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URGENT Field Safety Notice

PV.035 Digital IVUS Catheter
Instructions for Use (IFU) Missing Contraindications

May 2022

To: Name / Title / Customer Name
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 a copy with the equipment Instruction for Use.

Dear Valued Digital IVUS Catheter Customer,

Philips IGTD identified a problem with the PV.035 Digital IVUS Catheter Instructions for Use that may pose a risk for patients or users. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur
Philips has identified a labelling issue with specific PV.035 Digital IVUS Catheter configurations that are missing the following Contrainidications in the Instructions for Use provided with the product:

- Severe calcification
- Vessel spasm
- Severe vessel tortuosity

Philips IGTD erroneously removed these contraindications from the Instructions for Use (part number 300004856772 Revision A, released May 2021) prior to receiving approval from all global notified bodies resulting in this Regulatory Non-Compliance. There are no complaints associated directly with the product IFU not containing the approved contraindications. However, one complaint has been received associated with product being “kinked” inside the body while advancing to lesion, which may be associated with potential effects of the missing contraindication information. There was no injury reported associated with this complaint. Philips IGTD has not received any reports of Deaths or Serious Injuries related to this issue.

2. Hazard/harm associated with the issue
The worst-case scenario may be vessel trauma if a Physician did not use the IVUS catheter as per the usual standards of care defined as:

- not advancing through tortuous anatomy
- stopping when there is severe calcification
- or use in vessels with pre-existing untreated vessel spasm

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If a catheter was stuck in a vessel or plaque with subsequent kinking of the catheter and loss of image, this may lead to a delay of procedure, as the physician would remove the catheter and a new catheter may be needed. Delay of procedure would be the most likely short-term consequence, if this were to result in harm. There are no known long-term health consequences associated with the use of product impacted by this labeling non-compliance.

3. Affected products and how to identify them

There are only two (2) affected configurations of PV.035 Digital IVUS Catheters, as shown in the table below:

Affected Products Table			
Product Name	**Catalog Number**	**12NC**	**IFU Part Number**
Visions PV.035 Digital IVUS Catheter	88901	300005384002	300004856772 (Rev A - Date: 05/2021)
Visions PV.035 Digital IVUS Catheter	81234	300007367341	

If you received one of these specific PV.035 Digital IVUS Catheter configurations between August 2021 and January 2022, it is likely the Catheter included the non-compliant Instructions for Use (IFU) (with missing Contraindications). The non-compliant Instructions for Use can be easily identified by the part number, revision, and date located at the bottom of page 1 for each language. All IFUs labeled with "300004856772/A Revision Date: 05/2021", which were distributed beginning August 2021, are affected.

CONTRAINDICATIONS:
THE VISIONS PV .035 DIGITAL IVUS CATHETERS ARE GENERALLY CONTRAINDICATED IN SITUATIONS PRESENTING A REASONABLE PROBABILITY OF TISSUE OR ORGAN DAMAGE. THIS DEVICE IS NOT CURRENTLY INDICATED FOR USE IN CEREBRAL VESSELS.

Figure 1 - Affected Instructions for Use

CONTRAINDICATIONS:
THE VISIONS PV .035 DIGITAL IVUS CATHETERS ARE GENERALLY CONTRAINDICATED IN SITUATIONS PRESENTING A REASONABLE PROBABILITY OF TISSUE OR ORGAN DAMAGE. THIS DEVICE IS NOT CURRENTLY INDICATED FOR USE IN CEREBRAL VESSELS.

- Vessel spasm
- Severe Calcification
- Severe vessel tortuosity

Figure 2 - Corrected Instructions for Use

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

Philips recommends reviewing the enclosed compliant Instructions for Use, in Appendix A, before proceeding as normal.

As per standard practice, precaution should always be used when advancing or removing a catheter in complex vessel anatomies, such as not forcing a catheter into a narrow vessel or a tight stenosis. Vessel calcification, tortuosity and pre-existing untreated vessel spasm are key components to any complex vascular anatomy. Additionally, if the initial guidewire faces resistance or requires further manipulations, please use this as an indicator of complex patient anatomy.

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Philips is providing this Urgent Field Safety Notice letter to affected customers and recommends forwarding this notification to all staff who need to be aware within your organization or to any organization where the potentially affected devices may have been transferred.

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

5. Actions planned by Philips IGTD to correct the problem

Philips will send all affected customers a copy of the compliant Instructions for Use, see Attachment 1, that contains the approved set of Contraindications. Philips has resolved the Instructions for Use labeling non-compliance for all products manufactured after 03-FEB-2022.

If you are a distributor or have forwarded affected device(s) to another end user, it is imperative that all end-users with affected devices receive this URGENT Field Safety Notice. Therefore, send a copy of this notification to any customer whom you have distributed the affected product to. If you need any further information or support concerning this issue, please contact your local Philips representative:

Philips IGTD Customer Service:
Email: IGTDCustomerService-Int@philips.com
Hours of Operation: Monday - Friday 8:00AM – 5:00PM CET

Region	Phone number
APAC	+3222750171
Austria	+431501375037
Belgium	+3222566604
CEE (excl. Poland)	+31202046550
Denmark	+4543310566
Finland	+358922943008
France	+33157324031
Germany	+494028991234
IIG (excl. Italy)	+31202046555
Italy	+390245281151

Region	Phone number
LATAM	+525515001184
META	+31202046527
Norway	+4722971709
Poland	+48223064475
Portugal	+351800785164
Spain	+34918362954
Sweden	+4687515241
Switzerland	+41445292374
The Netherlands	+31202046525
UKI	+442079490027

Philips regrets any inconvenience caused by this problem.

Sincerely,

Megan Olen
Head of Quality, Philips IGTD
Phone: +1 (719) 447 - 2592
Megan.Olen@philips.com

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: PV.035 IFU Missing Contraindications, 2022-IGT-IGTD-001

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.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:
We 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 PV.035 Digital IVUS Catheters.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return this Response Form to your local Philips representative or the following addresses:
Email: IGTD_INTL_FieldSafety@philips.com
Postal:
Philips Image Guided Therapy
ATTN: Emily Vandaele (2022C01)
Plesmanstraat 6, 3833
Leusden, Netherlands

It is important that your organization acknowledge receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this corrective action.