Date: 2026-05-12

Temporary risk reduction measure for End-Of-Life devices

User instructions for temporary risk reduction on Soluscope ENT washer-disinfectors in the context of SLC-FSCA-003

1. Scope and regulatory status

This document **applies exclusively to Soluscope ENT washer-disinfectors** because they are classified as end-of-life devices and are impacted by SLC-FSCA-003.

Soluscope ENT devices are no longer supported by the manufacturer and remain classified as end-of-life products. The final corrective action defined by the manufacturer remains the cessation of use and removal of the device from clinical service.

This document provides temporary risk reduction measures only, intended to reduce the identified risk during a limited transitional period, until the effective end-of-life date of the device.

This document does not establish product support, does not guarantee long-term safe use, and does not constitute an alternative equivalent to supported products.

2. Relationship with the User Manual

This document does not amend, replace, or update the User Manual of the Soluscope ENT washer-disinfectors.

No update of the User Manual, labelling, or technical documentation is associated with this temporary risk reduction measure.

This document is issued as a vigilance-related communication, in connection with SLC-FSCA-003, and is strictly limited to temporary risk reduction for end-of-life devices.

3. Limitations

The measures described in this document are temporary in nature and apply only under the specific conditions defined herein.

Cessation of use remains the recommended and final corrective action for Soluscope ENT devices.

The manufacturer reserves the right to discontinue these temporary measures at any time, in accordance with the end-of-life management strategy.

4. Description of the identified risk (reference with SLC-FSCA-003)

As described in the Field Safety Notice (FSN) associated to SLC-FSCA-003, the investigations identified a potential risk of contamination related to the leak test socket of Soluscope washer-disinfectors over time.

This risk is associated with routine use and maintenance conditions and, in rare cases, could potentially lead to contamination of reprocessed devices.

To date, no transfer of microorganisms from the leak test socket to reprocessed endoscopes has been observed. However, as a precautionary measure, risk control actions have been defined and communicated via SLC-FSCA-003.

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This document does not introduce any new risk and does not modify the risk assessment previously performed in the context of SLC-FSCA-003.

5. Temporary risk reduction instructions

The following instructions describe temporary technical measures defined by the manufacturer to reduce the identified risk on Soluscope ENT washer-disinfectors during the end-of-life transitional period.
These measures are provided for exceptional use under restricted and temporary conditions and do not constitute validated reprocessing instructions, standard operating procedures, or product support.

5.1. Required equipment and products

- Gloves
- Swab or brush
- 70% ethyl alcohol ready to use in a spray bottle (method 1)
- Sterile gauze (method 2)

5.2. Temporary technical procedure for risk reduction

This procedure describes temporary manual cleaning and disinfection actions intended to reduce the identified risk related to the leak test socket and associated connectors.
It shall be performed daily during the end-of-life transitional period as part of the temporary risk reduction measure. These actions do not constitute validated reprocessing instructions.

- Wear gloves to protect your hands.
- Disconnect any device connected to the leak test connector.

5.2.1. Cleaning

If the leak test socket is visibly soiled, be sure to clean the inside of the socket with a swab or brush to remove any dirt or debris.

Two cleaning methods are available:

- *Method 1: Spraying*

1. Make sure the 70% ethyl alcohol is in a ready-to-use spray bottle (not diluted in-house).
2. Spray (2 sprays) 70% ethyl alcohol directly onto the leak test socket from approximately 10cm.
3. Be sure to cover all internal surfaces of the leak test socket.

- *Method 2: Using gauze*

1. Ensure you have a sterile gauze pad and ready-to-use 70% ethyl alcohol (not internally diluted). Gauze must be changed for every connector.
2. Fold the sterile gauze in half.
3. Soak it with 70% ethyl alcohol. Make sure the gauze is sufficiently saturated for effective disinfection, while preventing any risk of leakage into the air irrigation tubing.
4. Fold the gauze to form a cone shape.
5. Insert the gauze into the leak test socket and rotate it to coat the interior of the leak test socket with the 70% ethanol solution (mechanical action for 10 seconds). Be sure to cover all internal surfaces of the leak test socket

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- *Contact time*

Depending on the disinfectant used, please follow the contact time recommended by disinfectant manufacturer. If there is no recommendation, leave for 5 min to ensure effective action.

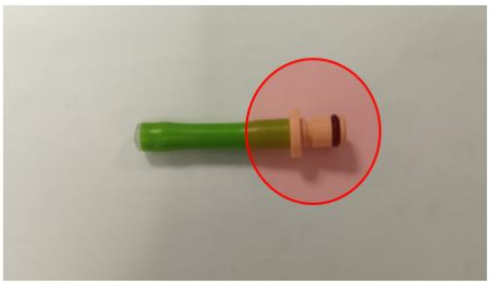
5.2.2.Blowing

1. Do not connect anything to the leak test socket in the bowl.
2. Close the lid and initiate cycle 2 using the endoscope code 1000, in order to perform an air flushing phase of the leak test socket.
3. After approximately 3 minutes of blowing, alarm 1 is expected to appear.

If necessary, the lid seal may also be manually cleaned at this stage using appropriate materials.

5.2.3.Wiping

Use a clean cloth soaked in 70% ethyl alcohol to disinfect the SL-OTE connector tip. Make sure the connector is completely dry before plugging it in.



5.3. Precautions and warnings

- Using a water-based disinfectant as an alternative is strictly prohibited. It may damage the endoscope.
- Avoid excessive alcohol application in order to prevent flooding of the leak test socket.
- Do not spray at close range; maintain an approximate distance of 10 cm.

The instructions described above are temporary risk reduction measures only. They do not establish product support, do not ensure long-term safety, and do not replace the final corrective action consisting of cessation of use and removal of the device from clinical service.

6. End-of-life timeline and final action

Soluscope ENT washer-disinfectors are classified as end-of-life devices and are no longer supported by the manufacturer.

The temporary risk reduction measures described in this document are intended to apply only during a limited transitional period, until the effective end-of-life of the device.

Cessation of use and removal of the device from clinical service remain the final and recommended corrective action for Soluscope ENT devices, as defined by the manufacturer.

These temporary measures do not extend the supported lifetime of the device and do not constitute a reauthorization for long-term clinical use.

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