December 12th, 2014

URGENT FIELD SAFETY NOTICE: RA2014-126

FSCA Identifier: Product Field Action RA 2014-126

Legal Manufacturer: Stryker Leibinger GmbH & Co. KG, Boetzingerstraße 41, D-79111 Freiburg, Germany

Type of Action: Field Safety Corrective Action

Description:

MEDPOR Surgical Implant - Contoured Two Piece Chin - Part 86001
MEDPOR BARRIER Sheets – Orbital Floor Implant - Part 9305
MEDPOR BARRIER Sheets – Rectangle - Part 9312

Affected part and lot codes:

Catalog Number **REF**	**Batch Code** **LOT**
86001	- A1404026 - A1405048
9305	- 69698 - 77004 - 81799 - A1310051 - A1311008 - A1311044 - A1312011 - A1402023 - A1404010
9312	- A1403008

Dear Valued Stryker Customer,

Please find attached details of a Product Field Action “PFA” that has been initiated by Stryker Leibinger GmbH & Co. KG / CMF concerning the above referenced devices.

Our records indicate that you have received at least one of the devices referenced in the description above and you are therefore affected by this action. It may be that you no longer have any physical inventory on site.

This action has been taken to ensure that users are aware of important Information concerning the devices listed above. You are required only to read the attached Field Safety Notice, sign the notice and return the PFA acknowledgement form confirming that you have completed the actions requested by the manufacturer.

Completing the PFA acknowledgement form will allow us to update our records and will also negate the need for us to send any further communications on this matter. Therefore please complete the form even if you no longer have any of the subject devices in your physical inventory.

We request that you respond to this notice within **7 calendar days** from the date of receipt. The target date for completion of this action is February 10th 2015; your timely response will ensure that we meet this target and help us remove the impacted devices from the market as quickly as possible.

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:	X
Position:	Regulatory Affairs Specialist
E-mail:	X
Tel:	X
Fax:	X

In line with the recommendations of the MEDDEV Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA (Field Safety Corrective Action) has been notified appropriately to the National Competent Authority for your country.

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

Yours faithfully,

X
Quality Assurance and Regulatory Affairs

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9312	- A1403008

Dear Valued Stryker Customer,

Stryker Leibinger GmbH &Co.KG CranioMaxilloFacial has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue

Stryker has become aware that there is a higher occurrence rate of implant damaged during intra-operative handling for the part number noted above. For all affected parts numbers, a higher occurrence rate of implants breakage intra-operatively may be experienced. Additionally, for the BARRIER Sheets, a loss of adhesion between the barrier sheet and the porous sheet may be also experienced during intra-operative handling and modification.

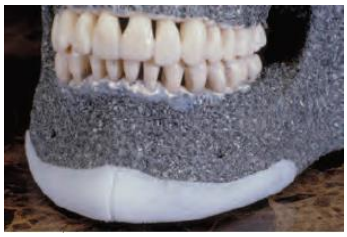

Figure 1: Contoured Two-Piece Chin Implant (Part 86001)

Figure 2: BARRIER Sheet Implants (Parts 9305, 9312)

Potential Hazards

To date, no injuries have been reported due to this reported anomaly. If the Contoured Two-Piece Chin Implant or the BARRIER Sheet implants are damaged, it would likely occur during contouring or modification and will be detected by the surgeon. If a breakage occurs, the surgeon should use an alternate implant.

In all cases, the use of the Contoured Two Piece Chin Implant and the BARRIER Sheet Implants from the affected lots may potentially lead to the hazard “Implant Damaged”. The most severe potential harm associated to this hazard is a prolongation of surgery between 15 to 60 minutes. This harm is caused by the replacement or the rework (e.g. suturing) of the damaged implant.

Stryker’s investigation confirms that the implant breakage and the loss of BARRIER adhesion will only occur during surgical implant modification. No post-operative harm is associated or identified with the use of the affected devices.

Mitigating Factors

1. As per the devices’ respective Instructions for Use (IFU), do not use excessive force when removing or handling the implant, as this may result in implant breakage.

2. Plan surgery with a back-up device available.

Type of Action

Distribution of Field Safety Notice – Recall of subject devices.

Immediate actions

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. Please inform users of MEDPOR Surgical Implant – Contoured Two Piece Chin (Part 86001) and MEDPOR BARRIER sheets (Parts 9305 and 9312) of this Medical Device Recall. Also please pass this notice to all those individuals who need to be aware within your organization.
2. Complete and sign the enclosed PFA Acknowledgment Form and return to X by fax (X) or by email (X) within 7 calendar days. A Stryker representative will then be in contact to arrange for product return
3. Keep a copy of the completed and executed PFA Acknowledgement Form for your records.
4. Report all adverse events or product quality problems to Stryker.

We sincerely regret any inconvenience that this action may cause you and on behalf of Stryker would like to thank you for your help and support in completing this action in a timely manner.

Should you have any queries on this matter please do not hesitate to contact the undersigned.

Yours faithfully

X
Quality Assurance and Regulatory Affairs

Appendix:
PFA Acknowledgment Form

RA2014-126: PFA ACKNOWLEDGMENT FORM

FSCA Identifier: Product Field Action RA 2014-126

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MEDPOR Surgical Implant Contoured Two Piece Chin - Part 86001
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86001	A1404026 ; A1405048
9305	69698 ; 77004 ; 81799 ; A1310051 ; A1311008 ; A1311044 ; A1312011 A1402023 ; A1404010
9312	A1403008

I acknowledge receipt of the Field Safety Notice for RA2014-126 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 :				
Product description	**Product Reference**	**Lot Number**	**Qty**	**Qty Quarantined**
We have further distributed subject devices to the following organizations:				
Facility Name :				
Facility Address:				
Form completed by:				

Contact Name _____ **Contact Facility** _____

Contact address _____ **Contact Position** _____

_____ **Contact Tel No** _____

_____ **Contact Fax No** _____

_____ **Contact e-mail** _____

PLEASE COMPLETE AND FAX THIS FORM TO X
OR EMAIL TO X.

RA 2014-126 – MEDPOR® Surgical Implant Contoured Two Piece Chin (Part 86001) and MEDPOR® BARRIER Sheets 1.6 mm (Parts 9305 and 9312)