

Customer

Manager Quality Management
and Product Development

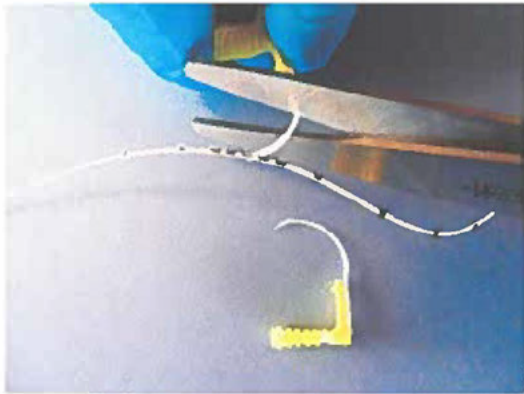
Tel.: 0241 / 91 30 0
Fax.: 0241 / 91 30 106
Email: [REDACTED]

Aachen, 28.03.2022

Field Safety Notice on peelable cannula used in the listed products

As legal manufacturer of the affected article, we would like to inform you about a possible malfunction of the peelable introducer cannula included in the set. After catheter placement and withdrawal of the peelable cannula, in a few cases it may happen that the cannula cannot be peeled completely and one half of the cannula snaps off at the distal part of the cannula. A small rest of the cannula tip is unpeelable and remains on the catheter tube.

In this case, we recommend that you leave the catheter in the patient and pull the non-removable part of the cannula back as far as possible and fix it there. To make the fixation easier, the yellow cannula wing and the peeled half of the cannula can be cut off with a pair of scissors, leaving the unpeeled distal part of the cannula on the catheter tube. Please make sure that there is sufficient safety distance to the catheter during this procedure so that it will not get accidentally damaged during cutting (see photo).



The catheter can then be used as planned.

The following products are involved:

Product Description	Code No.	Batch No.
microsite	1147.02	091221GG 060122GG 210122GG
nutriline	1252.030	240122GP
nutriline twinflo	1252.230	120122GS



Value Life

nutriline twinflo	1252.235	110122GP
premicath	1261.208	050122GS
epicutaneo cava	2184.030	201221GL
epicutaneo2	2484.152	170122GL
epicutaneo2	2484.302	260122GL
peelable cannula	7370.19	151221GI

Please acknowledge receipt of this letter and complete and return the attached form.

Your National Competent Authority has been informed about this Field Safety Notice.

If you should require further information, please contact your local Vygon distributor via telephone number detailed below.

We apologize for any inconvenience this Field Safety Notice may cause.

Yours sincerely,

Manager Quality Management and Product Development

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ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

**Please complete and return this form:
by fax: 0241 / 91 30 106 or e-mail to vigilance@vygon.de**

Name and address of the institution :	
Full name of the person to contact:	
Function :	
☎ Phone number:	
✉ E-mail:	

We acknowledge receipt of the above FSN and that the information contained in this field safety notice has been shared with all recipients / end users of above-mentioned products within our organization.

Signature and Date : _____