PHILIPS

URGENT Field Safety Notice

Tack Endovascular System
Discontinue Use of Tack Implant Product

January 2025

<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 equipment

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 Tack Endovascular System Customer,

Philips Image Guided Therapy Devices has made a difficult decision to no longer distribute Tack Endovascular System. This URGENT Field Safety Notice is intended to inform you about:

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

Effective immediately, Philips is requesting that all customers stop using the Tack Endovascular System. Philips has become aware of challenges some customers may have experienced during use. There have been instances where additional intervention was required. To our knowledge, there has been no occurrence of serious injury or death accompanying use of the Tack Endovascular System. You are receiving this notification as our records indicate you may currently have inventory that is now being Recalled.

2. Hazard/harm associated with the issue

Complaints of the following hazards primarily included problems with deployment and stability of the device in the vessel after deployment. Specific events included: jumping or flexing of the delivery system, deployment in an unintended location, interaction/snagging of deployed Tacks with other interventional devices, incomplete or tilted Tack deployment. The following harms were observed or could reasonably be expected: failure to resolve dissection, migration of implant, bailout stenting, reintervention, unintended removal of tack devices, and ischemia.

3. Affected products and how to identify them

The Tack Endovascular System is intended for single use only and is designed to treat vascular dissections with Tack implant(s) following angioplasty. When deployed, the Tack implants are designed to treat acute dissections of the inner wall or lining of an artery by tacking the damaged tissue to the inner luminal surface through a low outward radial force.

The following Tack Endovascular System (4F) and (6F) models, sizes and batches are impacted by this notification. Also See Figure 1 below for an example of a product label.

Catalog No.	Product Description	Batch Code
206135062	Tack, 6F Gen 2.0, 135cm CE	328643 - 345567
156135062	Tack, 6F Gen 1.5, 135cm CE	271330 - 283066
154150042	Tack, 4F Gen 1.5, 150cm CE	328641
206080062	Tack, 6F Gen 2.0, 80cm CE	321083 - 349035
156080062	Tack, 6F Gen 1.5, 80cm CE	302251 – 349034
154090042	Tack, 4F Gen 1.5, 90cm CE	322101

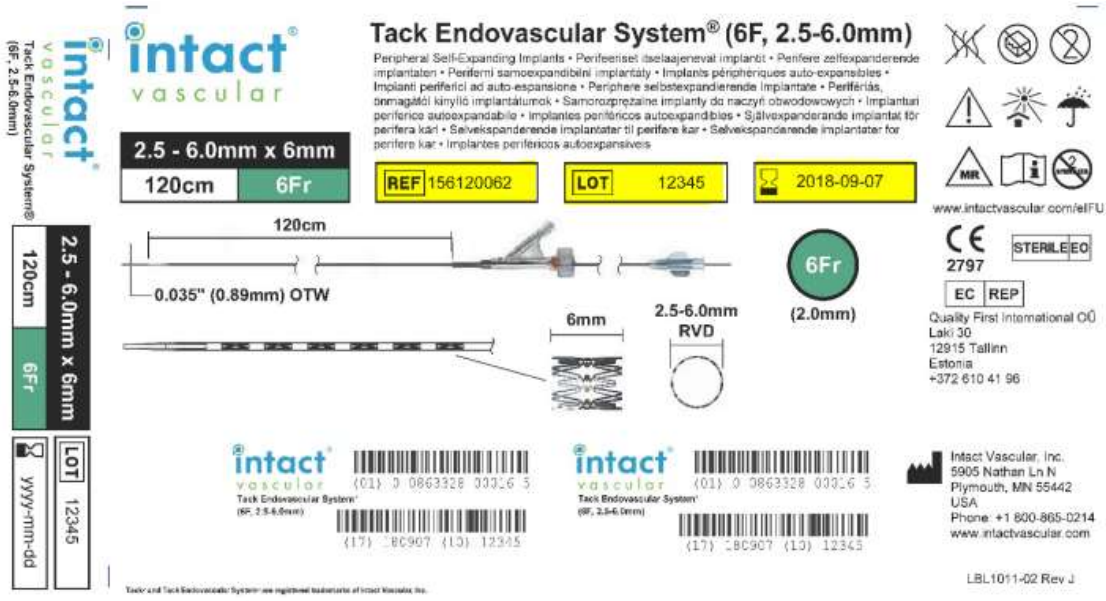

Figure 1: Example Tack Endovascular System® label to identify various size (4F) and/or (6F) products

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 affected devices to prevent use. **Do not open or use any products that have been identified within your inventory.**

Philips is requesting customers to immediately complete, return and sign the Response Form within seven days. Philips will then initiate the return and credit process, based on the completed form. If there is no affected product in your inventory, credit will not be needed. However, Philips kindly requests the return of the Response Form within seven days, even if indicating "zero" product, as applicable.

Please circulate this notice to all users of the device, or to any organization where the affected product may have been transferred, so they are aware of the product Recall.

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

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5. Actions planned by Philips Image Guided Therapy Devices (SRN: US-MF-000011102) to correct the problem

As a remedy, Philips will provide credit to customers who have impacted product in their inventory once the product is returned to Philips.

Again, we did not make the decision lightly to voluntarily discontinue the Tack Endovascular System without thorough consideration and we recognize that many of our customers and patients highly value this alternative treatment option for dissection repair.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Image Guided Therapy Devices Sales Support:

Region	Contact Information
APAC	+3222750171 IGTDsalessupportapac@philips.com
BENELUX	+31 202046525 (Netherlands) IGTDsalessupportbenelux@philips.com
DACH	+431501375037 (Austria) +494028991234 (Germany) +41445292374 (Switzerland) IGTDsalessupportdach@philips.com
Italy	+390245281151 IGTDsalessupportiig@philips.com
UKI	+44 2079490027 IGTDsalessupportuki@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

We apologize for any inconvenience this may cause and appreciate your understanding. We look forward to continuing our partnership and bringing new technologies to you in the future.

Sincerely,

Jeroen Verhoeven
i.l.o. Vandaele, Emily
QA Manager, IGT Devices Quality
IGT Devices International

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URGENT Field Safety Notice Response Form

Reference: Tack Endovascular System Product Recall (2024R05)

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 Field Safety Notice Recall Letter, 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 product listed in this notification. **Do not open or use any products that have been identified within your inventory.** If you do not have any impacted product in your inventory, kindly indicate this by entering "zero" in the quantity field of the Response Form. Leaving the quantity field blank will prompt follow-up correspondence from Philips. 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 Tack Endovascular System.

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 and enter original P.O:

If you do not have impacted product, kindly indicate this by entering "zero" in the quantity field

Catalog/Model Number (see box label)	Batch Code(s) (see box label)	Enter Quantity in your current inventory to be quarantined and returned, including zero*	Batch Code(s) of product(s) being returned (see box label)
206135062	328643 - 345567		
156135062	271330 - 283066		
154150042	328641		
206080062	321083 - 349035		
156080062	302251 - 349034		
154090042	322101		

***If impacted product is in your inventory, your account will be credited upon Philips receipt of product.

Enter original P.O Number to be credited, if available:_____

Return this Response Form within seven days upon receipt of this notice to Email:
IGTD_INTL_FieldSafety@philips.com