**Keywords**
- steam sterilisation
- surgical instruments
- process challenge device
- resistometer

ZENTRAL STERILISATION 4

# Steam Sterilisation of Reusable Surgical Instruments

## Effectiveness Limits

*I. Haas, H. Henn*, U. Junghannß, K. Kobel, D. Toth, H.C. Weiss and Working Group Instrument Preparation+*

**The aim of the present study was to investigate various process challenge devices (PCDs) already used in a previous study focusing on the sterilisability of reusable surgical instruments (Sterilisability Study) , but now using shorter sterilisation times. Sterilisation processes were conducted in a resistometer (134 °C) as well as in a test steriliser at temperatures of 132 °C (270 °F) and 134 °C (273 °F), using different hold times. The results obtained for the resistometer showed that in the "Thread" model no test organisms could be detected after a sterilisation time of 90 s. In the "Gap" and "Seal" models positive results were obtained after this sterilisation time because of the design features of these models. Complete inactivation of test organisms was achieved for the biological indicators used after 180 s. The other models used, i.e. the "Hose" model, both with and without a volume-reducing insert, and the two "Sliding surface" models, with metal as well as with plastic, continued to show microbial growth even after a 5-min exposure time.**

**The following results were obtained for the test steriliser: For the majority of tests conducted, with and without a load, in the test steriliser, there was no evidence of any test organism remaining after a hold time of either 90 s or 180 s and a temperature of 134 °C.**

**For the "Seal" and "Hose with insert" models, test organisms were detected in some cases, and this was confirmed by running a confirmatory test.**

**In the tests carried out at a temperature of 132 °C with hold times of 2 and 4 min, test organisms were recovered only in the "Hose with insert" model for the 2-min hold time, both with and without a ballast load.**

## Introduction

After being used on a patient, medical devices must be reprocessed to render them free of contamination, which could give rise to infection, for reuse on another patient. Decontamination processes that meet specific requirements must therefore be used to reprocess such medical devices. A maximum degree of microbial inactivation must be assured so that the sterility of the devices can be demonstrated. Whether a device can be viewed as being sterile and suitable for the intended purpose is something that must be critically appraised within the framework of quality assurance. DIN EN 556 and DIN EN 14937 contain information on this, e.g. a device can be deemed to be sterile if the theoretic value stipulating that no more than one microorganism may be present in one million sterilised units of the final product (i.e. sterilised medical device) is assured. Since in principle it is not possible to inspect each and every device for "sterility", in our opinion surrogate values have to be used to guarantee the requisite sterility. Hence a medical device may only be designated as "sterile" if a validated sterilisation process has been used and the instructions specified by the respective medical device manufacturer have been observed.

Since the hold time used in Anglo-Saxon countries is generally 3 min, additional tests to the Sterilisability Study were carried out to investigate and critically appraise the effectiveness of such a process.

## Materials and Methods

The effectiveness of a sterilisation process can in theory be demonstrated by means of the microbial survival curve. The exposure time needed to assure a specified survival probability of the microoganisms can thus be calculated and achieved. The influence exerted by constant physical variables on the respective microbial population is generally a reaction of the first order. Consequently, the half-logarithmic depiction of the time in relation to the microbial count present gives a linear inactivation curve, while taking account of the reaction kinetics constants. However, it must be borne in mind that marked differences are seen in terms of the microroganism species and their spores and also as regards the prevailing environmental conditions. The decimal reduction times (D-value) is the yardstick used to show the resistance of a microbial population.

In our tests we used the following types of biological indicators:

- Spore strips of *Geobacillus stearothermophilus* ATCC 7953 with an average baseline microbial count of $1.0 \times 10^6$ cfu/germ carrier (filter paper) and a D-value of 1.5 min at 121 °C.
- Spore suspensions of *Geobacillus stearothermophilus* ATCC 7953 with $2.6 \times 10^8$ cfu/ml and a D-value of 1.9 min at 121°C. Direct inoculation of the respective process challenge device (PCD) described below was performed with 10 µl spore suspension.

A resistometer manufactured by the firm Lautenschläger with individual programming facilities was used for the test series. The design of this apparatus meets the es-

* Helmi Henn, Richard Wolf GmbH, Pforzheimer Strasse 32, 75438 Knittlingen, Germany
E-mail: helmi.henn@richard-wolf.com

\+ For a list of members of the Working Group please see references at the end of the article

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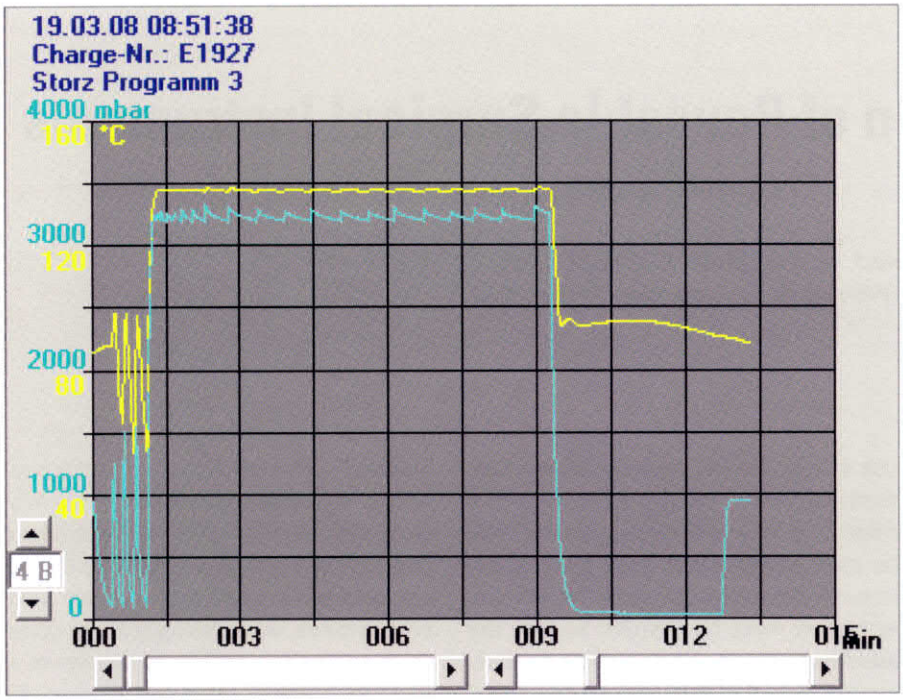


**Fig. 1:** Pulsed prevacuum process

sential requirements of DIN EN ISO 18472 and DIN EN 61010-1./-2-041. The chamber capacity is 9.3 l.

A test steriliser manufactured by the firm Lautenschläger (Protocert 716) was used in conformance with DIN EN 285.

Process: pulsed prevacuum (120 mbar, 3-fold pulses).

Thermologgers manufactured by the firm Yokogawa, Model MV200, were used to verify the process parameters.

The PCDs used to simulate the myriad surgical instruments were PCDs that had been standardised on the basis of the findings obtained in the Sterilisiability Study. Evaluation data showed the PCDs to be composed of different materials and of designs that were deemed to be difficult to sterilise:

– ***Thread model:*** This PCD simulates the type of thread found in many instruments (Fig. 2). To assure clear-cut microbial recovery, a metallic block with access from both sides was designed. Access was granted at both ends via a fine M10 fine thread. Two threaded pins, each measuring 25 mm in length, were screwed into the thread and tightened manually using a nut. Analysis by the working group revealed that of all the threads found in instruments, this fine thread represented a worst-case feature.

The PCD was contaminated using biological indicator strips that were placed in the hollow PCD and closed at both ends with the threaded pins.

– ***Gap model:*** This PCD was simulated by means of a clamp device with two metal surfaces, one placed on top of the other and pressed together by means of a clamping mechanism using screw pretensioning (Fig. 3). This construction allows for clear-cut microbial recovery and is intended as a means of simulating the gaps in instruments. Pretensioning by means of two clamping screws is defined as an additional word-case feature.

For contamination purposes, the inoculated germ carrier was placed between the two forceps parts, with the grooved side facing outwards in each case so as to conjure up a worst-case scenario in respect of heat conduction. Using the metal ring, the metal plates, which had already been positioned, were fixed and tightened using the hexagon screws of the PCDs.

– ***Seal model:*** This PCD was simulated by the same PCD as used in the gap model, see above diagram of gap model (Fig. 3), however, a silicone seal was placed additionally between the two metal plates. Here the silicone seal is pressed against the metal plate using screw pretensioning, thus simulating a seal.

The germ carrier was placed between the forceps item and silicone seal, and placed under tension using the metal plates and rings.

– ***"Hose with insert" model:*** This PCD simulates long lumens that are open at both ends. The PCD is used to check instrument hoses (tubes) and lumens that are open at both ends (Fig. 4). Here the spore carrier is placed in the hose chamber in the centre. The chamber contains a plastic insert reducing the existing volume. The germ carrier was placed in the plastic insert during sterilisation.

For the present model, a total hose length of 4000 mm was defined, representing a minimum length of 2000 mm for the steam penetration into a lumen open on one side.

The PCD was opened at one side and the germ carrier inserted into the PCD chamber and closed.

The germ carrier was placed in the model as described above.

– ***(Metal) sliding-surface model:*** The PCD is simulated by cocks that are defined as metal-metal pairs (Fig. 5). The two surfaces rubbing together are always composed of the cock chamber and cock plug. In this PCD model, the cock chamber and cock plug are always made of metal. But the cock plug is always pretensioned by means of a spring cap. This sliding surface has been defined as a worst-case feature for all sliding metal surfaces.

To contaminate, the internal contact surfaces of the cock were wetted with 10 µl of the spore suspension and then dried. When assembled, the cock was set to "throughput".

– ***(Metal-plastic) sliding-surface model:*** The PCD is simulated by cocks that are defined as metal-plastic pairs (Fig. 5). The two surfaces rubbing together are always composed of the cock chamber and cock plug. In this PCD model, the cock chamber is always made of metal and the cock plug of plastic. But the cock plug is always pretensioned by means of a spring

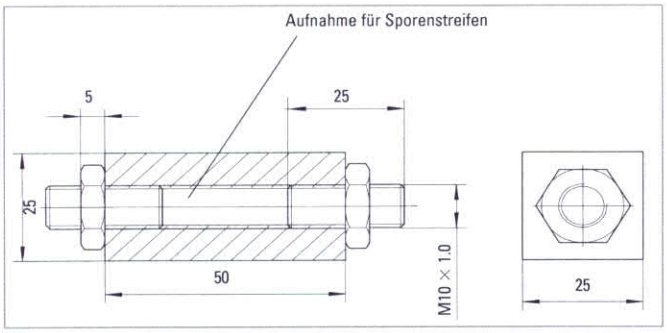


**Fig. 2:** PCD thread model

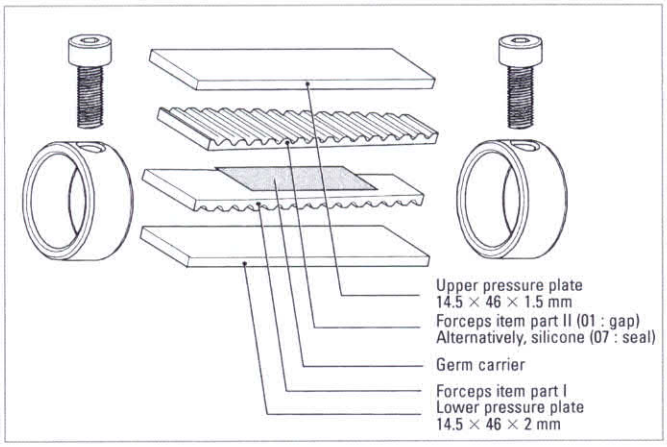


**Fig. 3:** PCD gap model

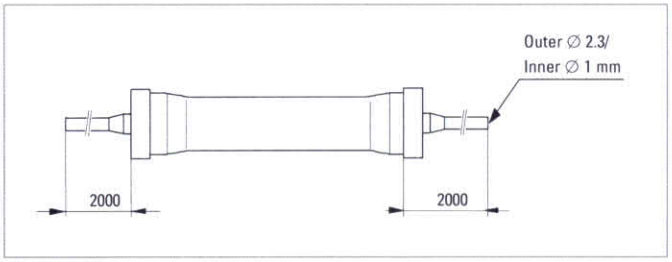


**Fig. 4:** PCD hose with insert model

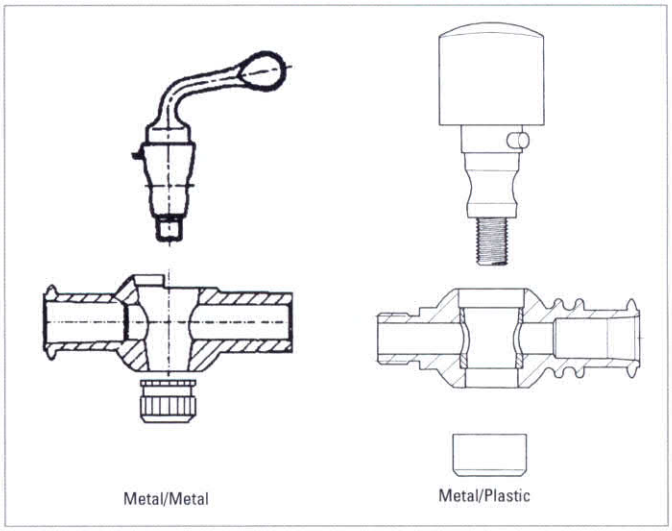


**Fig. 5:** PCD sliding surface model

**Fig. 6**

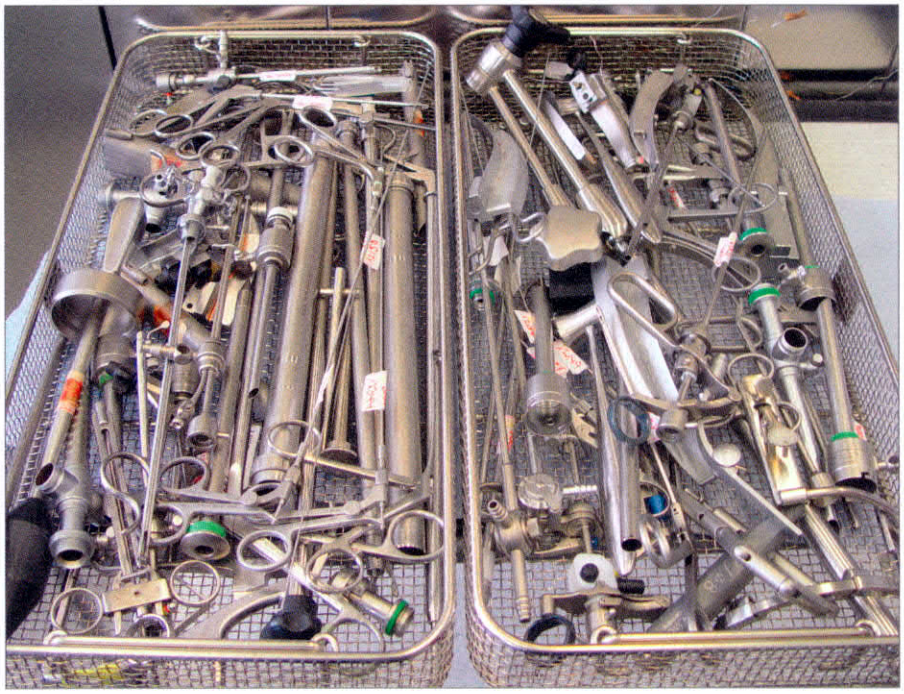

**Fig. 7**

| | Time in seconds | | | |
|---|---|---|---|---|
| Model | 90 | 180 | 240 | 300 |
| Thread | 45/0 | – | – | – |
| Gap | 45/2 | 45/0 | – | – |
| Seal | 45/6 | 45/0 | – | – |
| Hose with insert | 45/45 | 45/41 | 45/44 | 45/42 |
| Hose without insert | 45/45 | 45/34 | 45/29 | 45/14 |
| Metal sliding surface | 45/9 | 45/30 | 45/13 | 45/12 |
| Plastic sliding surface | 45/13 | 45/26 | 45/21 | 45/14 |

*xx/yy: Number of test/ samples with growth*

**Tab. 1:** Resistometer

| | Zeit in Sekunden | | | |
|---|---|---|---|---|
| | mit Beladung | | ohne Beladung | |
| Model | 90 | 180 | 90 | 180 |
| Thread | 4/0 | 3/0 | 3/0 | 2/0 |
| Gap | 4/0 | 3/0 | 3/0 | 2/1 |
| Seal | 4/1 | 3/1 | 3/0 | 2/0 |
| Hose with insert | 4/4 | 3/2 | 3/3 | 2/2 |
| Hose without insert | 4/0 | 3/0 | 3/0 | 2/0 |
| Metal sliding surface | 4/0 | 3/0 | 3/0 | 2/0 |
| Plastic sliding surface | 4/1 | 3/0 | 3/1 | 2/0 |

*x/y: Anzahl Versuche/Proben mit Wachstum*

**Table 2:** Test steriliser results 134 °C

| | Zeit in Sekunden | | | |
|---|---|---|---|---|
| | mit Beladung | | ohne Beladung | |
| Model | 90 | 180 | 90 | 180 |
| Thread | – | – | – | – |
| Gap | – | – | – | – |
| Seal | 3/3 | 3/1 | 3/3 | 3/2 |
| Hose with insert | 3/1 | 3/0 | 3/2 | 3/0 |
| Hose without insert | – | – | – | – |
| Metal sliding surface | – | – | – | – |
| Plastic sliding surface | 7/0 | 3/0 | 3/0 | 3/0 |

*x/y: Anzahl Versuche/Proben mit Wachstum*

**Table 3:** Test steriliser results 134 °C confirmatory test

| | Zeit in Sekunden | | | |
|---|---|---|---|---|
| | mit Beladung | | ohne Beladung | |
| Modell | 120 | 240 | 120 | 240 |
| Thread | 5/0 | 5/0 | 3/0 | 3/0 |
| Gap | 5/0 | 5/0 | 3/0 | 3/0 |
| Seal | 5/0 | 5/0 | 3/0 | 3/0 |
| Hose with insert | 5/4 | 5/0 | 3/3 | 3/0 |
| Hose without insert | 2/0 | 2/0 | – | – |
| Metal sliding surface | 2/0 | 2/0 | – | – |
| Plastic sliding surface | 5/0 | 5/0 | 3/0 | 2/0 |

*x/y: Anzahl Versuche/Proben mit Wachstum*

**Table 4:** Test steriliser results 132 °C

cap. This sliding surface has been defined as a worst-case feature for all sliding metal-plastic surfaces.

The PCD was contaminated in the same way as the metal sliding-surface model.

The resistometer was loaded by placing three models of a similar type in the chamber. In view of the sterilisation results obtained, 45 tests sufficed for the thread model. For both the gap and seal models, 90 test samples were conducted and evaluated (45 at 90 s and 45 at 180 s). The highest number of tests was run for the "Hose with insert" and "Hose without insert" models and metal sliding-surface and plastic sliding-surface models. Here 45 tests were run for 90 s, 180 s, 240 s and 300 s with each PCD.

Apart from the tests conducted in the resistometer, tests were also carried out in the test steriliser at a temperature of 132 °C for a hold time of 2 and 4 min and at 134 °C for a hold time of 1.5 and 3 min with double wrapping (paper/foil as per DIN EN 868). These tests were performed with and without a 10 kg load. The ballast load used here was an assortment of typical surgical instruments in addition to a number of minimally invasive surgical (MIS) instruments (see figures 6 and 7).

Reflecting our aims, microbial recovery was carried out using the qualitative method. The sterilised PCDs, together with the germ carriers were removed from the sterilisers, dismantled under sterile conditions and each germ carrier was transferred to 10 ml spore broth and then incubated at 56 °C for 5 days. For the two sliding-surface models, the PCD was dismantled and transferred to 20 ml spore broth and incubated for 5 days at 56 °C. Positive controls were also run for each test series. If no growth of the test organisms was seen, the culture media was reinoculated.

Tests were evaluated as outlined using a qualitative method. If growth of the test organism detected, a solid culture medium (trypticase agar) was re-inoculated.

## Results

The results obtained are given in tables 1 to 4.

*Positions of temperature/pressure loggers with load (Table 2 – 4):*

No. 1: lower level, between load and PCDs

No. 2: in the drain of the test steriliser (lower outlet, inserted by around 5 cm)

No. 3: around. 5 cm above the PCDs (between the upper and lower level)

No. 4: in the lower front left corner of chamber

No. 5: upper level in item (within a pipe of around 250 mm long with Ø 4mm)

No. 6: in the upper rear right corner of chamber

*For cycles without a load:*

No. 1: in tray beneath the PCDs

No. 5: in upper tray in the same instrument (individual)

Remainder: as above

*Positions of temperature/pressure loggers with load:*

No. 1: on top in ballast load

No. 2: on top in load

No. 3: on top in load

No. 4: on bottom in load

No. 5: on bottom in load

No. 6: in the drain of test steriliser

For cycles without a load:

No. 1: in tray beneath the PCDs

No. 5: in upper tray in same instrument (individual)

Remainder: as above

*Positions of temperature/pressure loggers with load:*

No. 1: lower level, between load and PCDs, front

No. 2: lower level, between load and PCDs, back

No. 3: upper level, between load and PCDs, front

No. 4: lower level, within a pipe of around 250 mm long and Ø 4 mm

No. 5: in the drain of the test steriliser (lower outlet, inserted by around 5cm)

No. 6: upper level in load, middle

*For cycles without a load:*

No. 1: lower level in a jaw (individual)

No. 2: lower level in a jaw (individual)

No. 3: upper level in a jaw (individual)

No. 4: upper level within a pipe of around 250 mm long and Ø 4 mm

No. 5: lower level, front left beneath the PCDs

No. 6: in the drain of the test steriliser (lower outlet, inserted by around 5cm)

## Discussion

The test results demonstrate that PCDs have proved to be suitable medical device simulators. Using the different hold times, it was possible to identify up to what maximum limit each PCD type could be reliably sterilised in the resistometer. It must be pointed here out that the results obtained for the resistometer represent worst-case conditions as the temperature rises much faster (higher temperature gradient) than in the case of the sterilisers and programmes used in everyday practice. For that reason, in addition to the tests conducted in the resistometer, a series of tests were run in the test steriliser. These results showed that it was not possible to sterilise all the constructional designs featured in the study on using hold times of less than four minutes. In everyday practice it cannot be ruled out that all the design features investigated in the study are represented in a load. For that reason it is recommended that a hold time of at least four minutes be used.

The tests also show that a reliable sterilisation result can be obtained under the conditions outlined above on using a hold time of four minutes at both 132 and 134 °C.

It is hoped that the investigations carried within the framework of the present study will enhance everyday practices. In view of the different applications and equipment used in any particular setting, the sterilisation processes and PCDs need to be further discussed.

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**Participating companies:**

Aesculap AG, Tuttlingen
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August Reuchlen GmbH, Tuttlingen
Bayha C. Bruno GmbH, Tuttlingen
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Weiss-Instrumente, Engen
Witte GmbH Chir. Instrumente, Solingen

**Participating university institute:**

HS Anhalt (Univerity of Applied Sciences) Köthen