



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

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

December 10, 2018

Dear Cath Lab Manager, Distributor/agent,
cc Chairman Medical Board and relevant Head of Department

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	April 30, 2020 - August 31, 2020
		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		

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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

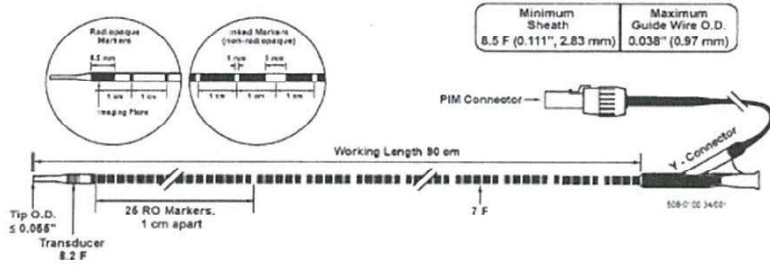
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Label example for catalog 88901:



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 ECOGRAFÍA INTRAVASCULAR DIGITAL, DIGITAL IVUS-KATHETER, ЦИФРОВОЙ IVUS КАТЕТЕР, DIGITAL IVUS-KATHETER, DIGITALINEN KAIKUKUVANTAMISKÄTTERI, ΨΗΦΙΑΚΟΣ ΚΑΘΗΤΗΡΑΣ IVUS, DIGITALIS IVUS (INTRAVASZKULÁRIS ULTRAHANG-) KATÉTER, DIGITAL IVUS-KATHETER, CATETER IVUS DIGITAL, CATETER DIGITAL IVUS, КАТЕТЕР ДЛЯ ЦИФРОВЫХ ВНУТРИСОСУДИСТЫХ УЛЬТРАЗВУКОВЫХ ИССЛЕДОВАНИЙ, DIGITAL IVUS KATERI, DIGITALNI IVUS KATHETER, CYFROWY CEWNIK IVUS, DIGITÁLNI KATÉTR 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 外箱の封が開いていたり、 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 エチレンオキサイドガス滅菌済
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

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

VOLCANO Length 90 cm Guide Wire 0.035" - 0.038" Min. Sheath 8.5 F
Visions PV .035 Catheter

有効期限 2019-02-28 SN 1 REF 88901
 PN 089609000491 BATCH 0301368259

Printed Unilabel3 P/N: 300000827281.A Released Date: February 2018 PN 400-0200.173

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