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URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Cirq Arm System 2.0: Risk of mechanical instability due to potential manufacturing error of the device
Product Reference:	Cirq Arm System 2.0
Date of Notification:	February 20, 2023
Individual Notifying:	Julia Mehltretter, Manager Product Surveillance
Brainlab Identifier:	CAPA-20230201-002522
Type of action:	Advice regarding use of device; Device modification; Device return

We are writing to inform you about the risk of mechanical instability of Cirq Arm System 2.0, due to a potential manufacturing error of the device.

There has been no negative effect on a patient or user reported to Brainlab by any user site due to this issue. The issue has been detected by Brainlab internally.

The purpose of this Product Notification letter is to provide you with the relevant user information on how this issue occurs and to inform you of the corrective actions Brainlab is taking to address this.

Effect:

Cirq Arm System 2.0 assists in maintaining the spatial positioning of instruments during surgical procedures.

Brainlab has determined internally that one batch of screws, used in the production of Cirq Arm System 2.0, did not meet Brainlab's quality requirements. Screws from this batch showed an increased risk of breaking under tension.

At the time of writing, screws that show this unintended behavior were only detected by Brainlab internally during production, prior to shipment to customers. There has been no report of broken screws received by Brainlab from a customer. However, it cannot be excluded that affected screws have also been used in production of devices that were delivered to customers.

Breakage of one or more of these screws, used in the area of joint 4 (see picture 1), can lead to reduced stability of Cirq Arm System 2.0 and, if several screws would break at the same connection point, loosening of device components.

As a result, serious injury to the patient and/or user could occur due to falling parts and/or due to unexpected movement of the device during a clinical procedure.

Picture 1 – Cirq Arm System 2.0 with the area around joint 4 marked, where potentially affected screws were used

User Corrective Action:

1. **Do not use** Cirq Arm System 2.0 **for clinical procedures.**
2. Remove Cirq Arm System 2.0 from the OR table (as applicable), following the description given in the applicable User Guide.
   When lifting Cirq Arm System 2.0, **ensure you carry the device only below joint 4** (see picture 1) to prevent user injury from falling parts.
3. Store the device in the corresponding transport and storage case delivered with it and ensure you mark the equipment appropriately to prevent it from being used inadvertently.

Brainlab Corrective Action:

1. Existing potentially affected customers will receive this product notification information.
2. Brainlab will recall all potentially affected customer systems for inspection and – if applicable – repair to correct this issue. Brainlab will actively contact you to schedule the return of the device, starting March 2023.

Please advise the appropriate personnel working in your department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation.

If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

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February 20, 2023

Kind Regards,

Julia Mehltretter
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Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.