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 Recall

DORO LUCENT® Base Unit, item no. 1101.021
DORO LUCENT® Locking Transitional Member, item no. 1101.031
DORO LUCENT® Transitional Member, item no. 1101.026

July 6th, 2018

Dear Device User,

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

1. Purpose of this letter

pro med instruments is herewith conducting a voluntary medical device field action (Recall) regarding the combination of different design revisions of the below concerned products.

The concerned products are part of the DORO LUCENT® Headrest System 1101.020. It has been discovered that the combination of concerned products of two different design revisions within one set up might lead to a malfunction and failure of the headrest system. If the malfunction and failure occurs the headrest system might not withstand applied loads. The malfunction and failure does not occur when concerned products of the same revision are being used in combination.

Serious injuries and/ or death could occur due to the failure mode associated with this recall. Up to this date there are no adverse events / no serious injuries and/or deaths reported.

2. Concerned Product

Only the combination of the following item no. with the following serial numbers might be affected:

Name	Item No.	Revision A	Revision B
DORO LUCENT® Base Unit	1101.021	[redacted]	[redacted]
DORO LUCENT® Locking Transitional Member	1101.031		
DORO LUCENT® Transitional Member	1101.026		

Only the combination (mix-up) of two different revisions in one set up might lead to a potential risk.

The item and serial numbers are edged/printed on the concerned product.

The DORO LUCENT® Headrest System is used in open and percutaneous craniotomies and spinal surgeries for rigid cranial fixation and when intraoperative CT imaging is used.

3. Reason for described Actions

The concerned products are part of the DORO LUCENT® Headrest System 1101.020. It has been discovered that the combination of concerned products of two different design revisions within one set up might lead to a malfunction and failure of the headrest system. If the malfunction and failure occurs the headrest system might not withstand applied loads. The malfunction and failure does not occur when concerned products of the same revision are being used in combination.

4. Risks:

There are two general combinations (mixture of revisions) possible with different risks associated:

Combination 1:

- DORO LUCENT® Locking Transitional Member, item 1101.031 **Rev A** in combination with
  - DORO LUCENT® Base Unit, item 1101.021 **Rev B**, and/or
  - DORO LUCENT® Transitional Member, item 1101.026 **Rev B**

In this case the concerned products cannot be mounted to each other. The procedure cannot be performed as no fixation of the DORO LUCENT® Headrest System is possible. There is no risk for the patient.

Combination 2:

- DORO LUCENT® Locking Transitional Member, item 1101.031 **Rev B** in combination with
  - DORO LUCENT® Base Unit, item 1101.021 **Rev A**, and/or
  - DORO LUCENT® Transitional Member, item 1101.026 **Rev A**

In this case the assembly of the concerned products is possible. The screw / thread combination to lock and fixate the concerned products might not withstand the applied loads. The user might not recognize the potential risk. There is a potential risk of a serious patient injury.

Combination of same revisions:

There is no risk associated with the use of concerned products within the same revision.

5. Actions to be taken by the Customer/User:

5.1. To Hospitals / Users

If you receive this Field Safety Notice from pro med instruments, you have been identified as a hospital / user that have been supplied with concerned products

- of both revisions A and B **(please refer to "Stage 1" and "Stage 2")**, or
- of only revision A **(please refer to "Stage 2" only)**, or
- of only revision B **(please refer to "Information Only")**

Stage 1

This stage is only relevant for hospitals / users who are in possession with concerned products of **two different revisions (mix-up)** (for revision check please refer to section 2):

a) Discontinue the use of the combination and quarantine the concerned products
b) Contact pro med instruments for further instructions relating to temporary replacement possibilities

Stage 2

This stage is only relevant for hospitals / users who are in possession of concerned products **of revision A** (for revision check please refer to section 2):

a) The hospitals / users with concerned products of **only revision A** may continue using the concerned products as usual. There is no risk associated with the use of concerned products of the same revision. Do not mix-up products of different revisions.
b) pro med instruments or its distributors / resellers will contact you regarding further instructions for the upgrade of concerned products with revision A to revision B. This action will prevent any possibility for future mix-ups of two different revisions.

Information Only

For hospital / users who are in possession of concerned products **only of revision B**, (for revision check please refer to section 2):

a) The hospital / user may continue using the products as usual.
b) No further action is necessary.

6. Alternative Products to be used

- DORO® Base Unit Radiolucent, Item No. 3031-00
  DORO® Transitional Member Radiolucent long, Item No. 3032-10
  DORO® Transitional Member Radiolucent short, Item No. 3032-20

7. Product and Distribution Information:

Name	Item No.	Revision A	Distribution Dates
DORO LUCENT® Base Unit	1101.021	[redacted]	May 04th, 2017 - Apr 5th, 2018
DORO LUCENT® Locking Transitional Member	1101.031		
DORO LUCENT® Transitional Member	1101.026		

Name	Item No.	Revision B	Distribution Dates
DORO LUCENT® Base Unit	1101.021	[redacted]	Mar 21st, 2018 - today
DORO LUCENT® Locking Transitional Member	1101.031		
DORO LUCENT® Transitional Member	1101.026		

8. Type of Action by pro med instruments GmbH:

There are two stages planned:

Stage 1:

Immediate action:

- Identification of customers / hospitals / users with concerned products with both revisions (mix-up).
- Recall of said concerned products.
- Prevention of new mix-ups at customers / hospitals / users.
- Inform relevant national competent authorities.

Stage 2:

Corrective action:

- Recall of all concerned products with revision A and upgrade to revision B

9. Contact INFORMATION for questions and response:

Headquarter in Germany:

Name Sandra Untenberger

Department	Regulatory Affairs
Company	pro med instruments GmbH
Phone	+49 761 384 222- 10 Monday through Friday, 8:00 AM to 5:00 PM, CEST (Central European Summer Time)
E-Mail	complaint@pmisurgical.com
Fax	+49 761 384 222 80
Address	Boetzinger Str. 38 79111 Freiburg, Germany

If you are a US-Customer please address your response to our US Subsidiary: Pro Med Instruments INC.

Name	Jillian Forster
Department	Quality Management
Company	pro med instruments INC.
Phone	+1 239 369 2310 Ext. 114 Monday through Friday, 8:30 AM to 5:30 PM, EST (Eastern Standard Time)
E-Mail	pmi.us@pmisurgical.com
Fax	+1 239 369 2370
Address	4529 SE 16th place, Cape Coral FL 33904 U.S.A.

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

[redacted]

Matthias Schüle
Managing Director
pro med instruments GmbH

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

cc. Chairman Medical Board
cc. Head of Departments

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

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For Hospitals / Users:

I have read and understand the Field Safety Notice instructions received.	Yes		No	
I have checked our stock and informed all relevant persons to discontinue the use of the concerned products of two different revisions.	Yes		No	
I have quarantined the concerned products of two different revisions.	Yes		No	
I understand that no mix-up between revision A and revision B is allowed.	Yes		No	

Any adverse events associated with recalled product/issue? Yes ___ No ___
If yes, please explain:

Affected Product Information: Include information that is applicable for affected product.

Product and Distribution Information Table

Pos	Product	Item No	Serial No.
1	DORO LUCENT® Base Unit	1101.021	
	DORO LUCENT® Locking Transitional Member	1101.031	
	DORO LUCENT® Transitional Member	1101.026	
2	DORO LUCENT® Base Unit	1101.021	
	DORO LUCENT® Locking Transitional Member	1101.031	
	DORO LUCENT® Transitional Member	1101.026	
3	DORO LUCENT® Base Unit	1101.021	
	DORO LUCENT® Locking Transitional Member	1101.031	
	DORO LUCENT® Transitional Member	1101.026	

Please add additional lines as needed.

Return Response Box:

Please provide any additional information, if applicable.

Hospital / User:

Hospital Name _____

Contact Name/Title _____

Address _____

Telephone _____

E-mail address _____

Date _____

Signature _____