

Safety Communication

Recall of DORO Sterile Disposable Skull Pins

Device/Product Name:

DORO Sterile Disposable Skull Pins, Stainless Steel, Adult

Lot numbers/Serials:

Item No. 3006-00
LOT 17041 and LOT 17072

Manufacturer:

Pro Med Instruments GmbH

Manufacturing country:

Germany

Problem:

The Manufacturer 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.

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

Recommendation/Actions:

- 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 the company. You will receive a replacement.
- 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.

Devices/Products photo:



For further information, please see the attached letter from the manufacturer. ([Click Here](#))

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Company name:	Al Amin Medical Instruments Co. Ltd.
Contact Person:	Shadi Qudsi
Phone:	(012) 6601149
Email:	squdsi@amicogroup.com

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting ([NCMDR Website](#)).

Medical Devices Sector

Saudi Food and Drug Authority

Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)

North Ring Road - Al Nafal Unit (1)

Riyadh 13312 - 6288

Tel: +966 (11) 2038222 Ext: 2406

Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit NCMDR website:

Sincerely,
NCMDR Team