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URGENT: FIELD SAFETY NOTICE

NAME OF PRODUCT: WASSENBURG® WD440, WD440 PT, WD415 Endoscope Washer-Disinfector

DATE: 15 November 2017

TYPE OF ACTION: Field Safety Corrective Action

ATTENTION: Decontamination / Endoscopy Department Manager

Details on affected devices:
The Field Safety Corrective Action (FSCA) affects WASSENBURG® endoscope washer-disinfectors (EWDs) configured for use with peracetic acid-based disinfectants and in which PureWeld XL dosing pump tubing has been installed. The PureWeld XL tubing has been available for use in the WASSENBURG® EWDs since 13 April 2017.

Description of the problem:
Backflow of process fluids in the EWD has been reported. Backflow is the situation in which fluid flows back from the basin via the disinfectant dosing pump into the disinfectant dosing glass. This results in dilution of the disinfectant in the dosing glass.

Root cause analysis concluded that the backflow was caused by incomplete closure of the disinfectant dosing tubing by the pump rotor. The rotor consists of two rollers that alternatingly push against the tube, thereby pushing the fluid forward. Each roller has two springs attached. The incomplete closure of the disinfectant was caused by one of the two springs of one roller which was slightly distorted and thus had a weaker spring force.

Backflow with the pump rotor containing a weaker spring is dependent on a number of factors relating to the position of the rotor and tubing when the pump stops. Therefore within one cycle, whether backflow occurs - and the extent to which it occurs - is variable. While the EWD can detect the possible existence of major backflow, a situation could occur in which minor backflow is not detected by the EWD. Undetected backflow can result in the dilution of disinfectant in the dosing glass to a level dependent on the extent of backflow. Consequently the disinfection step in the washing and disinfection cycle may run with less disinfectant than normal. The required microbiological log reduction can then not be guaranteed which could result in a diminished disinfection efficacy for the endoscope.

The risk that your EWD contains a rotor with a weaker spring is estimated to be less than 1%. To determine whether backflow can occur in your EWD we request that you take the following actions.

Action to be taken by the user:

- Arrange with the recognised Wassenburg service partner in your country when your EWD will be checked for backflow.
- If backflow is identified, stop use of the EWD until the pump rotor has been replaced by a Wassenburg certified field service engineer (FSE).
- If backflow is identified, provide the FSE with the information the FSE will request from you with which the impact of the failure can be investigated by Wassenburg.
- If backflow is identified, reprocess again any endoscopes that were reprocessed before the use of the EWD was stopped and that have not yet been used for patient treatment.
- Complete and return the accompanying Acknowledgement of this FSCA to your Wassenburg EWD supplier when all your affected EWDs have been checked for backflow.

Transmission of this Field Safety Notice:

This FSN needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this FSN to other organisations on which this action has an impact.

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

Contact reference person:

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The undersign confirms that the appropriate Regulatory Agency has been notified of this notice.

Wassenburg Medical B.V.

Dr Patrick Vronen
Regulatory Affairs Manager