

URGENT FIELD SAFETY NOTICE

WASSENBURG® WD4200 WASHER-DISINFECTOR

DATE: XX July 2021
TYPE OF ACTION: Field Safety Corrective Action (FSCA)
FSCA REF.: V21024DE
FSN REF.: 20210712GM04
FOR ATTENTION OF: Decontamination / Endoscopy Department Manager

RISK ADDRESSED BY FSN

Metal burrs found inside connector with which the endoscope is connected to the washer-disinfector may be transported into the internal channel of the endoscope and subsequently into the patient

CONTACT DETAILS OF LOCAL REPRESENTATIVE

INFORMATION ON AFFECTED DEVICE

Device type	WASSENBURG® WD4200 washer-disinfector
Intended use	The WD4200 is intended for the washing and disinfection of flexible endoscopes and other re-usable thermolabile devices in the health care sector
Device model	The FSCA affects all WD4200 units
UDI-DI	8719324979WD01EU

REASON FOR THE FSCA

Description of product problem:

Burrs from the manufacturing process have been detected in a number of stainless steel connectors in the WD4200. The connectors are located in the basin of the WD4200. There are eight connectors in total in the basin and they are used for individually connecting the internal channels of the endoscope to the WD4200. The burrs consist of stainless steel grade 316, vary in size and shape, and may or may not be retained within the connector during operation of the WD4200.

Hazard giving rise to FSCA:

Any burrs that are dislodged by the flow of process liquids through the connector during the endoscope reprocessing cycle may be transferred to the internal channels of the endoscope. Burrs still present in the endoscope during endoscopy may in turn be transferred to the patient.

Probability of problem arising:

Inspection of stocks of the channel connector has shown that burrs could be present in approximately 30% of connectors. In some cases the burrs may block the connector, which would lead to a blockage alarm in the WD4200 for the channel concerned. The presence of smaller burrs that do not block the connector would not lead to an

alarm. The probability that any burrs become loose, are small enough to enter the endoscope channels, and remain in the channels after the reprocessing cycle is considered to be low but cannot be excluded. There have been no reports of the transfer of metal burrs to the internal channels of the endoscope.

Predicted risk to patients/users:

Metal burrs may have sharp edges and could therefore pose a risk to the intactness of mucous membranes in the unlikely event that they are transferred to the patient during endoscopy. There have been no reports of the transfer of metal burrs to the patient.

Background on issue:

The presence of metal burrs in the connectors is due to manufacturing deficiencies that have now been corrected.

ACTION TO BE TAKEN BY THE USER

You will be contacted shortly by your Wassenburg service organisation to make an appointment to check and, if necessary, remove burrs from the WD4200.

Please fill in and return the accompanying FSN Customer Reply to the above-mentioned local representative by the date indicated in the accompanying FSN Customer Reply.

ACTION BEING TAKEN BY THE MANUFACTURER

Your Wassenburg service organisation will contact you shortly to arrange the on-site inspection and, if necessary, repair of the WD4200.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

TRANSMISSION OF THIS FIELD SAFETY NOTICE

- This notice 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 notice to other organisations 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 report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Wassenburg Medical B.V.

Date:

Regulatory Affairs Manager