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URGENT Field Safety Notice

Visions PV.014P, PV.014P RX, and PV.018 Digital IVUS Catheter
Instructions for Use (IFU) Precaution Update

June 2025

Customer Name
Attn: Cath 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 Digital IVUS Catheter Customer,

Philips is updating the Instructions for Use (IFU) for Visions PV.014P, PV.014P RX and PV.018 Digital IVUS Catheters, with a new precaution. 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 been informed of cases where physicians, during "radial-to-peripheral" procedures (radial access), have used a Digital IVUS Catheter without the appropriate sheath and/or guide catheter; this inappropriate use could lead to failure to provide adequate support for maneuvering the guidewire and catheter to peripheral vessels.

2. Hazard/harm associated with the issue

When using a short radial artery sheath with a Visions PV.014P Digital IVUS Catheter over an .014 guide wire, for example, the user may experience resistance while loading and removing the catheter. If the user removes the wire and catheter together without forcing, there should be no expected harm to the patient.

However, if the user continues the procedure despite resistance, the catheter and guide wire could get tangled, potentially requiring further intervention. In some cases, longer sheaths can assist, but surgical removal may be necessary. There have been 7 adverse events requiring additional intervention. No deaths have been reported for this issue.

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3. Affected products and how to identify them

Visions PV.014P and PV.014P RX Digital IVUS Catheters and PV.018 Digital IVUS Catheters are designed to evaluate vascular morphology in peripheral blood vessels, by providing cross-sectional images of the vessels. These devices serve as adjuncts to conventional angiographic procedures to image vessel lumens and wall structures. They are not currently indicated for use in cerebral vessels.

The affected products are listed in Table 1 below. See Figure 1 for an example image of where to identify the product number on the label and Figure 2 for identifying the IFU revision (found in the footer on each page of the IFU).

Table 1: *The Visions PV.014P, PV.014P RX, and PV.018 Digital IVUS Catheters and IFUs affected by this issue*

Affected Products and IFU Table		
Product/IFU Name	**Product Number**	**IFU Revision**
Visions PV.014 Platinum Visions PV.014P RX	85910P 014R	C
Visions PV.018 Digital IVUS Catheter	86700 86700J	A

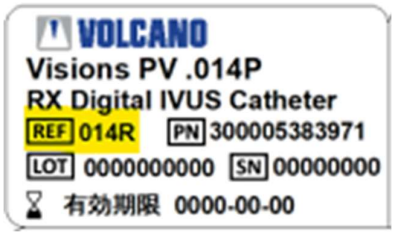

Figure 1: *Example of how to identify the impacted products.*

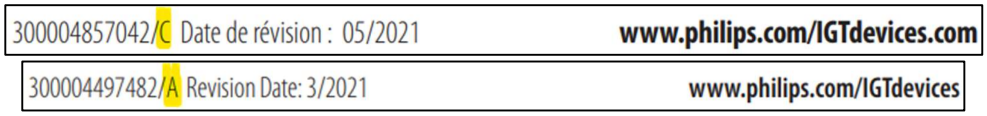

Figure 2: *Example of how to identify the IFU revision.*

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

Customers/users can continue the use of Visions PV.014P, PV.014P RX, and PV.018 Digital IVUS Catheters in alignment with the Instructions for Use. As per standard practice, take precautions when advancing or removing a catheter in complex vessel anatomies. Do not force a catheter into a narrow vessel or tight stenosis. Be aware that vessel calcification, tortuosity, and untreated vessel spasm are key components of complex vascular anatomy. If the initial guidewire faces resistance or requires further manipulation, consider this to be an indicator of complex patient anatomy.

The Instructions for Use currently contains the following related precautions for the user:

"Do not advance the guide wire against significant resistance. If binding occurs between the catheter and the guide wire while inside the patient, CAREFULLY REMOVE BOTH the wire and catheter and do not use. If binding occurs outside of the patient, remove the catheter and do not use."

Using a long radial sheath avoids this issue by preventing the catheter and guidewire from getting entangled within the sheath.

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The Instructions for Use highlights the minimum sheath/guide catheter Inner Diameter which does not prevent such complications; therefore, a new precaution will be added to the Instructions for Use:

"Use a guide sheath of appropriate length to provide adequate support to the rapid exchange IVUS catheter and guidewire."

Please 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. Philips also encourages all customers to post this letter on or near the affected products until Philips has updated the Instruction for Use.

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

5. Actions planned by Philips Image Guided Therapy Devices (SRN:US-MF-000020094 and US-MF-000018632) to correct the problem

Philips will modify the Instructions for Use for Visions PV.014P, PV.014P RX, and PV.018 Digital IVUS Catheters to include the new precaution: **"Use a guide sheath of appropriate length to provide adequate support to the rapid exchange IVUS catheter and guidewire."**

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	Region	Contact Information
IIG (excl. Italy)	+31202046555 IGTDsalessupportiig@philips.com	Italy	+39 0245281151 IGTDsalessupportiig@philips.com
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This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. Please do not hesitate to contact us with any further questions you may have.

Sincerely,

Molly Cowden
Quality Supply Chain Specialist
Philips Image Guided Therapy International

URGENT Field Safety Notice Response Form

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Reference: Instructions for Use (IFU) New Precaution for Visions PV.014P, PV.014P RX, and PV.018 Digital IVUS Catheter

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:

- To acknowledge receipt of this notification, please complete, sign, and return this Response Form upon receipt of this notice to Email: **IGTD_INTL_FieldSafety@philips.com**
- Philips recommends continuing the use of the Visions PV.014P, PV.014P RX, and PV.018 Digital IVUS Catheters while following the Instructions for Use. Please adhere to the new precaution: **"Use a guide sheath of appropriate length to provide adequate support to the rapid exchange IVUS catheter and guidewire."**

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 Visions PV.014P, PV.014P RX, and PV.018 Digital IVUS Catheters.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

<C&R customer ID>

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