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URGENT Field Safety Notice

Philips Image Guided Therapy Corporation

Turbo-Elite Laser Atherectomy Catheter

Potential Labeling Non-Conformance

November 2023

<Customer Name>
Attn: Lab / Risk Manager
<Street Address>
<City, State, Zip Code>

This document contains important information for the continued safe and proper use of your medical device

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Valued Turbo-Elite Customer,

Philips Image Guided Therapy Devices (IGTD) has become aware of a potential labeling compliance issue with the Turbo-Elite Laser Atherectomy Catheter where a limited number of shipped units from four specific lots may not include the same size device that is stated on the exterior box label. This Urgent Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

Philips received 3 complaints in which the exterior box was labeled as a 1.4mm RX Turbo- Elite device and erroneously contained a pouch including the larger 2.0 mm RX Turbo-Elite device. There have been no adverse events reported for this issue. **Although the devices may be incorrectly labeled on the exterior box label, the pouch label packaging inside the box does reflect the correct Turbo-Elite size.**

2. Hazard/harm associated with the issue

Devices are typically selected for use based on the size listed on the exterior box label. Therefore, if the box label does not reflect the catheter size as shown on the pouch label, this may impact the procedure. If a larger catheter than intended was used, it could potentially lead to adverse health consequences (i.e. peripheral perforation, potential delay in care upon noticing the size mismatch and obtaining the correct size).

3. Affected products and how to identify them

The Turbo-Elite devices are indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. This Product is offered in a sterile single use configuration and is intended to be used for peripheral vascular intervention. The following model and lot numbers are considered in scope of this notice:

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Table 1: List of the 4 potentially impacted Lot Numbers to be verified on the outer box label

Potentially Affected Products Table		
Model #	**Description**	**Lot Number**
420-159	2.0 RX Turbo-Elite	FBH23F02A
420-006	2.0 OTW Turbo-Elite	FBA23F09A
414-159	1.4 RX Turbo-Elite	FBF23F05B
417-152	1.7 OTW Turbo-Elite	FAZ23F06A

Figure 1: Example of the exterior box label not matching the interior pouch label

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

Please immediately check your product inventory and quarantine any potentially affected devices having a Lot Number listed below to prevent use. The Lot Number can be identified on the lower left corner of the outer box label as represented below. **Do not open or use any products that have been identified within your inventory.**

Impacted Lot #
FBH23F02A
FBA23F09A
FBF23F05B
FAZ23F06A

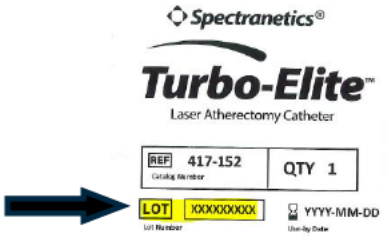

Figure 2: Example of how to identify the four potentially impacted products by Lot Number

- Philips is requesting all customers to complete and return the Response Form as soon as possible but within 30 days maximum. Philips will then initiate the return and replacement process as applicable, free of charge, based on your completed Response Form.
- If you do not have a potentially impacted Lot Number in your inventory, Philips recommends the continued use of the Turbo-Elite Laser Atherectomy Catheter and to follow the Instructions for Use.
- Circulate this notice to all users of the device, or to any organization where the potentially affected devices may have been transferred, so they are aware of the product issue and associated hazard/ harm.

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To acknowledge receipt of this notification, please complete, sign, and return the Response Form, within 30 days upon receipt of this notice to the following Email: **IGTD_INTL_FieldSafety@philips.com**

5. Actions planned by Philips *Image Guided Therapy Devices (IGTD) US-MF-000018632* to correct the problem

As a remedy, Philips will replace impacted products as applicable, free of charge, based on your completed Response Form.

If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Image Guided Therapy Devices Order Management:

Philips Order Management:

France	[redacted]	IGTDsalessupportfrance@philips.com
Germany	[redacted]	IGTDsalessupportdach@philips.com
Italy	+[redacted]	IGTDsalessupportiig@philips.com
Poland	+[redacted]	IGTDsalessupportcee@philips.com
Spain	+[redacted]	IGTDsalessupportiberia@philips.com

Hours of Operation: Monday- Friday 8:00AM - 5:00PM CET

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax.

Philips regrets any inconvenience caused by this problem.

Sincerely,

[redacted]
Quality Manager
Philips Image Guided Therapy International

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URGENT Field Safety Notice Response Form

Reference: Turbo-Elite Laser Atherectomy Catheter Potential Labeling Non-Conformance

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

Please immediately check your product inventory and quarantine any potentially affected product having a Lot Number listed in this notification. The Lot Number can be identified on the lower left corner of the outer box label. **Do not open or use any products that have been identified with an affected Lot Number within your inventory.** If you do not have a potentially impacted Lot Number in your inventory, Philips recommends the continued use of the Turbo-Elite Laser Atherectomy Catheter and to follow the Instructions for Use.

By signing this form, you acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the Turbo-Elite Laser Atherectomy Catheter.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete the below table by providing the appropriate quantities:

Product Name	Lot Number	Quantity in your inventory to be quarantined and returned*
2.0 RX Turbo-Elite	FBH23F02A	
2.0 OTW Turbo-Elite	FBA23F09A	
1.4 RX Turbo-Elite	FBF23F05B	
1.7 OTW Turbo-Elite	FAZ23F06A	

*If impacted product is in your inventory, please provide a No Charge P.O. below for the replacement unit(s):

No Charge P.O. Number: _____

To acknowledge receipt of this notification, please complete, sign, and return this Response Form within 30 days upon receipt of this notice to Email: **IGTD_INTL_FieldSafety@philips.com**