



URGENT FIELD SAFETY NOTICE: RA2019 – 2197654 UPDATE

FSCA identifier: RA2019-2197654 UPDATE
Type of action: Field Safety Corrective Action: Recall
Legal Manufacturer: Howmedica Osteonics Corp. 325 Corporate Drive. 07430 Mahwah, N.J. USA
Product affected: 0942-8-025 (X-Change Wall Mesh Small (6-Petal)) with lot number G6091225

February XX, 2020

Dear Customer,

Stryker has initiated an update to the urgent, voluntary, lot-specific recall for the above referenced product on October 2019. Stryker has completed technical and medical assessments and is providing this follow-up (update) to communicate that there are no hazards and harms associated with the aforementioned product.

Issue

Stryker has discovered that certain boxes of the 6-Petal X-Change Wall Mesh Small (Part # 0942-8-025) contain the 4-Petal X-Change Wall Mesh Small (Part # 0942-8-015).

Potential hazards/harms

There have been no potential hazards or harms identified.

Actions Needed

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending to return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. 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.
- 5. Please inform Stryker of any adverse events concerning the use of the subject devices.

Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.
- 6. Complete the attached customer response 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 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 PFA.
 - a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt.

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:
Telephone:
E-mail:

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, 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 within the target date and regret any inconvenience that may be cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,



**URGENT FIELD SAFETY NOTICE: RA2019 - 2197654 UPDATE
BUSINESS REPLY FORM**

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I acknowledge receipt of the Field Safety Notice for RA2019-2197654 and can confirm that:

| | | | |
|---|------------------------------------|----------------|-----|
| We have not located any of these devices in our inventory: (please delete if not applicable) | | | |
| We have located the following devices: | | | |
| Catalog number | Description | Lot number | Qty |
| 0942-8-025 | X-Change Wall Mesh Small (6-Petal) | G6091225 | |
| | | | |
| We have further distributed subject devices to the following organizations: | | | |
| Facility Name | | | |
| Facility Address | | | |
| Please sign and return this form to acknowledge receipt of product notice. | | | |
| Name of Hospital / Organisation | | Department | |
| Contact Name | | Address | |
| Contact Title | | | |
| Contact Signature | | E-mail Address | |
| Contact Phone No. | | Date | |

**PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE
EMAIL, **XX**, OR FAX, **XX**.**