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)

A nyone 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.

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 temperature and the contact pressure must be defined for each packaging ma­
terial (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 bench­
mark 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?
A sealing seam must be endowed with sufficient strength, and if necessary, be peel­
able 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 main­
tained between the sealing seam and the medical device.

4. Must the sealing process be validated?
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 re­
quirements for forming, sealing and assembly processes. Validation comprises the fol­
lowing tasks, inter alia:

Packaging materials and systems are des­
ignated in the standards as a “preformed ste­
rile barrier system”.

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

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

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

The sealing process must be validated.
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

The SEALING SEAM STRENGTH must be at least 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 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?

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).

Performance requalification is recommended annually

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

Practical tips for transparent film packaging

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

Abb. 2: SealCheck – insertion into the sealer