

Instructions for use

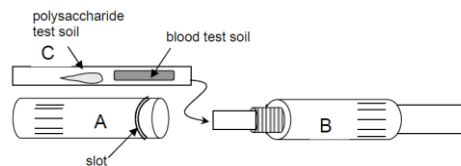
Product name / Trade name

TOSI®-FlexiCheck

Product Description / Intended Purpose

The devices TOSI-FlexiCheck/FlexiCheck are used for routine monitoring and validation of cleaning efficacy of endoscope washers. The devices are used by medical professionals and trained CSSD staff in CSSD departments of Hospitals and medical practices.

Instructions for use



Gloves must be worn throughout the test procedure to avoid contamination of the test.

1. Unscrew FlexiCheck-device: detach part A (marked with slot) from part B (see picture).
2. Open protective pouch of TOSI®-FlexiCheck and insert the test object (part C) in part B as shown in picture. Do not touch the area covered with test soil.
3. Close FlexiCheck-device again.
4. Connect FlexiCheck-device with one of the channel irrigation systems of the washer (luer-lock) and start the cycle according to your manufacturer manual instructions.
5. Open the device after the reprocessing cycle: disconnect part A from part B to remove the TOSI®-FlexiCheck without touching the test soil area! Check for visible residue.
6. In case of unsatisfactory results, please refer to the troubleshooting guide.



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Performance characteristics

Standardised test soil according to EN ISO 15883-5 consisting of purified bovine protein fractions.

In the event of malfunction / performance changes

Only completely clean instruments are safe. Residue left on a TOSI- FlexiCheck is an indication of an inefficient cleaning process.

Precautions:

- Open package carefully and handle with care.
- Don't eat and drink at work. No smoking. Keep away from food.
- Avoid contact with skin and eyes.
- On principle during handle with chemicals eye protection is necessary. Wear chemical resistant gloves.
- Don't use twice.
- Use only for the intended purpose.
- Read the instructions carefully before interpreting the results.

Restrictions on combinations

TOSI-FlexiCheck is only a test item to verify the cleaning performance of endoscope washers.

Each test kit consists of:

25 X tests

Special storage and/or handling condition

- Store at +2°C to +25°C
- Store in closed original packaging.
- Store in original packaging. Do not open protective pouch until use.
- Store protected from light, heat and chemicals.
- Keep away from disinfectant and fumes.

Side-effects:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which you are located.

Safe disposal of device

Dispose of TOSI-FlexiCheck in accordance with valid local regulations.

Version and date of the issuance of the IFU.

Version: 2.0 Date: 22.07.2025