STRYKER GmbH (Trauma & Extremities Division)

URGENT FIELD SAFETY NOTICE

PFA_2045882 Version 1
Field Safety Corrective Action (Lot specific)
Affected Product: TACTYS - IPP Prosthesis -Proximal Surface

2nd April 2019

Legal Manufacturer: Stryker GmbH, Bohnackerweg 1
2545 Selzach, Switzerland

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

Type of Action: Field Safety Corrective Action / Removal

FSCA Identifier: PFA_ 2045882

Identification of the Affected Product(s):

Catalogue #	Manufacturer Part Name	Lot #
WIPSP11	TACTYS - IPP Prosthesis -Proximal Surface Size L	Y23259
WIPSP10	TACTYS - IPP Prosthesis -Proximal Surface Size M	Y23263

Dear Customer,

The purpose of this notification is to advise you that Stryker GmbH (Trauma & Extremities Division) is conducting a voluntary recall. These products were distributed to customers from 12th of July 2018 - today. Please refer above for catalogue and lot numbers that were identified as shipped to distributors and end users.

Reason for Voluntary Recall
Stryker has identified a mismatch between the packaging label (size L) and the actual device packed inside (size M). The internal investigation reveals that the packaging TACTYS - IPP Prosthesis -Proximal Surface Size L of the lot Y23259 can contain a TACTYS - IPP Prosthesis -Proximal Surface Size M of the lot number Y23263, and vice versa. The deviation is limited to the catalogue numbers and lot numbers above.
One related complaint for the concerned products has been received from the market. A surgical delay of 5 minutes is reported without harm to the patient. No other complaints have been received.

Risk to Health
The deviation can lead to a prolongation of surgery time. There are potential harms associated with the deviation if the implant size is not appropriate and no spare device of the correct size is available. The usage of the wrong size can cause the attempt to implant a too big/too little stem into the proximal/distal part of the joint. If a correct sized prosthesis is not available, a revision surgery or a change of the surgery method can be necessary. Harm to the bone may occur. The worst-case scenario will be a change of the surgery method or a revision surgery.

Mitigating Factors
Other products with the appropriate size might be available.
The wrong size of the product is easily recognizable for the user.

Recommendations for patients already treated with an affected device
No specific recommendations for patients already treated with affected devices. The nonconformance is limited to the lot numbers Y23259 and Y23263. An explantation of an affected or potentially affected device does not appear appropriate, the risk of a revision operation by far outweighs the possible advantages of correction to the proper implant size.

Potential Alternative Products
The removal of the products is lot specific. Not affected lot numbers can be ordered and are available.

Actions to be taken by the Customer/User:
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. Inform individuals within your organization who need to be aware of this device recall.
2. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. **Response is required, even you may not have any physical inventory on site anymore.**
3. Quarantine and discontinue use of the recalled devices.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility
5. 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.
6. Complete the attached customer response form (acknowledgement 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 Action.

We request that you **respond to this notice within 7 calendar days** from the date of receipt. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions. We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

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: *Dominik Blaser*

Address: *Bohnackerweg, 2545 Selzach, Switzerland*

Position: *Lead Product Field Action Specialist*

Email *dominik.blaser@stryker.com*

Telephone *+41 32 641 7200*

STRYKER GmbH (Trauma & Extremities Division)

ACKNOWLEDGMENT FORM (FSCA)

FSCA Identifier: Product Field Action PFA_2045882

Type of Action: Field Safety Corrective Action / Removal

Legal Manufacturer Stryker GmbH, Bohnackerweg 1
2545 Selzach, Switzerland

Identification of the Affected Product(s):

Catalogue #	Manufacturer Part Name	Lot #
WIPSP11	TACTYS - IPP Prosthesis -Proximal Surface Size L	Y23259
WIPSP10	TACTYS - IPP Prosthesis -Proximal Surface Size M	Y23263

I acknowledge receipt of the Field Safety Notice for PFA_2045882 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.