

## **DOK-124.1**

### **EasyStop-Filter System**

### **Proof of sterilization duration**

**created by**

**Name, date**

Alexander Schwoy, 05.04.2022

---

**released by**

**Name, date**

Marten Töwe, 05.04.2022

---

#### **Change history**

<b>Version</b>	<b>date</b>	<b>changed by</b>	<b>description</b>
1.0	05.04.2022	Alexander Schwoy	creation

**INHALT**

1	Purpose.....	3
2	EasyStop-Filter System .....	3
2.1	Benefits .....	4
2.2	Prinzip .....	4
3	Sterility time validation .....	5

## 1 Purpose

This document describes and specifies how long the sterility of the products is guaranteed after reprocessing according to the specifications in the USTOMED Instructions for Use. The article number 481.01.04.1 from the following validation report of the accredited test laboratory "Zwisler Laboratorium GmbH" corresponds to all subsequent USTOMED sterilization containers with EasyStop filter system and all other containers that work with this system.

- 90-626-040
- 90-626-065
- 90-628-040
- 90-628-065

## 2 EasyStop-Filter System

The EasyStop-Filter System stops microorganisms even more effectively than conventional filters and can be resterilized without a limited number of sterilization cycles. No consumables are required. One single hand step is all that is needed to open or close the filter: push in the filter cover and turn it.

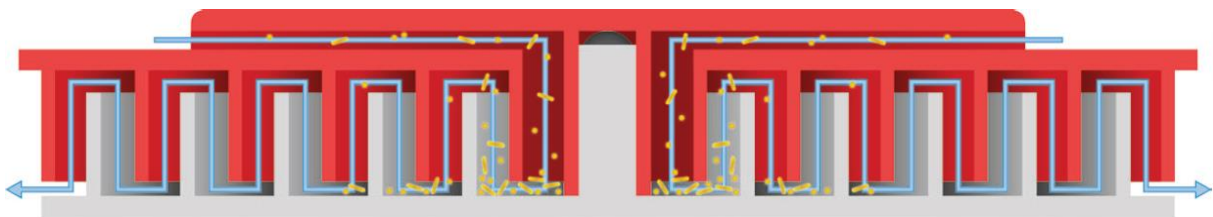


## 2.1 Benefits

- Very high abrasion resistance due to precise, machined production from solid aluminum material
- Dirt and germ repellent
- Fast, residue-free drying during steam sterilization
- High-quality material for triple safety: adhesion free, non-porous and corrosion free

## 2.2 Prinzip

The two-part aluminum filter system, consisting of the insert and the lid of the sterile container serves as a germ barrier under the principle of the "Pasteur's loop", by forming a labyrinth of ring ribs that reliably separates microbes, germs and particles. The meandering flow path achieves a separation efficiency of 99.997%.



### 3 Sterility time validation

commentary to report 1809.2716 page 1  
1 specimen (1809.2716)



D-78462 Konstanz, Germany  
Akkreditied Laboratory  
DAKS: D-PL-13207-01

Zwisler Laboratorium GmbH, Blarerstraße 56, 78462 Konstanz, Europe



## Commentary to Report N° 1809.2716

The following remarks are not part of the study report. They may only be considered as additional information for the sponsor without responsibility. This commentary is valid without a signature.

### Notice

The intended use of a sterilisation container is to maintain the sterility of its content after sterilisation for a certain period of time. To demonstrate that the used sterile barrier system (HardTop Box mit EasyStop Filter (310x190x50 mm), Art. No.: 481.01.04.1, lot: 046550) maintains integrity over 9 months under not controlled environmental conditions one test specimen was packed with stainless steel bars and instruments by the sponsor:  
The test specimen was sterilised by the sponsor in an Autoklav Typ B60.

After the sterilisation the test specimen was kept at room temperature under non controlled environmental conditions for 9 months and 6 days followed by the test of sterility in compliance with ISO 11737-2:2009.

From the container the following test items were tested for sterility:

5x5 instruments and the cloths after wiping the container and the lid.

Therefore each test item was immersed in a suitable container with Soy-bean casein digest-bouillon (Caso-b) and was incubated for 14 days at 30°C (aerobic). While incubation and after 14 days the bouillon was visually checked for turbidity / microbial growth. Then an aliquot of the bouillon was tested for the absence of microbicidal or microbiostatic substances. This growth promotion test was performed with *Bacillus subtilis* (ATCC 6633), *Aspergillus brasiliensis* (ATCC 16404) and *Candida albicans* (ATCC 10231).

Sample No. and Sample name	Sterility Test	Growth Promotion Test
1809.2716: test item 1 (5 instruments)	no growth	growth of all tested strains
test item 2 (5 instruments)	no growth	growth of all tested strains
test item 3 (5 instruments)	no growth	growth of all tested strains
test item 4 (5 instruments)	no growth	growth of all tested strains
test item 5 (5 instruments)	no growth	growth of all tested strains
cloth after wiping container	no growth	growth of all tested strains
cloth after wiping lid	no growth	growth of all tested strains

Zwisler Laboratorium GmbH  
Register Freiburg HRB 381817  
Blarerstraße 56  
78462 Konstanz

TEL 0049 7531 98 11 00  
FAX 0049 7531 98 11 01  
E-MAIL [info@zwisler-laboratorium.com](mailto:info@zwisler-laboratorium.com)  
URL [www.zwisler-laboratorium.com](http://www.zwisler-laboratorium.com)

BANK DATA BLZ 69050001 Konto 69948  
SWIFT Sparkasse Bodensee SOLADES1KNZ  
DE12 69050001 00000 69948  
VAT DE214544148

complementary to report: 1889.2716 page 2  
1 specimen (1889.2716)

  
**Zwisler**  
smart lab solutions

D-78462 Konstanz, Germany  
Akcredited Laboratory  
DAkkS: D-PL-13207-01

Since the test for sterility showed no bacterial growth in any of the test items after 14 days of incubation and no microbicidal or microbiostatic substances in the incubation medium were observed, the examined sample is considered to be **STERILE**. The performed storage suggests a stable microbial integrity of the medical device of 9 months.

Dr. Christian Draing, Study Director

Konstanz, 12/10/2018

Zwisler Laboratorium GmbH  
Register Freiburg HRB 381817  
Blarerstraße 56  
78462 Konstanz

TEL 0049 7531 99 11 00  
FAX 0049 7531 99 11 01  
E-MAIL [info@zwisler-laboratorium.com](mailto:info@zwisler-laboratorium.com)  
URL [www.zwisler-laboratorium.com](http://www.zwisler-laboratorium.com)

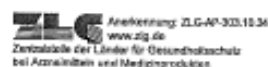
BANK DATA BLZ 69050001 Konto 69948  
SWIFT Sparkasse Bodensee SOLADES1KNZ  
DE12 69050001 00000 69948  
VAT DE214544148

report 1809.2716 page 1  
 1 specimen (1809.2716)



Zwisler Laboratorium GmbH, Blarerstraße 56, 78462 Konstanz, Europe

D-78462 Konstanz, Germany  
 Akkreditiert Laboratory  
 DAkkS: D-PL-13207-01



## Report N° 1809.2716

Sampling and tests were performed according to specifications under 'specimen data' and 'methods' respectively. Particulars about best measurement capability and technical standards are available on request.

### Results

#### HardTop Box mit EasyStop Filter (310x190x50 mm), storage 9 months

##### Loading of container

stainless steel bar and instruments performed by sponsor

##### Sterilization

Autoklav Typ B60 performed by sponsor

##### Storage

planned storage condition not controlled for 9 months  
 environmental conditions

storage condition, period 21.12.2017-27.09.2018 (= 9 months and 6 days)

##### direct inoculation, aerob

Test of Sterility of five instruments (5 parts) no growth after 14 days

Test of Sterility of cloth after wiping container no growth after 14 days

Test of Sterility of cloth after wiping lid no growth after 14 days

Test of Sterility test passed after 15 days

##### Growth promotion tests

Sterility Testing Control growth after 1 day

methods RealTime Ageing ISO 17664:2004

Storage-1e.doc

Zwisler Laboratorium GmbH  
 Register Freiburg HRB 381817  
 Blarerstraße 56  
 78462 Konstanz

TEL 0049 7531 99 11 00  
 FAX 0049 7531 99 11 01  
 E-MAIL info@zwisler-laboratorium.com  
 URL www.zwisler-laboratorium.com

BANK DATA BLZ 69050001 Konto 69948  
 SWIFT Sparkasse Bodensee SGLADES1KNZ  
 DE12 69050001 00000 69948  
 VAT DE214544148

report 1809.2716 page 2  
1 specimen (1809.2716)



D-78462 Konstanz, Germany  
Akkredit. Laboratory  
DAkkS: D-PL-13207-01

Sterility ISO 11737-2:2009, ZLG  
Sterility Testing ISO 11737-2:2009, ZLG

steritest-2e.doc, Vers. 4  
steritest-2e.doc, Vers. 4

specimen data: number 1809.2716, lot 046550, receipt of specimen 14.09.2018, experimental starting date 27.09.2018, experimental completion date 12.10.2018, under the designation 'inactive medical device', Medizinprodukt, manufactured by Innovations Medical GmbH, sampling was performed by sponsor, principal code 481.01.04.1, 1 unit, delivery by Innovations Medical GmbH, temperature at delivery: 23°C,

The sign '<' means 'less than the quoted value', '>' means 'more than the quoted value'. Detected microorganisms are reported as '+ n.' and negative test results as 'n.n.' this means the microorganism was not found in the specified volume. Methods labeled with an 'A' are out of the accredited ambit; methods labeled with a 'U' were performed by a sub contractor. Test results exclusively refer to the specimen and not to the entire lot, bundle etc. This test report may only be copied or published as a complete document including the signature on the last page and all data of 1 specimen (number 1809.2716) with permission of the laboratory.

To improve our service we would like to ask you for a feedback. Are you happy with our service or how could we improve this service? Please feel free to send us your comments and recommendations. Thank you for your input and the continuing good cooperation

Dr. Christian Draing, Study Director

Konstanz, 12/10/2018



DOK-124.1  
 EasyStop-Filter System  
 Proof of sterilization duration

