stryker

URGENT:
MEDICAL DEVICE RECALL

T2™ Rigid Reamers

Attn: Health Care Professionals, Operators of Medical Devices, Distributors

Recall Number: PFA RA2025-3846165

XX-January-2025

Product Affected

Catalog number	GTIN	Product description	Batch Lot #	Distribution Dates
18062012	07613327095975	T2™ Rigid Reamers	K1D9CF6	23-Sep-2024 to 6-Nov-2024

The purpose of this notification is to advise that Stryker GmbH is conducting a field action for one batch lot of T2 Rigid Reamers. Please refer to the table above for catalog and lot number within the scope of this field action that were identified as shipped to distributors and end users.

Product description

The T2 Rigid Reamer is an orthopedic surgical instrument designed to open and enlarge the medullary canal for the insertion of various devices during prosthesis implantation or fracture fixation procedures. It is designed as a long, cylindrical, rigid shaft with straight, spiraled, or contoured flutes that function as cutting surfaces; it may include a transverse milling burr to level the end of the bone. It is made of high-grade stainless steel and is available in various sizes. It is intended for manual or powered rotation. This is a reusable device intended to be sterilized prior to use.

Product issue

Stryker has identified an issue that impacts one lot of T2 Rigid Reamers. Our investigation found that the product from this lot incorrectly contained Convex Reamers. The products are labeled as 1806-2012 but contain 6514-7-310.

Potential risks

The hazard associated with this issue is that the device may not be fully functional. The product issue is detectable, see Addendum A. If the nonconformance is not detected preoperatively, surgery time may be prolonged in order to obtain a backup device.

Actions needed by Customers and Distributors

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. Immediately check your internal inventory to locate the product(s) listed on the attached Business Reply Form, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.
2. Sign and return the enclosed Business Reply Form by email to <XXXXX@stryker.com> to confirm receipt of this notification/documenting product segregation.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** 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 eliminate the need for us to send further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
3. Upon receipt of the completed Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations
7. 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:

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

Addendum A

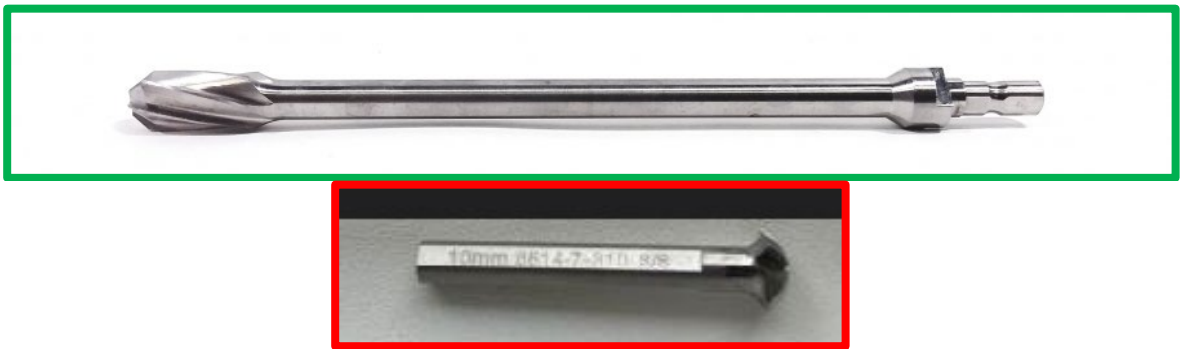

Figure 1: As labeled, conforming part 1806-2012 (top/green), and non-conforming part 6514-7-310 (bottom/red)

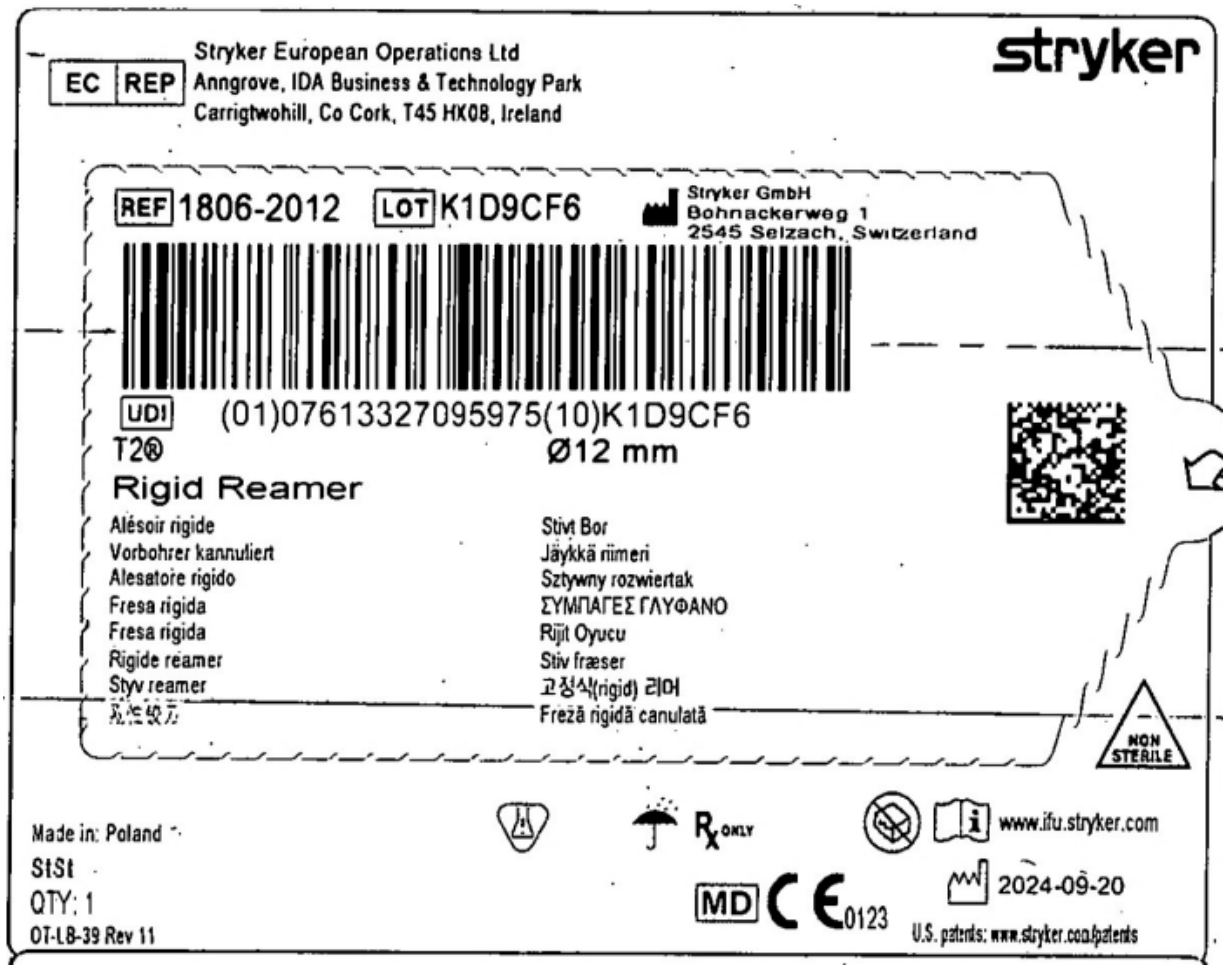

Figure 2: Sample Label to T2 Rigid Reamer

Business Reply Form

Account name:
Account Address:

T2™ RIGID REAMERS

Recall Number: PFA RA2025-3846165

XX-January-2025

Please complete and sign this form. Email the completed form to **xxxx@stryker.com** by **XX-JAN-2025**.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product description	Batch Lot number	Quantity on Hand
1806-2012	T2 Rigid Reamer	K1D9CF6	

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate to whom, if possible:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			