URGENT - FIELD SAFETY NOTICE

Re/erences of the affected medica/ devices:

PATIENT SET for Aqua-Vision, reference AV4509, batch number 1175616

N° FSCA: MV22-022

Date: 28 October 2022

To the attention: Vigilance correspondent

Dear Madam, Sir,

The Competent Authority of your country has been informed of this field safety notice. We thank you for reading it and implementing the actions specified therein.

- **Affected medical devices:**

Reference	Designation	Batch number
AV4509	PATIENT SET for Aqua-Vision	1175616

- **Rationale for the security corrective action:**

As part of the post-market surveillance, HEMODIA, legal manufacturer, has been informed by its customers of an incident involving PATIENT SET tubing with a non-return valve for the AQUAVISION® arthroscopy system: the appearance of a crack in the tubing passing around the pump head when the pump is used.

These incidents involve the same lot of PATIENT SET for Aqua-Vision, reference AV4509, lot 1175616.

Please note that:

- No patient incident has been reported to HEMODIA. The possible consequences of this event are, in the most unfavorable situation, a leak of the aspirated fluid from the patient set tubing.
- These events can occur and are easily detected during the procedure. They simply require replacement of the tubing during the procedure.
- The increase in operating time in case of tubing replacement is negligible.

HEMODIA has decided to implement a corrective safety action with the objective of recommending to the concerned institutions to have a stock available quickly during the procedure in case of failure of the Patient set tubing, reference AV4509, lot 1175616.

- **Actions to be taken:**

  This field safety notice must be sent to any person who needs to be informed within your organization or to any organization to which you have transmitted the relevant arrangements.

  Identify concerned devices in the stock.

  During use, have a safety stock nearby and pay particular attention during the operation to the tubing passing around the pump head.

  In case of failure of the tubing, replace the tubing

- **Contact details:**

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Fax : +33(0)5 610047 40
Email: hemodia@hemodia.com

We thank you for your understanding and apologize for any inconvenience this may cause to you.

We believe this safety information is necessary to ensure that our customers use only quality, effective and reliable products.

Best regards,

... ...

Attachments: Acknowledgment of receipt to be returned.

ACKNOWLEDGEMENT OF RECEIPT - FIELD SAFETY NOTICE

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AV4509	PATIENT SET for Aqua-Vision	1175616

Field safety notice from 28 October 2022

Please complete and return this form within 1 week to: adv@hemodia.com

specifying in subject the FSCA reference

1 have received, read and understood the information contained in this field safety notice. With this form:

1 confirm that I have received the field safety notice and that I have complied with the instructions contained in this document;

1 confirm that this field safety notice has been sent to all persons who need to be informed within my organization or to any organization to which I have distributed the relevant devices.

Organization (name and address):	Contact Name: Function: Date: Signature and stamp: