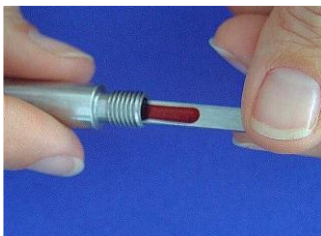
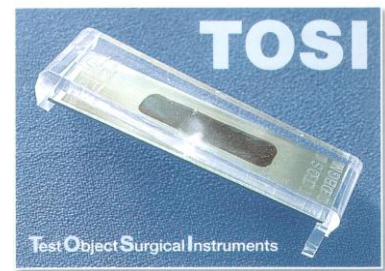


Clean Monitoring

Indicators for Monitoring Cleaning Processes

Product information



09/08

BAG-Cleaning Indicators

TOSI[®] Test Object Surgical Instruments

Routine monitoring and validation of cleaning efficacy in accordance to ISO 15883.

Order-No.: 8302 Packaging unit: 12 tests

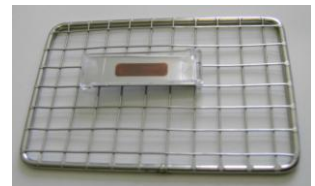
Product features

- Ready-to-use (single use product)
- Test provides efficient and reliable results
- Test soil correlates to human blood acc. to ISO 15883
- Crevice simulates joint of surgical instruments
- Clips for quick and reproducible fixation
- Transparent cover to enable visual check
- Size: 15 x 50 mm



Instructions for Use

- ✓ Remove packaging immediately prior use and clip TOSI[®] on tray.
- ✓ Test objects are processed in instrument trays like surgical instruments.
- ✓ After cleaning and disinfection process is completed the cleaning efficiency of the machine is indicated by the visible TOSI[®] result.



Evaluation

- ✓ Immediate evaluation of the test objects by visual control: Since protein residues in a microgram range are visually detectable an immediate and safe evaluation is possible.
- ✓ Perfect cleaning efficiency: **clean metal surface**
- ✓ Poor cleaning efficacy: blood and / or protein: **residues on metal surface**, see trouble-shooting guide



Storage: Store in protective cover at 2 - 25°C, keep away from high temperatures, disinfectants and chemicals

Shelf life: 18 months from date of manufacture

12/07

TOSI[®]-LumCheck

Routine Monitoring for Cleaning Efficacy for Instruments with Lumen

TOSI[®]-LumCheck with Test Soil

Order-Nr.: 8303

Packaging unit: 25 tests

LumCheck Test Device

Order-Nr.: 8305

Packaging unit: 1 test device

Product features

- TOSI[®]-LumCheck test soil correlates to human blood acc. to ISO 15883
- LumCheck test device simulates surgical instruments with lumen / hollow loads
- LumCheck test device provided with LuerLock connection

Instructions for Use

- ✓ Open LumCheck test device
- ✓ Remove TOSI[®]-LumCheck immediately prior use from pouch and place in test device. Do not touch test soil.
- ✓ Connect LumCheck test device to washer-disinfector (LuerLock, nops, tubes) and load instruments. Start cleaning program.
- ✓ After program has finished, remove LumCheck test device from machine, disassemble test device. Remove TOSI[®]-LumCheck and evaluate results



- ✓ Perfect cleaning efficiency: **clean metal surface**
- ✓ Poor cleaning efficacy: blood and / or protein: **residues on metal surface**, see trouble-shooting guide



Storage: Store in protective cover at 2 - 25°C, keep away from high temperatures, disinfectants and chemicals

Shelf life: 18 months from date of manufacture

12/07

TOSI[®]-FlexiCheck

Monitoring of cleaning efficacy of endoscope washers with channel irrigation system according to ISO 15883-4

TOSI[®]-FlexiCheck with test soil

Order-No.: 8298

Packaging unit: 25 tests

FlexiCheck test device
with silicone tube (length: 1 m)

Order-No.: 8299

Packaging unit: 1 test device

Product features

- TOSI[®]-FlexiCheck combines two different test soils: TOSI[®] test soil correlating to human blood + polysaccharide test soil simulating mucus / secretion
- FlexiCheck test device simulates endoscope channel
- FlexiCheck test device provided with LuerLock connection

Instructions for Use

- ✓ Open FlexiCheck test device

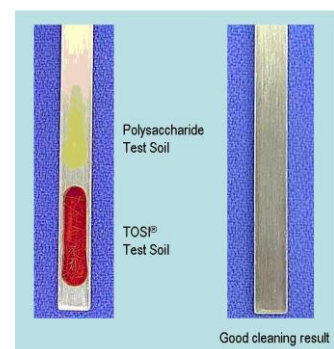
Remove TOSI[®]-FlexiCheck immediately prior use from pouch and place in test device. Do not touch test soil.



- ✓ Connect FlexiCheck test device to endoscope washer channel and start cleaning program (adapters for Wassenburg and Olympus machines available)

- ✓ After program has finished, remove FlexiCheck from machine and disassemble test device. Remove TOSI[®]-FlexiCheck and evaluate result.

- ✓ Perfect cleaning efficiency: **clean metal surface**
- ✓ Poor cleaning efficacy: blood and / or protein / polysaccharides: **residues on metal surface**, see troubleshooting guide



Storage: Store in protective cover at 2 - 25°C, keep away from high temperatures, disinfectants and chemicals

Shelf life: 18 months from date of manufacture

09/08

HemoCheck-S

Test Kit for Detection of Blood Residues on Surfaces

Order-No.: 8295 **Packaging unit:** 12 tests

Product features

- Ready-to-use test
- Test method acc. to ISO 15883
- Enzymatic reaction for a quick color change, color change to blue/green indicates blood residues within 1 minute
- Detection limit: 0.1 µg blood
- Insensitive to fingerprints: no misinterpretation



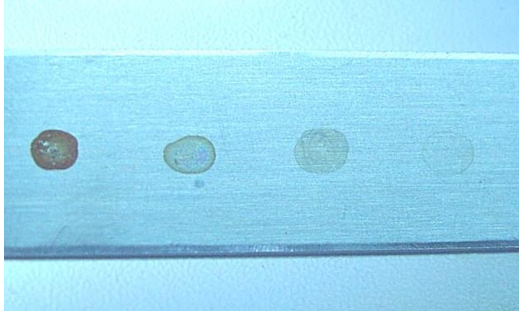
Instructions for Use

- Open HemoCheck-S.
- Contents: A = Indicator (transparent cap), B = Activator (green cap) und C = swab
- Keep away from direct sunlight or UV light
- Swab the surface or item to be checked. For swabbing dry surfaces or instruments the swab is moistened with pure (non-chlorinated) water.
- Open indicator (A) and add solution to activator vial (B)
- Drop the swab (C) into activator vial and shake 5 times
- A color change to blue/green within 1 minute indicates blood residues on the tested surface / instrument. Large quantities of blood residue will cause the whole solution change color to blue.
- A yellow color of the solution after activation is part of the activating reaction and does not indicate blood residues.
- Record the results immediately as the color change is not stable.

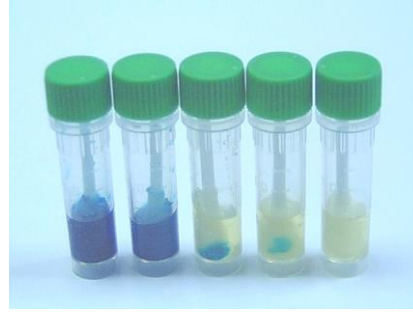


NOTE: HemoCheck-S is used to detect blood residues or test soils containing blood components (e.g. TOSI[®] test soil). Bleached blood residues (e.g. after contact with hydrogen peroxide or peracetic oxide) can not be detected.

Evaluation of HemoCheck-S



From left to right: denatured blood residues.
100 µg, 10 µg, 1 µg, 0.1 µg



Evaluation of Hemocheck-S with different quantities of blood:
From left to right: 100 µg, 10 µg, 1 µg, 0.1 µg, 0 µg.
All tests except for the 0 probe with clear visible result.
Color change to blue.

Storage: Store in protective cover at 2 - 25°C, keep away from high temperatures, disinfectants and chemicals

Shelf life: 18 months from date of manufacture

Application of HemoCheck-S in small lumen:

Swab-Alu, Ø 1,0 mm

Order-No. 8293

Packaging: 120 Swabs

Swab-PP, Ø 2,5 mm

Order-No. 8294

Packaging: 120 Swabs



For introduction / first evaluation:

HemoCheck-S Starter-Kit

Order-No. 82951

Contents:

3 x HemoCheck-S

3 x positive stainless steel discs containing 2 µg TOSI test soil

1 x vial pure water for moistening swabs

12 x swab-Alu, Ø 1,0 mm

12 x swab-PP, Ø 2,5 mm

09/08

Pyromol-Test

Test Kit for Detection of Protein Residues on Surfaces

Order-No.: 8291 **Packaging unit:** 20 tests

Product features

- Ready-to-use test
- Detection of protein residues in less than 10 minutes
- Dye binding method for a detection limit of 1 µg for all kinds of proteins, no incubation
- No interference with Glutaraldehyde or Peracetic Acid



Instructions for Use

- Wear gloves! Human skin is covered with proteins.
- Pyromol packaging unit contains dye binding reagent and swabs.
- Swab the surface or item to be checked. For swabbing dry surfaces or instruments the swab is moistened with pure water.
- Drop the swab into reagent vial and shake 5 times
- Check result after 10 minutes
- A blue spot on the swab may already be detected after 1 – 5 minutes. Longer incubation will intensify reaction.
- Large amounts of protein will cause the whole solution to change color to blue.



Evaluation: A blue color on the swab / in the solution indicates protein residue.

NOTE: Contact with alkaline substances may cause a color change. Contact with human skin may cause a color change. Use designated swabs only. Other swabs may cause a wrong result.

Storage: Store in protective cover at 2 - 25°C, keep away from high temperatures, disinfectants and chemicals

Shelf life: 12 months from date of manufacture

12/07

HemoCheck-E

Test Kit for Detection of Blood Residues in Biopsy Channels

Order-No.: 82955 **Packaging unit:** 6 tests

Product features

- Ready-to-use, swab length 2.55 m
- Detection limit: 0.1 µg blood, no incubation
- Insensitive to fingerprints: no misinterpretation
- Enzymatic reaction for a quick color change, color change to blue/green indicates blood residues within 1 minute



Pyromol-E

Test Kit for Detection of Protein Residues in Biopsy Channels

Order-No.: 82915 **Packaging unit:** 6 tests

Product features

- Ready-to-use test, swab length 2.55 m
- Detection of protein residues in less than 10 minutes
- Dye binding method for a detection limit of 1 µg for all kinds of proteins, no incubation
- No interference with Glutaraldehyde or Peracetic Acid



EndoSwabs !!!

Up to 2.55 m swabs (1.15 m for Ø 1.7 mm) for use with HemoCheck-S or Pyromol-Test



Diameter Ø 1.7 mm
Diameter Ø 2.8 mm
Diameter Ø 3.8 mm

Order-No.: 82921
Order-No.: 82922
Order-No.: 82923

Packaging unit: 10 Swabs
Packaging unit: 10 Swabs
Packaging unit: 10 Swabs

INFO: Regular HemoCheck-E (82955) and Pyromol-E (82915) are delivered with Ø 3.8 mm swabs only.

09/08

SonoCheck

Test Vial for Monitoring Ultrasonic Energy During Reprocessing of Instruments in Ultrasonic Baths

Order-No.: 8300

Packaging unit: 30 tests



- Monitors functionality of ultrasonic baths
- Ready-to-use
- Immediate result
- Color change from green to yellow
- No contamination of ultrasonic bath or instruments

Background information

- Cleaning efficacy of ultrasonic baths is based on cavitation
- Color change of **SonoCheck** is induced by cavitation.

Instructions for Use

- Run ultrasonic bath according to manufacturer's instructions.
- Place **SonoCheck** between instruments for routine monitoring or in empty baths for functional check for ultrasonic energy generators / transducers.

Evaluation

- ✓ A color change from green to yellow indicates sufficient ultrasonic energy / cavitation.
- ✓ Slow color change may be caused by wrong load or overload, incorrect water level or insufficient de-gassing (see trouble-shooting guide).
- ✓ No color change indicates no ultrasonic energy at test location.

Storage: Store in protective cover at 2 - 25° C, keep away from high temperatures

Shelf life: 12 months from date of manufacture

12/07

SonoCheck trouble-shooting guide

In case of unsatisfactory results during functional or routine testing (no color change or color change much slower than average) please check the following instructions:

Parameter	Possible reason	Corrective actions
De-gassing	Dissolved gasses may absorb ultrasonic energy	Refer to the instruction manual for proper de-gassing
Water level	Reflection of ultrasonic energy on the surface may change energy distribution	Refer to the instruction manual for correct water level
Cycle time	Depending on the energy provided in the bath a longer time may be needed for sufficient energy	Extend cycle within a reasonable time (e.g. 5-10 minutes) to obtain better result
Load	A heavy load or certain type of material can absorb ultrasonic energy	Perform functional test, reduce load or check for absorbing material like plastic or silicone
Transducers	The efficacy of the transducers may decrease with age or individual transducers may be out of order	Perform functional test and check transducers individually
Low energy	Not enough energy supplied by the transducers or the ultrasonic basket may absorb too much energy	Perform functional test without ultrasonic basket, compare energy level with another equipment/call for ultrasonic bath service

NOTE: If the ultrasonic cleaner is taking longer than 15 minutes to indicate a positive result during optimization procedures, there might be a "blind spot" at that location. If the test is taking longer than the average performance time (approx. 1-3 minutes) it will indicate a weak spot for ultrasonic cleaning at that location.