

Urgent Field Safety Notice

Product code : AU-0-001; AU-0-002
Product name : CADISS REMOTE Kit; CADISS MANUAL Kit
Reference : NOCO2020-011

Type of action:

- Return of a MEDICAL DEVICE to the supplier;
- Device modification;
- Device exchange;
- Device destruction;
- Retrofit by purchaser;
- Design change;
- Advice regarding the use of the device

Details on affected devices:

CADISS Kits (no batch-related)

Description of the problem:

After a surgery of a Vestibular Schwannoma with the CADISS System; vasospasm has been reported about the patient. Vasospasm has been confirmed by a CT-scan. The patient is in critical condition (nonreacting, decerebration rigidity and neurogenic pulmonary oedema).

At this stage, it's not possible to conclude that there is no relationship between this serious adverse event and the use of CADISS System in the vestibular schwannoma dissection.

Advise on action to be taken by the user:

- identifying and quarantining the device
- method of recovery, disposal or modification of device
- return of the device back to the distributor or the supplier
- Advice regarding the use of the device
- Recommended patient follow-up
- Confirmation form to be sent back to the manufacturer

Use of the CADISS System for any surgery where the mesna solution could be in contact with the brain, such as acoustic neuroma/vestibular schwannoma surgery, should be strictly avoided.

Instructions for Use indicate that the CADISS System is contraindicated for patients with a known hypersensitivity to mesna. As a matter of clarification, the CADISS System should be contraindicated for patients with a known hypersensitivity to thiol compounds such as Coenzyme A, Glutathione, Cysteine, Grapefruit mercaptan or Pentachlorobenzenethiol.

In case of similar symptoms you may observed with your patients, please consider the possibility of peripheral cerebral vasospasm and of a pharmaceutical treatment with a Calcium antagonist such as Nimodipine.

In case of any other observation, please report immediately.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



Please fill the form below and return it to us.

Contact reference person:

Dr. Ir. Laurent FERRIERE
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+32 10 81 61 57
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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Signature

CUSTOMER REPLY FORM

(Please fill the form below and return it to us)

Company name and address:	
Reply confirmation completed by:	
Title:	

We have received the above-mentioned letter and have disseminated this information to our staff and to other accounts.

Signature / date:
REQUIRED FIELD
