URGENT FIELD SAFETY NOTICE (Version 1)

April 2020

To:	Surgeons, Hospital Risk Managers
FSCA Number:	2365134
Description:	Sterile packaging of T2 Locking Screws, Compression Screws, End Caps, Gamma3 End Caps
Catalog Number(s):	See below table for details
Legal Manufacturer:	Stryker Trauma GmbH, Professor Küntscher Strasse 1-5 24232 Schönkirchen, Germany
Lot Code(s):	Specific lot numbers – see below table for details

Dear Surgeons, Hospital Risk Managers,

The purpose of this notification is to advise you that Stryker Trauma GmbH (Trauma & Extremities Division) is conducting a voluntary recall. These products were distributed to customers from March 10, 2020 – March 23, 2020. Please refer above for the catalog and lot numbers that was identified as shipped to distributors and end users.

Catalog Number	Product Description	Lot Number
17965035S	Locking Screw, Fully Threaded S2 Ø5x35 mm	K0386FB
18220001S	Compression Screw, Advanced T2 Tibia	K020791
18220010S	End Cap T2 Tibia +10 mm	K020795, K020796
18300003S	End Cap, Standard T2 Humerus Ø6 mm	K020793, K020794
18300005S	End Cap T2 Humerus Ø6mm, 5mm height	K02803B
18300015S	End Cap T2 Humerus Ø6mm, 15mm height	K037E2D
18915055S	Locking Screw, Partially Threaded T2 Tibia Ø5x55 mm	K01CF9F
18964032S	Locking Screw, Fully Threaded T2 Humerus Ø4x32 mm	K0207C2
18965030S	Locking Screw, Fully Threaded T2 Tibia Ø5x30 mm	K0207B0, K02C1A8, K02C1A9, K0302E4
18965035S	Locking Screw, Fully Threaded T2 Tibia Ø5x35 mm	K02AE3F, K02C191, K02C1AA, K0302F9, K0302FA, K0302FD, K030307, K030313, K030315, K030EE3, K030EE4, K030EE5, K030EE8, K031B63, K032879, K0E902D, K0E9086, K0E90B7, K0E90BB, K0EAC03
18965037S	Locking Screw, Fully Threaded T2 Tibia Ø5x37,5 mm	K029C38, K029C39, K030EF6, K030EF7, K030EF9, K031B66
18965040S	Locking Screw, Fully Threaded T2 Tibia Ø5x40 mm	K0207B3, K031B6B, K031B6C, K033439
18965045S	Locking Screw, Fully Threaded T2 Tibia Ø5x45 mm	K02C1BB, K03033E, K030342, K03035D, K030F17, K030F1D, K031B6E, K031B70, K0328A5
18965050S	Locking Screw, Fully Threaded T2 Tibia Ø5x50 mm	K030F1E, K033442
30051100S	End Cap, Std, Ti Gamma3®	K03A7FF

Reason for Voluntary Recall
Stryker Corporation investigated a nonconformance with a supplier. The manufacturer found that the coating of the sealing lids for the sterile packaging was defective for a part of a certain supplier batch. It cannot be completely excluded that parts of it have been put on the market.
The seal integrity of the blister pack may be compromised. Stryker Trauma GmbH, Trauma and Extremities Division will recall all unused items from the above lots.

Risk to Health
Integrity of the sterile barrier cannot be assured over 5 years shelf life. Therefore, a risk of infection due to the use of an improperly sealed device cannot be excluded.

Mitigating Factors
None

Follow up
There is no recommendation. If these implants were used in a patient and no complications have occurred yet after these surgeries, it is not very likely these complications will still occur. Most infections occur and become apparent within the first 30-days after surgery. This is not a recall to explant the devices.

Potential Alternative Products
The recall is limited to specific lot numbers. All other lots are not affected and can be used.

Actions to be taken by the Customer/User:
Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Inform individuals within your organization who need to be aware of this device recall.
2. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. **Response is required, even if you may not have any physical inventory on site anymore.**
3. Quarantine and discontinue use of the recalled devices.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility
5. Inform Stryker if any of the subject devices have been distributed to other organizations.
   a) Please provide contact details so that Stryker can inform the recipients appropriately.
   b) If you are a Distributor, note that you are responsible for notifying your affected customers.
6. Complete the attached customer response form (acknowledgement form). It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this Action.

We request that you **respond to this notice within 7 calendar days** from the date of receipt. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions. We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

Other Information

We confirm that the competent national authorities in your country have been informed of this safety corrective action in accordance with regulatory requirement in your country.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:
Position:
Email:
Telephone:

Yours Sincerely,

Signature

Your personal contact in this matter is listed below. If you have any questions regarding this measure, please contact your contact person directly.

Name: ……. Position: ……..
E-mail: …… Phone: …….

On behalf of Stryker we would like to thank you for your help and support in the timely implementation of this measure and ask for your understanding. We would like to assure you that Stryker will do its utmost to ensure that only products that meet our strict internal quality criteria are on the market.

Yours sincerely

Stryker Entity

Name

Title

Country

AKNOWLEDGEMENT FORM (FSCA)

FSCA-ID: RA2020-2365134
Type of measure: **Urgent Product Recall**

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Customer no. _____

Hospital _____

Postcode, City _____

Contact person (name, position) _____

Phone no. _____

☐ Hereby we confirm the notification of Stryker Trauma about a Product safety information for above mentioned products.

We sold the products to the following institution:

Name: _____ Address: _____

Contact person: _____ Tel.-No.: _____

_____

Date / legal signature of a person of the medical institution