



**** URGENT MEDICAL DEVICE ADVISORY NOTICE ****

Re: Visions PV .035 Intravascular Ultrasound (IVUS) Catheter (Catalog Number 88901)

October 19, 2018

Dear Cath Lab Manager, Distributor/agent:

Philips Volcano is providing an advisory notice regarding Visions PV .035 Intravascular Ultrasound (IVUS) Catheters (Catalog Numbers 88901) due to the potential for inability to pass the guidewire through the y-port of the catheter. The issue has been corrected for Visions PV .035 catheters manufactured after September 20, 2018, but devices in your inventory may be impacted.

You are receiving this letter because our records indicate you have received a potentially impacted device. The affected Catalog, and Batch numbers are listed below (example labels identifying the location of batch numbers and expiry dates can be found on following pages):

Catalog Numbers	Product Description	Batch Numbers	Expiry Dates
88901	Visions PV. 035 Digital IVUS Catheter	0301438588 0301450807 0301465885 0301476728 0301438589 0301450810 0301465886 0301476729 0301438590 0301450811 0301465888 0301480926 0301438591 0301450812 0301465891 0301480927 0301440822 0301453522 0301469590 0301480929 0301441407 0301453523 0301465889 0301480928 0301441408 0301450809 0301465892 0301480938 0301442650 0301446748 0301469591 0301480937 0301442651 0301453524 0301457393 0301485799 0301442649 0301453525 0301453528 0301485800 0301442654 0301453527 0301469592 0301485801 0301442652 0301446747 0301469593 0301485802 0301442655 0301457389 0301472631 0301487960 0301442656 0301457391 0301469595 0301487961 0301442653 0301457390 0301469594 0301487962 0301442657 0301457392 0301469596 0301492145 0301446202 0301457394 0301472632 0301492146 0301446201 0301461994 0301472637 0301492147 0301446203 0301461995 0301472638 0301498206 0301446204 0301461996 0301472639 0301498207 0301446205 0301461997 0301476724 0301498208 0301450806 0301461998 0301476725 0301498209 0301450808 0301461999 0301476726 0301500961 0301450805 0301465887 0301476727	April 30, 2020 - August 31, 2020



Catalog Numbers	Product Description	Batch Numbers	Expiry Dates
81234	Visions PV. 035 Digital IVUS Catheter	0301438592 0301438593 0301440863 0301441405 0301441406 0301442658 0301446206 0301446207 0301450813 0301450814 0301453529 0301453531 0301457395 0301457396 0301457397 0301457398 0301462001 0301462002 0301462003 0301465894 0301465896 0301465897 0301453530 0301469598 0301469597 0301469599 0301472646 0301472651 0301476733 0301487363 0301487364 0301485883 0301485884 0301487964 0301481405 0301487965 0301492152 0301492153 0301500960 0301498211 0301501409	April 30, 2020 - August 31, 2020

Philips has received complaints that approximately 20% of devices in affected lots may demonstrate an inability to insert the guidewire into the catheter. This has caused no known adverse events. This issue is seen before entering the patient's body, and can lead to a delay of case while the defective product is exchanged for another device.

As always, if you experience an issue using a Visions PV. 035 device, please report it to the Philips Sales Contact or to the Philips Complaints department by email VEcomplaints@philips.com. Philips will provide a replacement unit for any devices experiencing this issue, or upon request, as inventory is available. Please contact Philips Sales Support by email IGTDsalesupportreturn@philips.com to arrange any replacement units.

We recognize the inconvenience this potential defect may cause you, your staff, and your patients. However, this action reflects Philips Volcano's commitment to high quality standards. Please inform all personnel within your organization who handle this product of this advisory notice. On behalf of Philips Volcano, we appreciate your partnership and continued support.

Sincerely,

Peter Dekempeneer
QA Manager IGT-D International

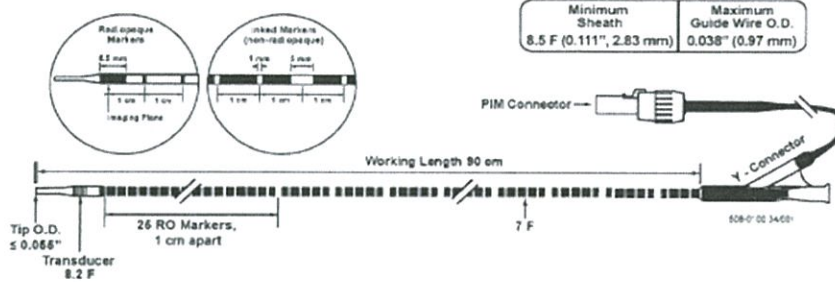
PHILIPS

Label example for catalog 88901:



REF 88901
Visions PV .035
Digital IVUS Catheter

DIGITAL IVUS CATHETER, DIGITALE IVUS-KATHETER, CATHÉTER IVUS NUMÉRIQUE, DIGITALER IVUS-KATHETER, CATETERE IVUS DIGITALE, CATÉTER DE ECOGRAFIA INTRAVASCULAR DIGITAL, DIGITAL IVUS-KATETER, ЦИФРОВОЙ IVUS КАТЕТЕР, DIGITALT IVUS-KATETER, DIGITAALINEN KAIKUKUVANTAMISKATETRI, ΨΗΦΙΑΚΟΣ ΚΑΘΗΤΗΡΑΣ IVUS, DIGITÁLIS IVUS (INTRAVASZKULÁRIS ULTRAHANG-) KATÉTER, DIGITALT IVUS-KATETER, CATETER IVUS DIGITAL, CATETER DIGITAL, IVUS, КАТЕТЕР ДЛЯ ЦИФРОВЫХ ВНУТРИСОСУДИСТЫХ УЛЬТРАЗВУКОВЫХ ИССЛЕДОВАНИЙ, DIGITAL IVUS KATETERI, DIGITALNI IVUS KATHETER, CYFROWY CEWNIK IVUS, DIGITÁLNI KATÉTER IVUS



Made in Costa Rica

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VOLCANO
Visions PV .035
Digital IVUS Catheter
REF 88901
SN 1
有効期限 2019-02-28

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SAMPLE

NOT For Human Use



Do not use open or damaged packages 外箱の封が破れている、 ダメージのある製品は使用しないでください	Store in a dry, dark, cool place 高温多湿、直射日光を避けて保管してください	Nonpyrogenic 非発熱性
Do not re-sterilize 再滅菌禁止	Contents: One (1) 包装単位: 1本	Sterilized using Ethylene Oxide エチレンオキシドガス滅菌済
Single Use Only 再使用禁止	Prescription Only 医家向け	Consult Instructions for Use 使用前には添付文書をご確認ください

CE 0086

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www.philips.com/IGTdevices
PATENT www.ip.philips/patentmarking

VOLCANO
Visions PV .035 Catheter

Length 90 cm	Guide Wire 0.035" - 0.038"	Min. Sheath 8.5 F
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有効期限 2019-02-28 SN 1 REF 88901
P/N 00960900491 BATCH 0301368259

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