MEDLANE®
LES INSTRUMENTS DE LA PERFECTION

ZIMMER BIOMET

Parc d'entreprises du Grand Troyes

5, rue de Berlin

10300 SAINTE SAVINE

Genas, February 2nd, 2,022

SAFETY INFORMATION AND CORRECTIVE ACTIONS

In relation with : Recall of medical devices with references X846 and X844

Dear Customer,

This letter is intended to inform you about corrective safety action carried out by Medlane regarding the screws referred as X846 and the screwdrivers referred as X844, identified in the return form herein-attached:

Purpose of the corrective safety action :

MEDLANE has been informed of the nonconformity of the screws with references X846 belonging to the batch 04V08-A2.

The screws with reference X846 from the batch 04V08-A2 which you had lent to a customer of yours, have been identified as being not in accordance with our requirements at the inspection when returning from surgery performed by LDR MEDICAL (part of ZIMMER BIOMET).

During the assembly, the incriminated screws do not adapt to the corresponding screwdriver with reference X844. This problem comes from the difference of the initial screws' length and from the positioning difference of the retaining groove of the screws allocated to our partner LDR MEDICAL (part of ZIMMER BIOMET).

Following our investigations, we have noticed that the items allocated to LDR MEDICAL (part of ZIMMER BIOMET), were in fact destined to other customers.

Health risk :

A risk analysis has been carried out. There are neither major nor minor risks for the patient with these products.

Actions which are expected from the customer :

- Inspect your stock to determine the number of the products with references X846 and X844.
- Fill in the return form by indicating the quantity of the products with the related references X846 and X844 that you have in your inventory and send back to Medlane the related return form.

- The products with references X846 and X844 will be sent back to you at the receipt of the return form.

In order to comply with the reglementary requirements, we would be grateful if you could fill in the return form and send it back to us per mail qualité@medlane.com as soon as you can.

We would like to apologize for all the inconveniences caused and thank you in advance for your understanding.

Belkheir TOUKAL

Chairman

Medical Device Vigilance Supervisor

MEDLANE®
LES INSTRUMENTS DE LA PERFECTION

RETURN FORM FOLLOWING A BATCH RECALL :

Please fill in this return form and send it back to qualité@medlane.fr

The related products

Reference	DESIGNATION	BATCH NUMBER	QUANTITY
X846	SELF-RETAINING CASPAR SPINE SIMPLE DISTRACTION RETRACTOR : 2 SCREWS 14 mm	LOT 04V08-A2	36
X846	SELF-RETAINING CASPAR SPINE SIMPLE DISTRACTION RETRACTOR : 2 SCREWS 14 mm	LOT 09V09-A2	28
X846	SELF-RETAINING CASPAR SPINE SIMPLE DISTRACTION RETRACTOR : 2 SCREWS 14 mm	LOT 20W05-A2	55
X844	SELF-RETAINING CASPAR SPINE SIMPLE DISTRACTION RETRACTOR : SCREWDRIVER	LOT 20W05-A2	25
X844	SELF-RETAINING CASPAR SPINE SIMPLE DISTRACTION RETRACTOR : SCREWDRIVER	LOT 04V08-A2	26

1. I acknowledge that I have read and understood the letter with this form.

☐ YES ☐ NO

2. Please fill in this table with the total number of the products in each batch related that you have in your stock :

REFERENCE	DESIGNATION	BATCH NUMBER	QUANTITY

3. Have you inspected all the related products being in your stock, which could be defected according to the description of the letter with this form ? Have you carried out all actions required ?

☐ YES ☐ NO

I have destroyed all related devices (please indicate the number of the destroyed devices and the date of the destruction in the table herein below) :

☐ YES ☐ NO

If not, please explain :

_____

_____

_____

REFERENCE	DESIGNATION	BATCH NUMBER	QUANTITY

4. Have you noticed or received any information on potential incidents* linked to the problem described in the letter with this form ?

☐ YES ☐ NO

*What is meant by incident, is related to any dysfunction or any alteration of the characteristics or of the performances of a device and to any inadequate labelling or user manual, which directly or indirectly could lead to or could have led to the patient's death, to the user's death, to any other people or to a serious alteration of their medical condition. Some incomplete or inaccurate results indirectly can lead to an incident because of a medical decision or because of an action being carried out or not based on the information or on the results given by the device.

If so, please explain :

6. Please give us your name and your contact details for the shipment. The screws and screwdriver will be sent to your address to the attention of the related person.

COMPANY NAME	
CONTACT PERSON	
TITLE	
E-MAIL ADDRESS	
NAME OF THE CONTACT PERSON FOR THE DELIVERY IF DIFFERENT	

Signature Date

Name in capital letters