DOK-124

EasyStop-Filtersystem

Nachweiserbringung der Sterilitätsdauer

created by	**Name, date**
	Alexander Schwoy, 01.04.2022
released by	**Name, date**
	Daniel Urbat, 01.04.2022

Change history

Version	date	changed by	description
1.0	01.04.2022	Alexander Schwoy	Erstellung

INHALT

1 Ziel und Zweck

Dieses Dokument beschreibt und gibt vor, wie lange die Sterilität der Produkte, nach einer Aufbereitung gemäß den Vorgeben aus den USTOMED Gebrauchsanweisungen gewährleistet ist. Die Artikelnummer 481.01.04.1 aus dem folgendem Validierungsbericht des akkreditierten Prüflabors „Zwisler Laboratorium GmbH", entsprich allen nachfolgenden USTOMED Sterilisationscontainern mit EasyStop-Filtersystem und allen weiteren Containern die mit diesem System arbeiten.

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

2 EasyStop-Filtersystem

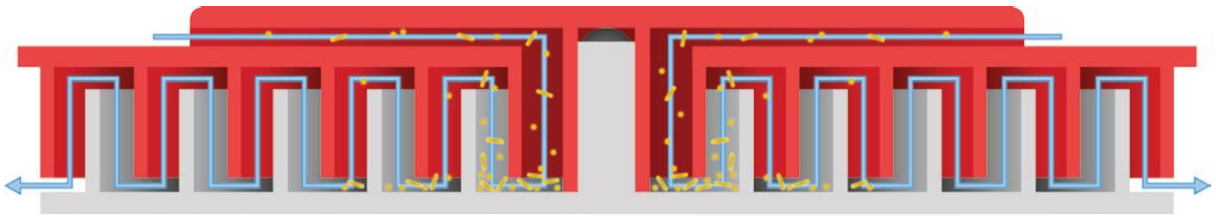
Das filterlose System stoppt Mikroorganismen noch wirksamer als herkömmliche Filter und lässt sich beliebig oft resterilisieren. Dabei bedarf es keinem Verbrauchsmaterial. Zum Öffnen bzw. Schließen genügt ein Griff: Filterabdeckung eindrücken und drehen.

2.1 Vorteile

- Sehr hohe Verschleißfestigkeit durch präzise, spanende Fertigung aus Aluminiumvollmaterial
- Schmutz- und keimabweisend
- Schnelle, rückstandsfreie Trocknung bei Dampfsterilisation
- Hochwertiges Material für dreifache Sicherheit: adhäsionsfrei, porenfrei und korrosionsfrei

2.2 Prinzip

Für das Prinzip der Pasteurschen Schleife als Keimbarriere, dient der zweiteilige Aluminium-Einsatz im Deckel des Sterilcontainers. Er bildet ein Labyrinth aus Ringrippen, das Mikroben, Keime und Partikel zuverlässig abscheidet. Der mäandrierende Strömungspfad erzielt dabei einen Abscheidegrad von 99,997%.



3 Validierung der Sterilitätszeit

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DAkkS: D-PL-13207-01

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DAkkS Deutsche Akkreditierungsstelle D-PL-13207-01-01 D-PL-13207-01-02

Anerkennung: ZLG-AP-383.10.34 www.zlg.de Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

GLP Good Laboratory Practice Statement of GLP Compliance

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 responsability. 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 steal 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 tems 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 (ATTC 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

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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

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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 steal bar and instruments	performed by sponsor	
Sterilization		
Autoklav Typ B60	performed by sponsor	
Storage		
planned storage condition	not controlled environmental conditions	for 9 months
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

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Sterility	ISO 11737-2:2009, ZLG	steritest-2e.doc, Vers. 4
Sterility Testing	ISO 11737-2:2009, ZLG	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, 1unit, 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 kopied 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

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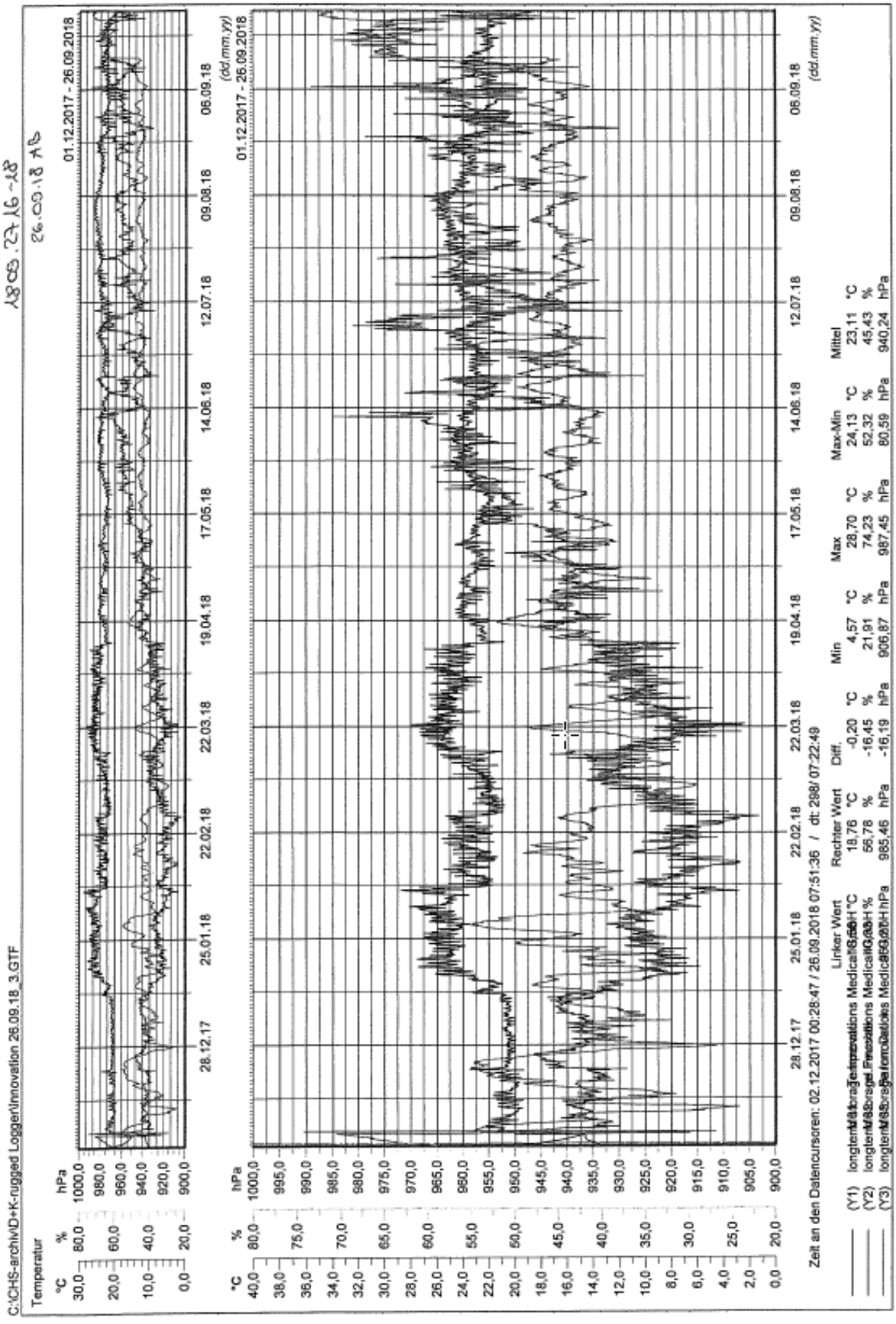
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