

 **URGENT FIELD SAFETY NOTICE****AFFECTED DEVICE: WASSENBURG® DRY320 DRYING CABINET
FOR FLEXIBLE ENDOSCOPES**

Date: 3 February 2020
Type of action: Field Safety Corrective Action (FSCA)
FSCA ref.: V19086IE
FSN ref.: 20200130GM02
For the attention of: Decontamination / Endoscopy Department Manager

Dear Wassenburg Customer,

This Field Safety Notice (FSN) is to alert you to a corrective action that must be carried out on all WASSENBURG® DRY320 drying cabinets intended for the drying and storage of reprocessed flexible endoscopes.

Why is this FSN necessary?

In a small number of WASSENBURG® DRY320 drying cabinets, one of the support arms on which the endoscope is loaded has fallen. The failure is caused by a manufacturing deficiency, due to which the screw securing the support arm hinge mechanism can become loose. This may lead to dislocation of the hinge and subsequent falling of the support arm. A falling support arm may lead to injury on impact with the user if they are in close proximity to the cabinet at the time.

Following the advice in this FSN will reduce the risk of injury to the user until the hinge mechanism is corrected.

Less than 0.5% of support arms across the installed base have been reported to become dislocated. There have been no reports of serious injuries sustained as a result of a falling support arm.

The failure does not influence the drying and storage performance of the WASSENBURG® DRY320 and therefore there is no risk to patients.

How will the deficiency be corrected?

Your Wassenburg service organisation will contact you to arrange the on-site modification of the WASSENBURG® DRY320. The modification consists of a correction to the hinge in order to ensure a robust and durable mechanism.

What can you do?

In the unlikely event that – prior to the modification – a support arm falls, we advise you to stop using the WASSENBURG® DRY320 and to contact your Wassenburg service organisation immediately.

Extreme caution must be exercised on opening the door if a support arm is seen to be leaning against the closed door of the WASSENBURG® DRY320, as the arm may fall further when the door is opened.

Please complete the accompanying FSN Customer Reply Form and return to your Wassenburg service organisation within five days of receipt of the FSN.

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

The FSN has been issued for the first time and a follow-up FSN is not expected.

Contact details of your Wassenburg representative

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Service Manager

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Transmission of this FSN

- 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 your Wassenburg supplier, and the national Competent Authority if appropriate, as this provides important feedback.

We sincerely regret any inconvenience this situation may have caused and we thank you for your cooperation.

Wassenburg Medical B.V.

Date: 03-01-2010



Dr Patrick Vronen
Regulatory Affairs Manager