Recommendations by the Quality Task Group (41) Production of Heat Sealing Seams for Packing Medical Devices

(based on the currently valid standards, ISO 11607, EN 868, DIN 58953)

Anyone engaged in decontamination of medical devices will no doubt already have produced thousands of sealing seams in the course of a working day. But the requirements to be met here are not universally known. Bearing in mind that these have been described in various standards, the Quality Task Force of the German Society for Sterile Supply (DGSV e.V.) deems it advisable to compile recommendations for production of heat-sealing seams.

Packaging materials and systems are designated in the standards as a "preformed sterile barrier system".

1. What are the most important basic points?

The quality of a sealing seam is essentially determined by the ➜ "**CRITICAL PROCESS PARAMETERS**". The critical process parameters for a sealing process include, at least, the temperature and contact pressure.

➜ **THE CRITICAL PROCESS PARAMETERS** for heat-sealing seams are the **temperature** and contact **pressure**.

The temperature and the contact pressure must be defined for each packaging material (preformed sterile barrier system as per the standards) and heat sealer at the time of validation (see Section 4). The benchmark values for the temperature and contact pressure are specified by the manufacturer of the packaging material. These benchmark values serve only as a guide to the values still to be determined for the critical parameters in the course of validation.

2. What must a sealing seam be able to do?

Based on the standard, the heat sealing seam must be at least 6 mm.

A sealing seam must be endowed with sufficient strength, and if necessary, be peelable to assure safe packaging for a medical device. Pursuant to ISO 11607 none of the following defects should be present across the defined sealing width:

- Channel formation or open seals, punctures or tears
- Material delamination or separation

The specified sealing width for the closure seam should normally not be more than 6 mm. Experience to date has shown that it is not advisable to produce a sealing seam with a width of more than 12 mm. In the case of a divided sealing seam, the partial widths of which the entire surface is composed must be added together.

3. What must a heat sealer be able to do?

The heat sealer must be able to produce a sealing seam that meets the specifications outlined in Section 2. The heat sealer must signal any deviation from the temperature and sealing pressure, and if necessary interrupt the sealing process.

A facility for electronic transmission of temperature and sealing pressure to a (PC) batch documentation system is recommended.

The heat sealer must also ensure that a defined distance is maintained between the sterile item and the sealing seam so that the prescribed ➜ **DEGREE OF FILLING** of 75% is not exceeded. The standard stipulates that a ➜ **DISTANCE** of 3 cm be maintained between the sealing seam and the medical device.

➜ **THE MAXIMUM DEGREE OF FILLING** is 75%.
➜ **A DISTANCE** of 3 cm must be maintained between the sealing seam and the medical device.

4. Must the sealing process be validated?

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The sealing process must be validated. This presupposes that an automated process is used.

The new ISO 11607-2:2004 features a detailed description of the validation requirements for forming, sealing and assembly processes. Validation comprises the following tasks, inter alia:

Installation qualification:
– The device is suitable
– The ambient conditions are suitable
– The user is trained

Operational qualification:
– Specification of temperature and pressure at the site of use with the materials being used.

Performance qualification:
– Testing the tensile strength of the sealing seam and ensuring it is complete
– Testing for peeling characteristics

Performance requalification is recommended annually

The ➜ **SEALING SEAM STRENGTH** must be at east 1.5 N for a 15-mm-wide strip before and after sterilisation. Too great a sealing seam strength is not recommended so as to assure pealing characteristics and avoid the bag being torn when opened. If the bag tears, there is a risk of recontamination of its contents.

➜ **THE SEALING SEAM STRENGTH** and **PEELING CHARACTERISTICS** must be tested during validation and this must be documented

The ➜ **PEELING CHARACTERISTICS** can be well defined as per DIN EN 868-5, Annex C (Method for assessment of the peeling characteristics): Citation: *„Slowly and carefully, separate the heat sealing seams by hand. Check whether the heat sealing seam extends across the entire width and length of the area to be covered with heat sealing seams and ensure that the paper does not unravel by more than 10 mm from this heat-sealing area.“* Impeccable heat sealing produces a mat appearance while, conversely, inadequate heat sealing produces a shiny seam.

The sealing seam tensile strength test must be carried out as part of validation and regularly (normally 1 x annually) repeated during revalidation (= performance requalification). In addition, revalidation must be conducted on changing over to a new packaging manufacturer and following maintenance and repair tasks on the heat sealer.

The test results must be documented and archived.

5. Was must be done as a routine everyday measure?

Practical tips for transparent film packaging

Anyone operating a heat sealer must be trained to do so.

The functional capabilities of the heat sealer must be checked daily before placing it in operation and this must be documented (e.g. "Seal Check", "Ink Test" as per EN 868, Part 1, Annex F).

The specifications enshrined in the pertinent standards and the standard operating procedure referring to "Transparent Film Packaging" must be observed when producing sealing seams. In particular, when using pouches, the following must be ruled out by taking suitable measures:
– Penetration of the packaging by pointed or sharp medical devices.
– Tears in the packaging material by using it to pack medical devices that are too heavy for this type of packaging.
– The packaging label must not conceal the medical device and must not penetrate the packaging (in the case of manual labelling).

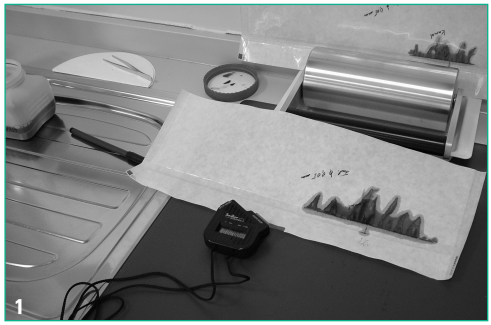

Fig. 1: Ink test – the photograph shows mainly channel-free zones. The visible channel was deliberately formed.

Abb. 2: SealCheck – insertion into the sealer