[redacted]

URGENT **Field Safety Notice**

pro med instruments GmbH, part of Black Forest Medical Group, Boetzinger Str. 86, 79111 Freiburg, Germany

Medical Device Recall

DORO® Easy-Connect Navigation Adaptor, BRAINLAB (item no. 1204.002)

March 14th, 2025

Dear Device Owner/Distributor,

Please forward this urgent information to all distributors and users, who have received the below mentioned device.

1. Purpose of this letter

pro med instruments GmbH, part of Black Forest Medical Group is herewith conducting a voluntary Medical Device Field Action (Recall) regarding the use of the DORO® Easy-Connect Navigation Adaptor, BRAINLAB (item No. 1204.002) in combination with Brainlab's Patient Reference Array for Skull Clamp (item No. 41725) or Brainlab's VV Mayfield Reference Clamp 2.0 (item No. 41730A).

It was determined that in certain instances the compatibility of the DORO® Easy-Connect Navigation Adaptor, BRAINLAB with one of the above-mentioned Brainlab products, might be compromised. This might have an influence on the positioning of the reference array. In this case an influence of the function of the navigation system cannot be excluded.

Based on Black Forest Medical Group's assessment, if the deviation is not detected, patient risks cannot be excluded. No incident has been reported up to the date of this Field Safety Corrective Action.

2. Concerned Product

DORO® Easy-Connect Navigation Adaptors, BRAINLAB (item No. 1204.002) with a distribution date of January 2025 or earlier are concerned by this notification.
The DORO® Easy-Connect Navigation Adaptor, BRAINLAB (item No. 1204.002) is used to connect Brainlab Navigation Reference Arrays to the DORO® Headrest System.

The DORO® Headrest System is a mechanical support system which is used in head and neck surgery when rigid cranial stabilization is desired. It is mounted with different Base Units/Adaptors to the OR table. This system allows the patient's head to be positioned and secured for surgery. The DORO® Headrest System provides an interface for accessories like retractor systems, navigation adaptors or other items.

[redacted]

3. Reason for described Actions

It was determined that in some instances the combination of the DORO® Easy-Connect Navigation Adaptor, BRAINLAB with one of the above-mentioned BRAINLAB products, may affect the accuracy of the navigation system.

4. Risks

The above-mentioned error can be identified based on a navigation verification by the users, if the procedure allows this. In procedures in which a navigation verification is not possible, this error may remain undetected. In these cases, potential risk of a patient injury cannot be excluded. No incidents have been reported so far.

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

If you receive this Field Safety Notice from pro med instruments GmbH, part of Black Forest Medical Group, you have been identified as a hospital or user that have been supplied with the concerned product.

The hospitals/ users/ distributors who are in possession with the concerned product are kindly requested to

- **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 contact person mentioned under section 9.
- **discontinue** the use of the concerned product.
- **check your stock** to determine if you have any affected products.
- **complete the attached "Acknowledgement and Receipt Form",** select your desired corrective action type (repair by the manufacturer or repair on-site) and return it by fax or email (see contact information under section 9 below) to pro med instruments, part of Black Forest Medical Group to confirm receipt by March 28th, 2025, at the latest.
  Repairs will be available from the 4th of April 2025 and can be conducted after receipt of the completed 'Acknowledgement and Receipt Form'.

If, after reviewing this notification, you have any further questions or queries please discuss them with your DORO® sales representative.

[redacted]

6. Product and Distribution Information:

Product and Distribution Information Table

Product	Item No	UDI Code	Distribution Dates
DORO® Easy-Connect Navigation Adaptor, BRAINLAB	1204.002	04250435506738	September 2011 - 28th January, 2025

7. Alternative Products to be used

The following Brainlab products may be possible alternatives to the product concerned by this notice:

- PATIENT REFERENCE ATTACHMENT ARM FOR SKULL CLAMP (item No. 52001F)

- PATIENT REFERENCE ATTACHMENT FOR SKULL CLAMP (item No. 41734)

Unless otherwise agreed in writing, no costs for replacement products from third parties will be borne.

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8. Type of Action by pro med instruments GmbH, part of Black Forest Medical Group:

Immediate actions:

- Identification of customers/ hospitals/ users with concerned products
- Recall of concerned products
- Information to relevant national competent authorities

Corrective Actions:

- Ensure that the affected devices in the field have been separated
- Restore product compatibility of separated devices within the field through free-of-charge upgrades of recalled products by:
  - upgrading of returned devices by the manufacturer's service department
  - provision of spare parts for upgrading the returned devices by the user or an authorized DORO sales representative on-site
- Ensure, there are no more defective products and associated subcomponents in the field.

9. Contact INFORMATION for questions and response:

Headquarter Germany:

Name	Nicholas Preissler
Department	Quality Management
Company	pro med instruments GmbH, part of Black Forest Medical Group
Phone	+49 761 384 222- 10 Monday through Friday, 8:00 AM to 5:00 PM, CEST (Central European Summer Time)
E-Mail	complaint@blackforestmedical.com
Fax	+49 761 384 222 81
Address	Boetzinger Str. 86, 79111 Freiburg, Germany

<u>If you are a US-Customer, please address your response to our US Subsidiary: pro med instruments Inc. part of Black Forest Medical Group</u>

Name	Nicholas Preissler
Department	Quality Management
Company	pro med instruments Inc. part of Black Forest Medical Group
Phone	+1 239 369 2310 +1 877 225 4086 (toll free) Monday through Friday, 8:30 AM to 5:30 PM, EST (Eastern Standard Time)
E-Mail	complaint@blackforestmedical.com
Fax	+1 239 540 5790
Address	4529 SE 16th place, Cape Coral FL 33904

pro med instruments GmbH, part of Black Forest Medical Group sincerely regrets any inconvenience caused to your organization by this action.

[redacted]

[redacted]
Director QM/RA

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

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

pro med instruments GmbH, part of Black Forest Medical Group
Boetzinger Straße 86
79111 Freiburg, Germany

Medical Device Recall
DORO® Easy-Connect Navigation Adaptor, BRAINLAB
(item No. 1204.002)

☐ I have read and understand the Field Safety Notice instructions received.
☐ I have checked my stock and have separated inventory consisting of products to be sent back.

Contact information

Establishment/ Hospital _____
Contact person _____
Address - Line 1 _____
Address - Line 2 _____
Telephone _____
E-mail address _____

Product and Distribution Information Table

(Please complete the relevant product information in the empty fields provided in the table below.)

For all recipients of this notice									For resellers only	
Product	Item No.	UDI Code	Serial Number	**Adverse events** associated with the product/issue known? (please check/ describe below, if applicable)		Product **status/ measures** (please check which applies)			**Country** to which delivery was made	Supplied **customer was informed** about this notice (please check)
				Yes	No/ Unknown	product was scrapped	product being returned for repair	product to be repaired on-site*		
DORO® Easy-Connect Navigation Adaptor, BRAINLAB	1204.002	4250435506738		☐	☐	☐	☐	☐		☐
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*If you are considering an on-site repair, you will be provided with instructions on how to proceed once we have received this form back from you, fully completed and signed.

Additional information (adverse event related ☐):

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(Date, signature)