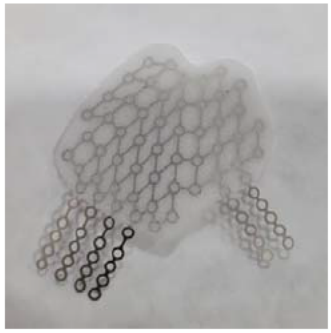
Field Safety Notice: RA2021-2895963

MEDPOR® Titan OFW – MTB – Right – 1.0mm



Attn: To Whom it May Concern
December 21, 2021

Product affected

Catalog number	UDI	Product description	Serial/Lot number	Distribution dates
81032	(01)07613252084334 (17)310117 (10)3R7YHD	MEDPOR® Titan OFW – MTB – Right – 1.0mm	3R7YHD	12Feb2021–30Nov2021

Product description

MEDPOR® BARRIER Surgical Implants are manufactured from a linear, high-density polyethylene biomaterial. MEDPOR® BARRIER Surgical Implants in block, sheet and preformed shapes are intended for non-weight bearing applications of craniofacial reconstruction surgery and repair of craniofacial trauma. MEDPOR® BARRIER Implants are also intended for the augmentation or restoration of contour in the craniofacial skeleton.

Primary clinical purpose of device(s)

MEDPOR® Implants in block, sheet and pre-formed shapes are intended for non-weight-bearing applications of craniofacial reconstruction surgery and repair of craniofacial trauma. MEDPOR® Surgical Implants and MEDPOR® BARRIER Implants are intended for the augmentation or restoration of bony contour in the craniofacial skeleton.

- Reconstruction of the orbital skeletal framework, including orbital floors, walls, rims and roof.
- Inlay and onlay grafts to restore or augment deficient tissue regions in the zygomatic arch (cheek bone, malar region), chin, mandible (angle augmentation and osteotomy void volume defects), nasal labial and nasal regions.
- To restore defects in the cranium, including frontal and temporal defects, soft tissue defects resulting from atrophy of the temporalis muscle, and cranial drill holes (burr holes) created by surgical cranial perforators.

- Reconstruction of the auricle (external ear) where defects occurred from trauma related accidents, including burns and birth defects, including, microtia.
- Void volume replacement following enucleation and/or evisceration of the eye.
- The Pterional Implant is indicated to correct temporal hollowing in patients who have had surgery involving the pterional approach to the cranium, including pterional craniotomy. This Pterional Implant augments the space normally occupied by the temporalis muscle. The implant is used for the reconstruction of temporal deformities; the reconstruction of temporal craniotomy defects and/or the augmentation/restoration of the space normally occupied by the temporalis muscle/ temporal area(s).

Indications for the MEDPOR® BARRIER Surgical Implant include situations in which a biomaterial may be used for augmentation or restoration of bony contour in the craniofacial skeleton, when the surgeon wishes to prevent tissue ingrowth into one area of the implant.

Product issue

Inside the packaging of one reported item #81032 (TITAN OFW-MTB, RIGHT) a non-conforming product was found. Contrary to the design, the barrier layer was manufactured on the inferior side of the implant versus the superior side.

Potential hazard and risks

The potential risk is that the device cannot be used. This would require a second device, or an alternative method be used and would cause a delay in procedure.

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 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.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

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 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 FSCA
    a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request your support in finalizing the required steps within 14 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: email:

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 caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

[redacted]

Business Reply Form- response required

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December 21, 2021

Please complete and sign this form. Email the completed form xxxx@Stryker.com by <MMM DD YYYY>

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

Catalog number	Product	Serial/Lot number(s)	Quantity on hand*
81032	MEDPOR® Titan OFW – MTB – Right – 1.0mm	3R7YHD	

*If 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:

Product(s) distributed		**Quantity distributed**	
Facility name		**Contact person**	
Full address			