Urgent Field Safety Notice

pro med instruments GmbH, Boetzinger Str. 38, 79111 Freiburg, Germany

Company
Contact name
Street Address
City, State, Zip Code
Phone, E-Mail

Medical device field safety notice – Recall

DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs), Item no. 3006-00

26. October 2017

Dear Device User/Distributor,

Please forward this urgent information to all distributers/users or otherwise concerned persons.

1. Purpose of this letter

pro med instruments is conducting a voluntary medical device field action (recall) for the following device:

DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs)
Item No. 3006-00
LOT 17041 and LOT 17072

Results of our investigations indicate that only the LOTs **17041** and **17072** may be affected.

Serious injuries could occur due to the usage of the affected products.

Our records indicate that you may have received one or more of the affected products.

2. Concerned Product

DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs)
Item No. 3006-00
LOT 17041 and LOT 17072

Results of our investigations indicate that only the LOTs **17041** and **17072** may be affected.

The Item and LOT numbers are printed on the product labels, which are attached to the packaging.

The sterile, disposable DORO® Skull Pins are components of a mechanical support system, which is used in head and neck surgery. They are usually attached to the DORO® Skull Clamp.

3. Reason for described Actions

Up to this date, we became aware of two breakages of the pin tips, which occurred during two identical surgery procedures, both with the same physician. The breakage occurred at the very distal end of conical part of the skull pin tip. These two breakages did not cause any injury for the patient and/or any third party. We are not aware of any further adverse events in this regard.

Even though we cannot exclude a user error, at this point we can also not exclude that irregularities in the manufacturing process of the metal component of the product, which was supplied by a third party, might have contributed to the described events. Each individual reason and/or the combination of both reasons might have contributed to the device failure of the above-mentioned manufacturing LOTs. If a pin tip broke, a slippage could occur and/or fragments of the affected pin could break off and remain in the patient's skull.

Even though we cannot exclude a user error, pro med instruments GmbH decided to conduct this voluntary recall in order to ensure the highest patient safety standards.

4. Risks:

The breakage of the tip of the affected pins could cause in the worst-case scenario:

a) Slippage which may require remedial action
b) Loosening of the positioning and delay in surgical procedure
c) If the user did not detect the breakage of the tip, the part that broke off could remain in the skull, which could lead to subsequent complications, such as skin irritations, wound healing disorders, inflammations, etc.

5. Actions to be taken by the customer / user:

- Review this notification and ensure that all users of the affected products are informed of this **urgent field safety notice**. If you have transferred the affected products to third parties, please forward a copy of this letter or inform the below mentioned contact person.

- Check your stock if you have any affected products

- If you have any affected products on stock, please quarantine them and send the products back to us. You will receive a replacement as soon as we have received your "Acknowledgement and Receipt Form" and know your current stock.

- Check any products or records of the affected LOTs used prior to receipt of this field safety notice if the tips have been intact after the surgery. If the tips have not been intact, ensure that any remaining parts are removed from the patient. There are no further specific patient monitoring actions necessary related to this Field Safety Notice.

- If after reviewing this notification you have any further questions or queries please discuss them with your pro med instruments sales representative

- Please complete the attachment "Acknowledgement and Receipt Form" and return by Fax or email (see under nr. 8. below) to pro med instruments GmbH to confirm receipt by the **10th of November 2017** at the latest

6. Alternative Products to be used

- **Item No. 3006-00:** DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs): All other LOTs except LOT 17041 and 17072

- **Item No. 3006-20:** DORO® Sterile Disposable Skull Pins, Titanium, Adult (36 pcs)

- **Item No. 3006-50**: DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs)

- **Item No. 3005-00:** DORO® Reusable Skull Pins Stainless Steel, Adult (3 pcs)

- **Item No. 3005-50:** DORO® Reusable Skull Pins Titanium, Adult (3 pcs)

7. Product Information:

Product	Item No	Lot/Serial Number	Distribution Dates
DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs)	3006-00	17041	May 25, 2017 - Oct 24, 2017
DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs)	3006-00	17072	Sep 06, 2017 - Sep 19, 2017

8. Type of Action by pro med instruments GmbH:

Corrective and preventive actions are planned and being implemented. The relevant national competent authorities were informed.

9. Contact INFORMATION for questions and response:

Name	Lutz Babilon
Department	Quality Management
Company	pro med instruments GmbH
Phone	+49 761 384 222- 10
	(Monday through Friday, 8:00 AM to 5:00 PM, CEST)
E-Mail	pmi@pmisurgical.com
Fax	+49 761 384 222 80
Address	Boetzinger Str. 38
	79111 Freiburg, Germany

pro med instruments sincerely regrets any inconvenience caused to your organization by this action.

Response to Attached Acknowledgement and Product Replacement Forms is strongly required.

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response to Field Safety Notice is required

pro med instruments GmbH
Boetzinger Straße 38
79111 Freiburg, Germany

Medical device field safety notice- Recall
DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (36 pcs), Item no. 3006-00 LOT 17041 LOT 17072

I have read and understand the Field Safety Notice instructions received.	Yes	No
I have checked my stock and have quarantined the affected inventory	Yes	No

I have quarantined the following quantities:

LOT 17041: _____boxes and/or _____blisters

LOT 17072: _____boxes and/or _____blisters

I will return all above quantities to pro med instruments GmbH. Any further quantities of affected products have already been used or disposed.	Yes	No
Are you aware of any adverse events associated with the recalled products or reported issue?	Yes	No

If yes, please explain:

_____

_____

pro med instruments

_____

_____

If you are a reseller:

I have shipped the affected LOTs of products to the following countries:

_____

_____

_____

I have informed all my affected customers about the adverse event and the content of this Field Safety Notice and requested them to inform their customers accordingly.	Yes	No
I have informed all my affected customers to not use, quarantine and return the affected products and requested them to inform their customers accordingly	Yes	No

pro med instruments GmbH
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Commerzbank Freiburg · IBAN Code No.: DE 44680800300402018200 · SWIFT-BIC: DRES DE FF 680HypoVereinsbank Freiburg · IBAN Code
No.: DE 48680201860321311458 · SWIFT-BIC: HYVE DE MM 357
Managing Directors: Matthias E. Schüle · Roman Maier · Registergericht Freiburg HRB 48 79 · VAT Reg No. DE 811 778 789

Return Response Box:

Please provide any additional information, if applicable.

Customer:

Company _____

Name/Title _____

Address _____

Telephone _____

E-mail address _____

Date _____

Signature _____