HEINEMANN
MEDIZINTECHNIK

G. Heinemann Medizintechnik GmbH, Leibnizstraße 13-15, D-24568 Kaltenkirchen

[redacted]

10/05/2021

Urgent Safety Information

Aquastop valve conversion/replacement

concerning

MODULA series ENT treatment units

Dear Sir or Madam,

During a service all, G. Heinemann Medizintechnik GmbH has detected call that a faulty component (manufacturing defect at the supplier) could cause the treatment unit to fail. The fault would occur on the Aquastop valve and cause the water supply to fail, and thus functions such as suction systems, ear irrigation or tube rinsing.

Conversion to an alternative valve will solve the potential problem. Our service technician will contact you to arrange an appointment.

Identification of affected medical devices:

The devices concerned are ENT treatment units from the MODULA series manufactured between 22 August 2020* and 10 May 2021. Please find attached an overview of the units concerned.

*The date of the start of installation of this type of aquastop valve

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Description of the problem and the cause:

- Due to a defect in the guide tube of the solenoid valve, a small amount of water will presumably leak out as a result of corrosion and may enter the coil core or the integrated electronics of the solenoid valve, which may lead to a short circuit at this point. The solenoid valve is then no longer actuated correctly, which in turn causes the upstream fuse to fail. In some cases, a malfunction caused by not opening has been detected.

- Any risk to the user or patient can be assessed as low. The solenoid valve is installed outside the treatment unit. This valve is controlled via a humidity sensor in the unit in order to protect the premises from any escaping water in the event of a fault. The built-in pressure switch in the device detects the lack of water pressure and blocks further ear irrigation processes. During glass or tube rinsing, the function does not work, but this does not pose a risk. Treatment without the available water inflow is not possible, so there are no risks for the patient.

What actions should be taken by the user?

- At the end of each working day, switch off the treatment unit at the main switch and disconnect the water supply.

- Avoid touching the solenoid valve as it may briefly heat up in the event of a fault.

- Should the Aquastop valve fail, please switch off the treatment unit at the main switch and leave it switched off until our service technician or authorised service partner has carried out the repair.

- Please confirm that you have read this Safety Information by returning the enclosed reply (see contact details) via e-mail, fax or post (also unfranked).

- Service technicians from G. Heinemann Medizintechnik GmbH will contact you and discuss the further course of action (arrangements of the replacement of the Aquastop valve).

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Dissemination of the information described here:

Please ensure that within your organisation, all users of the aforementioned products and other persons who need to be informed are made aware of this Safety Information. If you have provided the products to a third party, please forward a copy of this information and inform the contact person below.

Please retain this information at least until the measure has been completed.
The Federal Institute for Drugs and Medical Devices, the appropriate state authority and also our notified body have received a copy of this Safety Information.

Contact person:

Jakob Hoffmann (Safety Officer in acc. with German Medical Device Act (MPG)

Phone: +49 4191-95379-0 Email: qm@heinemann-ent.de

Please accept our apologies for any inconvenience this may cause.

[redacted]

[redacted]

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SAFETY INFORMATION RECEIPT CONFIRMATION

We hereby confirm receipt and acknowledgement of the document:

- **Urgent Safety Information (Aquastop Valve Conversion/Replacement) regarding MODULA series ENT treatment units**

We will implement the safety measures described immediately, inform all users and carry out the conversion as soon as we have received the spare parts.

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Contact Name (please print in capitals)

_____

Date, signature

[redacted]