Date

URGENT FIELD SAFETY NOTICE: RA2016-210

FSCA Identifier:	Product Field Action RA 2016-210
Type of Action:	Field Safety Corrective Action
Description:	Several Lots of MEDPOR Facial and Oculoplastic Sizer Set, TLS and SPG Drain Systems
Legal Manufacturer	Stryker Leibinger GmbH & Co. KG, Boetzinger Strasse 41, D-79111 Freiburg, Germany
Catalogue #s:	Refer to the attached list on page 5
Lot #s:	Refer to the attached list on page 5

Dear Customer,

Please find attached details of a Product Field Action that has been initiated by Stryker Leibinger GmbH & Co. KG, Division Craniomaxillofacial concerning the above referenced devices.

Our records indicate that you have received at least one of the subject devices 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 and then sign and return the customer response form confirming that you have completed the actions requested by the manufacturer.

Completing the Customer Response Form (see page 6) 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.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 3rd March 2017 and your timely response will enable us to ensure that we meet this target and ensure that non-conforming devices are removed 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 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 conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

X
Quality Assurance and Regulatory Affairs

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Dear Customer,

Stryker Leibinger GmbH & Co. KG, Division Craniomaxillofacial, has initiated a Product Field Action for the devices identified above. The purpose of this letter is to advise you that Stryker Craniomaxillofacial is voluntarily recalling several lots of MEDPOR Facial and Oculoplastic Sizer Sets, and TLS and SPG Drain Systems.

Reason for Voluntary Recall
Stryker received a report indicating that the outer label of a MEDPOR Sizer Set states ‘sterile’, whereas the product is actually delivered non-sterile. Investigations revealed that additional products and lots have an incorrect sterility status on their labels.
An incorrect sterility status on the label can lead to introduction of a non-sterile device into the sterile surgery field and/or operative site, which in turn could result in infection.

Potential Hazards
The introduction of a non-sterile device into the sterile surgery field can potentially cause infection requiring medical or surgical treatment to remediate.

Risk Mitigation
- SPG Bulb Drain System is delivered sterile.
- The TLS Quintube Monitor Pack is part of the post-surgical treatment without the necessity of being sterile.
- The MEDPOR Sizers are packed in a zip bag clearly different than that used to package sterile devices such as sterile barrier systems consisting of sealed (double) pouches or sealed (double) blisters.
- The Instructions for Use contain Cleaning and Sterilization Instructions for these Products

Type of Action
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:

Our records indicate that you have received at least one of the subject devices listed above. We therefore request that you:

1. Please inform users of this Medical Device Field Removal and 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). A Stryker representative will then be in contact to arrange for product return.
3. Keep a copy of the completed and executed Business Reply 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

RA2016-210 Affected Product and Lot Codes

Part Numbers	Manufacturer Part Name	Lot Numbers	Sterility status	Label information
6630	QUINTUBE Monitor Pack (5 tubes/pk, 24 pk/cs)	M1305008, M1305009, M1305010, M1305011, M1309004, M1309005, M1309006, M1309007, M1309008, M1309009, M1309010, M1607009, M1607010, T1309003	Non-sterile	Carton (shelf box) label states ‚sterile‘
6649	SPG Bulb Drain System, 4mm Flat w/Center Holes	M1508003	Sterile	Carton (shelf box) label states ‚non-sterile‘
9805	Orbital Volume Sizer Set with Tray	M1311023	Non-sterile	Pouch label states ‚sterile‘
9951	Design M Malar Sizer Set (Silicone, Non-Sterile)	M1305001	Non-sterile	Clamp shell label states ‚sterile‘
9952	Extended Contoured, Malar Sizer Set (Silicone, Non-Sterile)	M1603004	Non-sterile	Clamp shell label states ‚sterile‘
85000	Petite Nasal Dorsum Sizer Set (Silicone, Non-Sterile)	M1603003	Non-sterile	Clamp shell label states ‚sterile‘

RA2016-210: PFA ACKNOWLEDGMENT FORM

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I acknowledge receipt of the Field Safety Notice for RA2016-210 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 organisations:				
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.