stryker

UPDATE / URGENT

Field Safety Notice – Scope Expansion

TMJ Bilateral Implant and Unilateral Implant

Attn.: XXX

FSCA-Number: RA2025-4108109

March 2026

Purpose of this letter

The purpose of this letter is to inform you that Stryker Craniomaxillofacial (CMF) has initiated an expansion for a field safety corrective action that was initiated on September 30, 2025, for the TMJ Bilateral Implant. The field safety corrective action has been expanded to include additional devices which may exhibit the hazard. The table below includes the devices impacted by the field safety corrective action.

Catalog	Produkt Description	GTIN	Affected Lot
CHG010	TMJ Unilateral Implants	07613327626551	**2410011097**
			2304191025
CHG020	TMJ Bilateral Implant	07613327626575	**2211241006**
			2308221008
			2309131028
CHG024	TMJ Unilateral Implants oversized	07613327626605	**2410091014**
			2310101020
			2503071017

Product description

The Patient-Fitted Temporomandibular (TMJ) Reconstruction Prosthesis is comprised of a mandibular component and a glenoid fossa component that have been customized for the patient identified on the front of the product insert. The system also includes TMJ Fixation Screws, TMJ Fixation Instruments, and an anatomical Bone Model. The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System is intended to be used for the reconstruction of the temporomandibular joint.

Product Issue

With certain TMJ implants, slight variations in the screw hole position, together with local bone thickness, may result in the recommended screw length exceeding the available bone thickness.

Stryker has received one surgeon reported complaint associated with the issue. The complaint indicated a screw penetrated the cranial vault, no patient harm was reported.

Potential risks

If an implant has a screw hole located in an area of thin bone and a screw length longer than the bone thickness is used, there is a potential risk for cranial vault penetration. This could lead to a risk of dural damage which could result in bleeding or cerebral spinal fluid leak (CSF). CSF leaks increase the risk of infection including meningitis and may require intervention to prevent serious injury.
Per Stryker Medical Risk Assessment, an epidural or subdural bleeding would likely be present in the first 72 hours following surgery, if it were to occur.

Requested Customer Actions

As the manufacturer, Stryker, requests that you take the following actions:

1. Immediately check your inventory to determine whether any affected products remain in your possession.
2. If an affected product is still in your inventory and has not yet been implanted, please do not use the device and contact Stryker at xxxxxx@stryker.com
3. Acknowledge the above-mentioned risks in relation to this field safety corrective action by returning the enclosed Business Reply Form (BRF) to xxxxxx@stryker.com.
4. Inform all appropriate members of your organization who need to be made aware of this action.
5. Stryker advises that patient monitoring should be maintained in accordance with your established care protocols.

6. If you have further distributed the affected product, please notify the applicable parties at once about this field safety corrective action. 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.
7. Please inform Stryker of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

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: E-mail:

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,

Post Market Quality

Business Reply Form

TMJ Bilateral Implant and Unilateral Implant

FSCA-Number: RA2025 - 4108109

March 2026

Please complete and sign this form. Email the completed form to XXXX@stryker.com.

RESPONSE IS REQUIRED

Catalog number	Product Description	Lot number/Case number	Quantity on hand*

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

Form completed by:

Facility Name			
Address			
Printed Name		**Title**	
Signature		**Phone**	
Date		**E-Mail**	

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

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

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

☐ **I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.**

☐ **I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.**

Name (print)_____**Signature**_____**Date**_____