

KARL STORZ GmbH & Co. KG • P. O. Box 230 • 78503 Tuttlingen/Germany

Adressat



Your ref.

Date of your letter

Our ref.

Date

ST-Sc-Jun

09.03.2017

Urgent Safety Information Recall regarding FLIPPTACK, Fixation button

REF: 28729FT Batches: 61603728, 61603837, 61603844, 61700023, 61700063, 61700154

Dear Customer,

We hereby inform you of a batch-specific recall of the product, 28729FT FLIPPTACK, Fixation button.

Description of problem, including the established cause:

Due to a deviation in production at the supplier, drill holes of affected products may have sharp edges on the inside. This may potentially result in damage to the suture material used for application and therefore perhaps in a loss of the implant during implantation.

This is a voluntary recall, no incidents have been made known in this context up to this point in time.

Which measures will the recipient need to take?

Please check your stock, and block unused products from the aforementioned batch immediately! Please return them immediately to the following address together with the enclosed returns form:

KARL STORZ GmbH & Co. KG,
Logistikzentrum,
Take Off Gewerbepark 83,
D-78579 Neuhausen ob Eck

You will receive an equivalent replacement.

Products already implanted in the patient may remain there, because this problem can only occur during the implantation itself. No other measures need to be taken in this case!

Please send back the returns form also when there are no longer any affected products in your facility.

The goal of KARL STORZ is to deliver products with the highest quality standards and we guarantee you unlimited support. We regret any inconvenience possibly arising, or having arisen in regards to this recall.

Sharing of information described here:

Please make sure that in your organization all users of the aforementioned products and other persons to be notified will be made aware of this **Urgent Safety Information**. If you have passed the products on to third parties, please forward a copy of this information, or inform the contact person stated below.

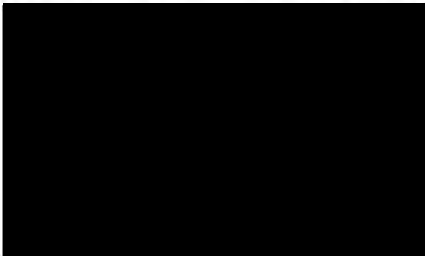
Please retain this information at least until this measure is completed.

Contact person:

Robert Herz
Phone: +4974617087348
Fax: +49746170845581
Mobile: +491622800515
vigilance@karlstorz.com

With best regards

KARL STORZ GmbH & Co.KG



KARL STORZ GmbH & Co. KG
Logistikzentrum
Take Off Gewerbepark 83
D-78579 Neuhausen ob Eck

Robert Herz
Phone: +4974617087348
Fax: +49746170845581
vigilance@karlstorz.com

Returns form

Please complete this form and send it to the aforementioned contact (to avoid repeated inquiries) as required by the supervisory authority in charge of supervision of this procedure.

We herewith confirm that we are aware of the safety information regarding the product:

FLIPTACK, Fixation button REF: 28729FT

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Please mark with a cross where applicable:

There are no affected products in stock in our facility.

Or

We are returning the following products

Batches (no./quantity of returned products)

61603728 _____

61603837 _____

61603844 _____

61700063 _____

61700154 _____

61700023 _____

Facility:

Name:

Date:

Signature:

KARL STORZ GmbH & Co. KG
Logistikzentrum
Take Off Gewerbepark 83
D-78579 Neuhausen ob Eck

Robert Herz
Phone: +4974617087348
Fax: +49746170845581
Mobile: +49162 2800515
vigilance@karlstorz.com

Destruction Log

Please complete this form and send it to the aforementioned contact

We herewith confirm that the following products were destroyed, and can no longer be applied for use:

FLIPPTACK, Fixation button REF: 28729FT

Batches (no./quantity of destroyed products)

61603728	_____
61603837	_____
61603844	_____
61700063	_____
61700154	_____
61700023	_____

Exemption from liability:
KARL STORZ GmbH & Co. KG does not assume any liability for incidents with products applied despite this confirmation.

Facility:

Name:

Date:

Signature: