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URGENT:
MEDICAL DEVICE RECALL

PYROCARDAN® TMC RESURFACING IMPLANT

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

Recall Number: RA2023-3499794

JANUARY-2024

Product affected

Catalog number	GTIN	Product description	Lot number	Distribution Dates
PYRC-14	03700386942259	PYROCARDAN TMC RESURFACING IMPLANT, SIZE S	Starting with 4638AZ	20-Jun-2023 to 20-Oct-2023
PYRC-15	03700386942266	PYROCARDAN TMC RESURFACING IMPLANT, SIZE M	Starting with 4780AZ	

The purpose of this notification is to advise that Tornier SAS (a wholly owned subsidiary of Stryker) is conducting a field action of two lots of Pyrocardan® TMC Resurfacing Implants.
Please refer to Attachment A for a list of the serialized lot numbers that were identified as shipped to distributors and end users.

Product description

The Pyrocardan® TMC Resurfacing Implant is an unfixed resurfacing implant designed to be used for pure interposition in the trapeziometacarpal joint or in the scapho-trapezio-trapezoid joint. Pyrocardan maintains bone capital, decreases pain compared to the pre-operative condition, allows mobility across two axes thereby reproducing the anatomical joint and preserving all existing surgical strategy options in the event of failure.

Product issue

Stryker has identified an issue that impacts two lots of Pyrocardan® TMC Resurfacing Implant. The parts from these two lots have been comingled. Lot 4638AZ of PYRC-14 incorrectly contains parts from Lot 4780AZ of PYRC-15, and vice versa.

Potential risks

The hazards associated with this issue is compromised traceability and the device may not fully functional due to the incorrect size implant being present in packaging.

- If the issue is detected intraoperatively, the potential harm is elongation of surgery time to obtain a replacement.
- If a back-up of the same catalog number is not available, selection of an implant size that is less optimal may necessitate a revision surgery.
- Or an alternate surgical method may be completed intraoperatively.

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 nby_qara@stryker.com to confirm receipt of this notification/documenting product disposition.
    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.

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: Amandip Auluck
Position: Associate Manager, Post-Market Surveillance
email: Amandip.auluck@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.12-1 and EU 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 that may be 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,

Nina Goddard
Regulatory Affairs and Quality Assurance

Attachment A: Product Affected

Item Number	Lot Serial Number	
PYRC-14	4638AZ001	4638AZ013
	4638AZ002	4638AZ014
	4638AZ003	4638AZ015
	4638AZ004	4638AZ016
	4638AZ005	4638AZ017
	4638AZ006	4638AZ018
	4638AZ007	4638AZ019
	4638AZ008	4638AZ020
	4638AZ009	4638AZ021
	4638AZ010	4638AZ022
	4638AZ011	4638AZ023
	4638AZ012	
PYRC-15	4780AZ001	4780AZ013
	4780AZ002	4780AZ014
	4780AZ003	4780AZ015
	4780AZ004	4780AZ016
	4780AZ005	4780AZ017
	4780AZ006	4780AZ018
	4780AZ007	4780AZ019
	4780AZ008	4780AZ020
	4780AZ009	4780AZ021
	4780AZ010	4780AZ022
	4780AZ011	4780AZ023
	4780AZ012	

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Business Reply Form

PYROCARDAN® TMC RESURFACING IMPLANT

Recall Number: RA2023-3499794
JANUARY-2024

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

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	Lot number	Lot and Quantity on Hand
PYRC-14	PYROCARDAN TMC RESURFACING IMPLANT, SIZE S	Starting with 4638AZ	
PYRC-15	PYROCARDAN TMC RESURFACING IMPLANT, SIZE M	Starting with 4780AZ	

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

Form completed by:

Hospital Name		**Address**	
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			

☐ **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_____