JOTEC®

Urgent Field Safety Notice

Voluntary recall
concerning

E-tegra Stent Graft System

7/27/2015

Dear valued customer,

This letter is to inform you about our decision to voluntarily recall our E-tegra Stent Graft System.

Details on affected devices

All LOT and REF numbers of the E-Tegra Stent Graft System.

JOTEC®

Description of the problem

Quality problems as well as possible resultant damage to the sheath catheter of the E-tegra Stent Graft Systems could lead to incomplete expansion of the loaded stent graft. Possible risks resulting from this type of malfunction include prolonged surgical time, vascular injury and the need to surgically remove the incompletely deployed stent graft and the delivery system. To date, JOTEC has received reports of three cases (0.3%) in which the E-tegra Stent Graft was not able to be completely released.

Important note

The issue described is a potential defect of the delivery system which does not have any adverse effects on E-tegra Stent Grafts already implanted. Stent Grafts which have already been implanted are not affected by this recall.

Advice on action to be taken by the user/customer

According to our documentation, your institution has received products from the product line affected by this Urgent Field Safety Notice from us. Therefore we ask you to proceed as follows:

1. Please remove all products affected by this recall from your stock and quarantine the products. The products must not be used anymore.

2. If you have affected products within your stock, please return these products with the attached reply letter to the given address.

3. If you don't have affected products, please confirm this using the reply letter.

Transmission of this Field Safety Notice

1. Please ensure in your organization that all users of the products affected by this safety notice and other persons who need to be informed are made aware of this Urgent Field Safety Notice.

2. If you have transferred the products to third parties, please forward a copy of this notice and inform the contact person below. Please ensure that all customers fill out the enclosed reply letter and send it to the email address or fax number indicated below.

The European National Competent Authorities have received a copy of this field safety notice.

Contact person
Steffen Rauschenberger
Director QA/RA
Tel.: +49 (0)7471/922 172
Fax: +49 (0)7471/922 122
Email: qa@jotec.com

Steffen Rauschenberger
Director QA/RA

Attachment - Reply letter

Please replay quickest possible to:

JOTEC GmbH, Lotzenäcker 23, 72379 Hechingen
Fax: +49 7471 922 122, e-mail qa@jotec.com

Reply letter - Urgent field safety information

Voluntary recall E-tegra Stent Graft System

Institution:		**Customer #**	
Address: Street: Zip Code / City: Country			
Contact person:			
Telephone.			
Fax			

Mark checkbox with `x'

☐ **our stock does not contain Products affected by this field safety information**

☐ **the following E-tegra stent Graft Systems will be returned**

REF No.	Lot-No.		REF No.	Lot-No.

Name Signature Date Stamp

Please complete the template and send it back by fax or e-mail. Our customer service will contact you to organize the return and refund of the products. If you don't have affected products, please confirm this by sending the reply letter to JOTEC.