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.

Office Address:
KARL STORZ GmbH & Co. KG
Mittelstraße 8
78532 Tuttingen/Germany

Bank account:
Volksbank Donau-Neckar eG Tuttingen
SWIFT: GENODES1TUT
IBAN: DE97 6530 0130 0000 7720 03

Phone: +49 (0)7461 708-0
Fax: +49 (0)7461 708-105
E-Mail: info@karlstorz.com
Web: www.karlstorz.com
WEGE Reg. No. DE 74465857

Commercial Register: Stuttgart HRB 450442
VAT DE 142931059

Kreissparkasse Tuttingen
SWIFT: SOLA DEUT 170
IBAN: DE79 6435 0000 0000 3305 00

Kommendiggesellschaft:
KARL STORZ GmbH & Co. KG
Registered in Tuttingen
Commercial Register Stuttgart HRB 450442
VAT DE 142931059

Bank account:
Kreissparkasse Tuttingen
SWIFT: SOLA DEUT 170
IBAN: DE79 6435 0000 0000 3305 00

Unlimited Partner:
KARL STORZ-Verwaltungsgesellschaft mbH
Registered in Tuttingen
Commercial Register Stuttgart HRB 450225
Managing Partner: Sybill Storz; Dr. h. c. mult.

Deutsche Bank AG Tuttingen
SWIFT: DEUT 6530 03
IBAN: DE99 6530 0075 0211 5380 00
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
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:

**FLIPPTACK, Fixation button REF: 28729FT**

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)

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
</tr>
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<tbody>
<tr>
<td>61603728</td>
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<td>61700154</td>
<td></td>
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<tr>
<td>61700023</td>
<td></td>
</tr>
</tbody>
</table>

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)

<table>
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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: