proximal end of the coil.

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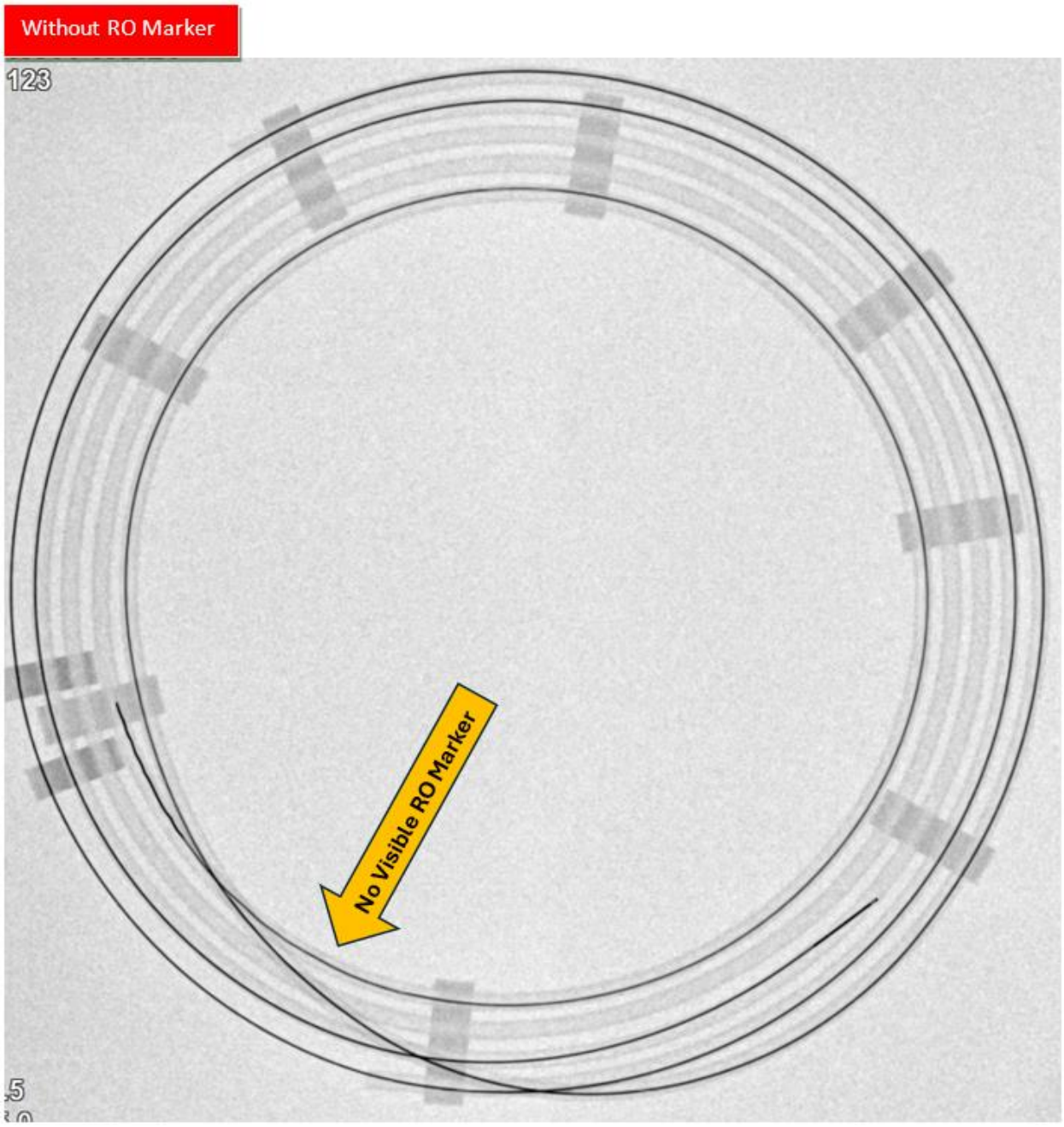

Figure 2. Representative image taken of the coil system inside of the sealed pouch in the unopened box with **no visible RO marker** that is intended to be located 3 cm from the proximal end of the coil.

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If product return is desired, follow the instructions from the pertinent section as a distribution agent or as hospital staff.

Procedure to be applied by distribution agents:

- Inform customers about this notice.
- Identify and locate the Optima Coil System concerned by this recall procedure and cease all use of the affected product(s).
- For returning the applicable products and lots from the provided list to Balt USA.
    - Collect and put in quarantine the Optima Coil System concerned by this recall and then return them to Balt USA through the usual "RMA" (Return Materials Authorization) procedure by contacting our Customer Service department.
    - Keep Balt USA informed of the status of products concerned by this recall.
    - Fulfill the "Notice of Receipt" (refer to the annex on page 5 to 7), then return it to Balt USA via the indicated contact.
- Contact Balt USA at FSCA_QA@baltgroup.com for any additional information.

Procedure to be applied by hospital staff:

- Inform your hospital staff including safety officers, purchasing agents, pharmacists, radiology staff, physicians, and head of healthcare centers, as well as any other person, if deemed necessary.
- For returning the applicable products and lots from the provided list to Balt USA and cease all use of the affected product(s).
    - Collect and put in quarantine the Optima Coil System concerned by this recall and then return them to Balt USA through the usual "RMA" (Return Materials Authorization) procedure by contacting our Customer Service department or confirm the presence of RO marker as described above.
    - Keep Balt USA informed of the status of products concerned by this recall.
    - Fulfill the "Notice of Receipt" (refer to the annex on page 5 to 7), then return it to Balt USA via the indicated contact.
- Contact Balt USA at FSCA_QA@baltgroup.com for any additional information.

Should you require any additional information about this medical device recall, do not hesitate to contact our Quality Department.

Contact:
Quality Department
✉: FSCA_QA@baltgroup.com

EU Authorized representative:
BALT Extrusion SAS
10 Rue de la Croix Vigneron, 95160 Montmorency, France
+33 1 39 89 46 41

Manufacturer:
Balt USA, LLC
29 Parker Suite 100 | Irvine CA, 92618 | USA
☎: +949.788.1443 | Fax: +949.788.1444

We apologize for this inconvenience and thank you for your cooperation in this regard.

Thomas Colson
VP, Global Quality Assurance

Claus Freyinger
VP, Global Regulatory, Clinical, Medical Affairs

Annex: Notice of Receipt ref. # 3014162263-0505-25-001-R

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*	3014162263-0505-25-001-R
FSN Date*	13 MAY 2025
Product/ Device name*	Optima Coil Systems
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	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 Optima Coil	N/A

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	System product(s) concerned by this recall procedure listed within Attachment 1	
☐	We opt to not return the product(s) concerned by this recall. We have confirmed the presence of the RO marker for the affected Optima Coil Systems listed within **Attachment 1**.	Distributor/Importer to document the information in the table on page **7**.
☐	We declare as having physical Optima Coil System product concerned by this recall listed within Attachment 1. We have indicated the lot number, model/size and volume of Optima Coil System product(s) concerned by this recall and will return the affected units to Balt Extrusion SAS.	Distributor/Importer to enter quantity and date on page **7**
☐	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 **7**
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 "3014162263-0505-25-001-R" and we undertake to implement the actions mentioned therein.

Affected Lot Number	Model Number	Check one: ☐ Quantity To Be Returned to Balt USA ☐ Quantity Verified to Contain the RO Marker

- End of document -

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