Operating Manual

MELAseal® 100+

Sealing device

EN

Dear doctor,

We thank you for your confidence demonstrated by the purchase of this MELAG product. As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument treatment and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing **"competence in hygiene"** and **"Quality – made in Germany"**, we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with ISO 13485 and ISO 9001. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE

Contents

1 General Guidelines

Please read this operating manual carefully before commissioning the product. The instructions include important safety information. The functionality and value-retention of this device depend primarily on the care accorded to it. Make sure to keep the Operating Manual near to the device. It represents a component of the product.

Symbols used

Symbol	Explanation
	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
	Draws your attention to important information.

Formatting rules

Example	Explanation
see **Chapter 2**	Reference to another text section within this document

2 Safety

When operating the device, comply with the following safety instructions as well as those contained in subsequent chapters. Use the device only for the purpose specified in these instructions. Failure to comply with the safety instructions can result in injury and/or damage to the device.

Power cable and power plug

- Only the power cable included in the scope of delivery may be connected to the device.
- The power cable may not be replaced by a cable determined to be insufficient.

Danger of short circuit

- Liquids may not be permitted to reach the interior of the device. This could result in an electrical shock or short circuiting.

Repair

- Never open the housing of the device. Incorrect opening and repair can compromise electrical safety and pose a danger to the user. The guarantee and warranty are forfeited as soon as the device is opened by anyone other than a member of a MELAG-authorized technical customer service.

3 Description of the device

Scope of delivery

Please check scope of delivery before connecting the device.

Standard scope of delivery

- 1x MELAseal 100+ sealing device
- 1x Operating Manual
- 1x Declaration of conformity
- 1x Warranty certificate
- 1x Power cable
- 1x Lever
- 1x Torx key for the fastening screws of the rear housing cover

Intended use

This sealing device is designed for application in a medical context, e.g. clinics and medical and dental practices. It was developed for the heat sealing of instruments in sterilization packaging.

Suitable materials

It is suitable for the heat sealing of instruments in transparent sterilization packaging in accordance with DIN EN 868-5 e.g. MELAfol. Should you wish to use any other packaging materials as those named above, please consult your stockist first or contact MELAG directly.

Unsuitable materials

- Pure hose film (double-sided film), as these types tend to become glued together in the sealing bar, and can restrict the functionality of the sealing device.
- Polythene film
- Soft PVC film
- Hard PVC film
- Polyamide film
- Polypropylene film

NOTICE

The use of unsuitable packaging materials carries the risk of damage to or malfunction of the device.

- Please observe the manufacturer information regarding the respective packaging materials as well as the recommended sealing temperatures.

Views of the device

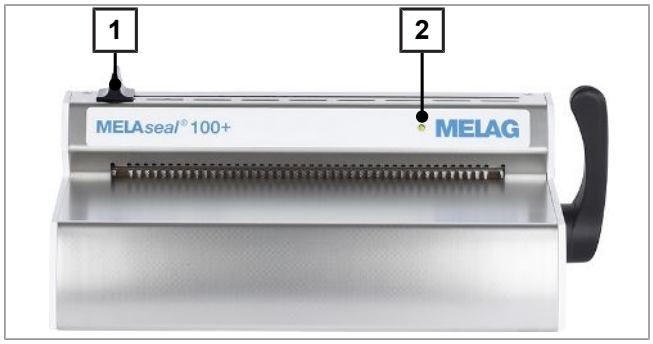


Fig. 1 : Front view

1 Knife handle
2 Control lamp

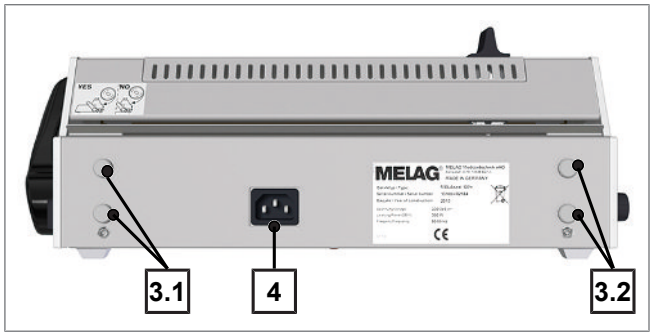


Fig. 2 : View from rear

3.1 Bracket for roll dispenser (left)
3.2 Bracket for roll dispenser (right)
4 Socket for power cable

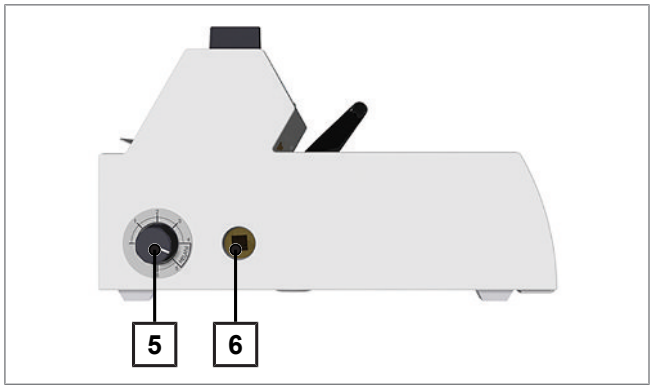


Fig. 3 : Fore left view

5 Rotary knob for temperature adjustment
6 Square hole for lever (on both sides)

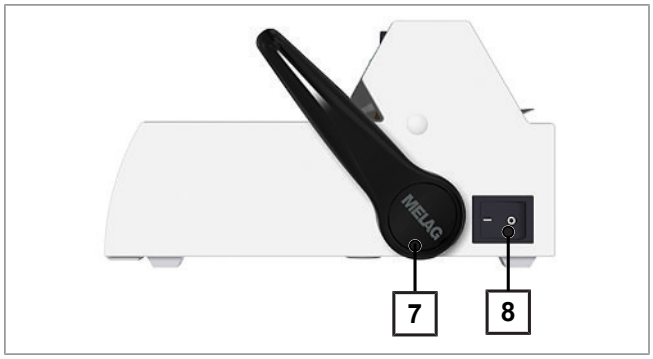


Fig. 4 : Fore right view

7 Lever
8 Power switch (ON/OFF)

Status display and acoustic signal

Table 1: The meaning of the control lamps and signal tones

	Control lamp/ acoustic signal	Possible cause	Measure
	LED Illuminates orange	▪ Sealing device is in the heating up or cooling down phase	Please wait until the pre-set sealing temperature has been reached.
	LED flashes red, Warning signal sounds	▪ The lever is depressed during the heating phase ▪ The sealing temperature has not yet been reached.	Please wait until the LED is constantly illuminated green.
	LED Illuminates green	▪ The sealing device has reached the pre-set sealing temperature and is ready for operation. ▪ The pre-set sealing time (3 sec) has been reached and the sealing procedure has been ended.	Raise the lever and remove the packaging.
	LED flashes green	▪ The sealing procedure runs when the lever is depressed (3 sec).	Please wait until the LED is constantly illuminated green.
	LED flashes red, Warning signal sounds (fault)	▪ The lever has been raised early, despite the required sealing time not having been reached.	▪ Please keep the lever depressed until the green LED is constantly illuminated.
		▪ The lever has not been raised, despite the required sealing time having been completed.	▪ Lift the lever as soon as the sealing time has been reached so that the film is not burnt.
		▪ Device fault: The heating phase is taking too long (> 5 min.); the sealing device cannot reach the pre-set sealing temperature.	▪ Upon repeated occurrence, inform your stockist / MELAG customer services

PLEASE NOTE

If further status displays or acoustic signals occur, contact the MELAG customer service/ service technician.

4 Commissioning

Requirements of the installation location

CAUTION

Failure to comply with the set-up conditions can result in malfunctions or damage to the device and/or human injury.

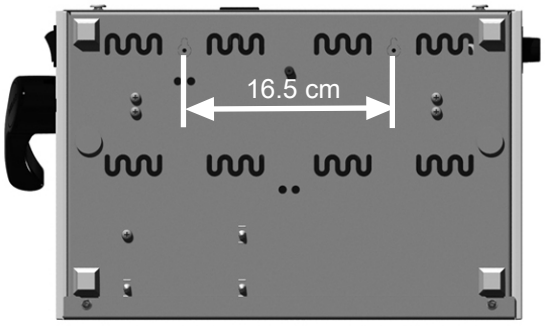
- Observe all the information contained in this chapter during commissioning.

- In accordance with current German specifications (VDE), the device is unsuitable for operation in areas exposed to the danger of explosion.
- The device is only intended for use in interior spaces.
- The device is conceived for use outside patient surroundings. The device should be located at least 1.5 m away (radius) from the treatment area.
- Install the device in a dry and dust-protected location.
- Maintain sufficient clearance to the surrounding surfaces in order to ensure sufficient ventilation.
- Ensure that the device is located away from direct sunshine and outside the range of other sources of heat.
- The device must be protected against blows or vibration.

Wall mounting

If the device is not to be placed on a table, it can be mounted on a wall. If this is the case, we recommend using the wall-mounted roll bracket optionally available. Proceed as follows:

1. Remove the perforated metal wall-mounting metal panels from the base of the sealing device.
2. Drill two Ø 6 mm boreholes in the wall with a clearance of 16.5 mm at the desired mounting height.



3. Insert two rawl plugs (Ø 6 mm) with round-head screws (Ø3.5 x 45 mm) in the boreholes.
4. Hang the sealing device on the screws.

Connecting the sealing device

Check the following points before connecting:

✓ *The sealing device has been switched off.*

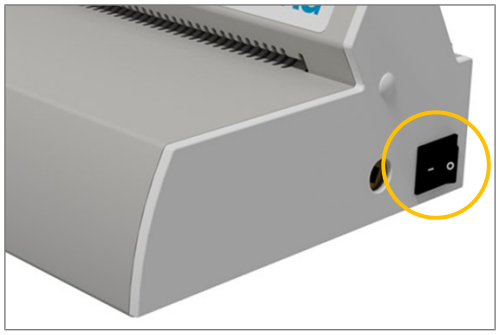
✓ *Use only the network cable included in the scope of delivery.*

1. Connect the one end of the power cable with the port on the rear of the sealing device and the other end with a mains socket with an approved voltage supply.

2. Insert the lever in the square hole on the left or right hand side of the device as required.

Switching on the sealing device

▸ Switch on the sealing device at the power switch. The control lamp on the fore side of the sealing device will illuminate yellow after activation.



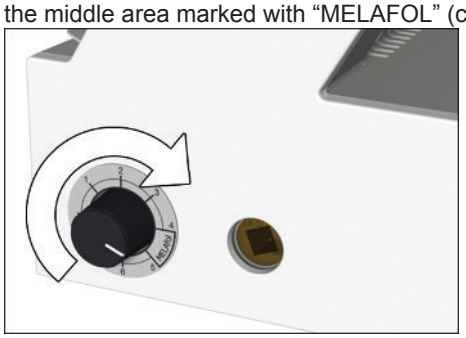
Operational Readiness

Chapter 3 – Initial Commissioning 10 Initial Commissioning Switching on the sealing device Switch on the sealing device at the power switch. The LED at the front of the sealing device will illuminate yellow after switching on. As soon as the control lamp is continuously illuminated green, the pre-set sealing temperature has been reached and the sealing device is ready to operate.

5 Sealing procedure

Sealing temperature

Continuously variable temperature regulation is performed using the rotary knob on the left-hand side of the sealing device. The sealing temperature is determined by the type of sterilization packaging. When using MELAfol transparent sterilization packaging as provided by MELAG, the rotary knob must point to the middle area marked with “MELAFOL” (corresponds to 180°C).



To reduce the sealing temperature, turn the knob leftwards in an anti-clockwise direction. To increase the sealing temperature, turn the rotary knob rightwards in a clockwise direction.

Sealing procedure with pre-finished film bags

CAUTION

Danger of burns from hot metal parts. The sealing rail is heated continuously when the sealing device is switched on.

- Never touch the metal surfaces on the cutting bar or in the area of the rear and fore paper guide directly.

NOTICE

Should the packaging be inserted incorrectly, this could result in the deposit of film residue on the sealing rail.

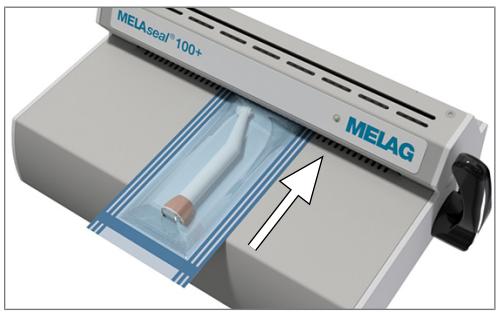
- The film side of the packaging must always face upwards.

PLEASE NOTE

When sealing MELAfol bags with a side crease, ensure compliance with the specifications of the relevant operating manual, especially when wishing to seal cassettes.

In order to perform a sealing procedure with prefabricated foil bags, proceed as follows:

1. Introduce the packaging in the paper guide with the foil side facing upwards and push the packaging through the pressure rail and sealing rail. Ensure maintenance of the correct clearance between the instrument and seal seam (consult the section DIN Specifications [▸ page 21]).



2. Press the lever forwards to its fullest extent until it snaps.

3. Leave the lever depressed as long as the control lamp flashes green in short intervals.
4. When the control lamp is continually illuminated green again, return the lever to its starting position.
5. After every successful sealing process carry out a visual inspection of the film.

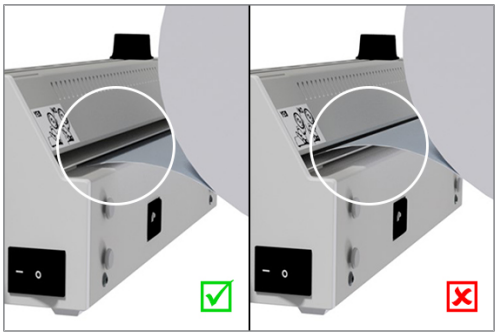
   ➥ The sealing procedure has been completed successfully.

Sealing procedure for film rolls

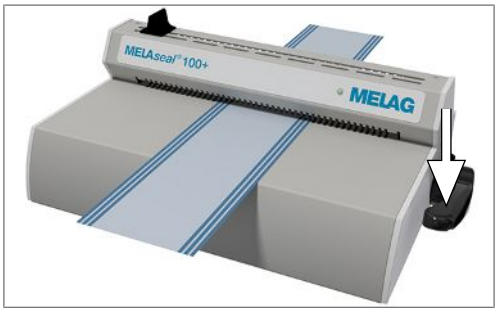
Produce film bag

If the instruments are packaged from the roll in transparent sterilization packaging bags, proceed as follows:

1. Introduce the film in the paper guide **from the rear** with the film side pointing upwards (**lower slit**) and slide the film forward between the pressure and sealing rail up to the desired length.

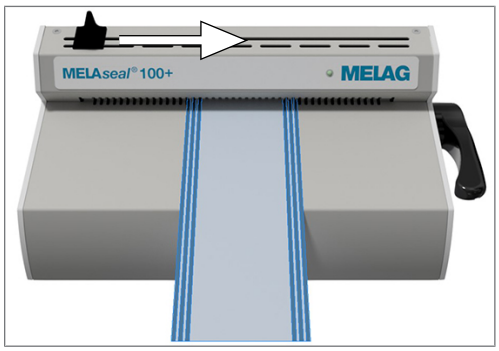


2. Press the lever forwards to its fullest extent until it snaps.



3. Leave the lever depressed as long as the control lamp flashes green in short intervals (for 3 seconds).

4. Ideally, the film should be cut off during the sealing procedure. Move the knife to the other end of the sealing device quickly; the lever should remain depressed. Do not return the knife handle.



5. If the control lamp illuminates continuously green, raise the lever and remove the film bag thus produced.

Sealing film bags

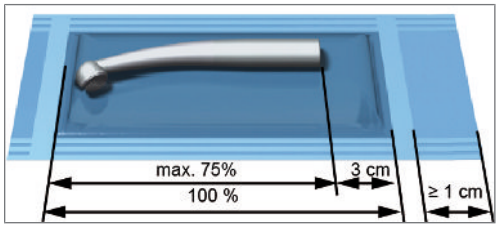
NOTICE

Should the packaging be inserted incorrectly, this could result in the deposit of film residue on the sealing rail.

- The film side of the packaging must always face upwards.

To seal on the corresponding length, proceed as follows:

1. Place the instrument in the film bag. Ensure maintenance of the correct clearance between the instrument and seal seam. Consult the section DIN Specifications [▸ page 21].



2. Slide the open side of the film bag from the front into the paper guide.

3. Press the lever forwards to its fullest extent until it snaps.

4. Leave the lever depressed as long as the control lamp flashes green in short intervals.
5. When the control lamp is continually illuminated green again, return the lever to its starting position.
6. After every successful sealing process carry out a visual inspection of the film.

↪ The sealing procedure has been completed successfully.

6 Maintenance

Cleaning and regular controls

Frequency	Action
Every 6 months	Clean the exterior of the sealing device with a non-fuzzing cloth and a stainless steel-cleaning agent suitable for use with medical products. It should not deposit any oily residue. Follow the following information when cleaning: ▪ Switch off the sealing device at the mains and remove the cable before cleaning. ▪ The cleaning cloth may never be allowed to become entirely wet in order to prevent water from entering the interior of the sealing device.

7 Pause times

Pause times

The sealing device can remained switched on over longer operating pauses of many hours. We recommend that the device remain switched off during long operating pauses so as to save energy.

Transport and storage

NOTICE

The use of unsuitable packaging can result in damage to the housing and the device interior.

- The device should only be transported in its original or otherwise suitable packaging.

Storage

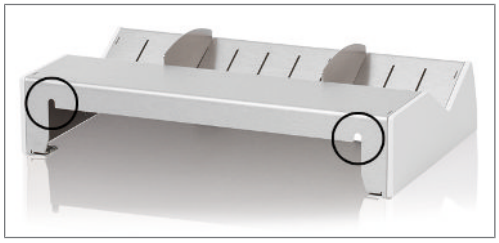
The device should be stored in such a way to protect against humidity.

8 Optional accessories

Roll dispenser “standard”

The roll dispenser "standard“ is placed directly behind the sealing device. The rolls of film are placed into the cavity and held in position using additional spacers located to the left and right. This prevents them from slipping.

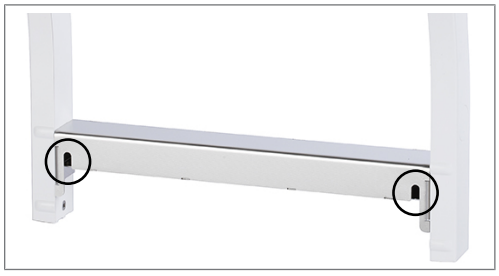
- Hook the roll dispenser "standard" into the outside brackets to fix it on the rear panel of the sealing device.



Roll dispenser “comfort”

The roll dispenser “comfort“ enables space-saving storage of the film rolls over the sealing device. The rolls are slid onto the rod laterally and held in position via additional spacers to the left and right. This prevents the roll from slipping.

- Hook the roll dispenser into the outside brackets to fix it on the rear panel of the sealing device.



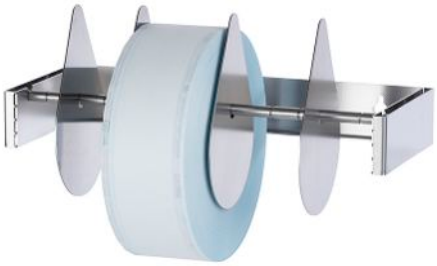
Roll dispenser "Deluxe“

In the roll dispenser "Deluxe", the rolls of film are stored above the sealing device, thus saving space. The integrated feeding device enables easy feeding of the film via a hand wheel.

Further information regarding assembly and operation is specified in the appendent operating manual.

Wall-mounted roll dispenser

Mounted on the wall directly over the sealing device, the wall-mounted roll dispenser saves space.



9 Manufacturer's Recommendation for Routine Operation

Frequency	Check/action	Criteria
Daily before operation	Making and checking a sample seal seam	**Visual check:** ▪ The seal seam should be distinct and even and not contain any creases or defects. ▪ The sealing seam should be almost identical with the works sealing seam, i.e. an industrial seal with an identical edge in terms of colour. ▪ The seal seam may not be too light or exhibit a brown colour. If too light → sealing temperature and/or contact pressure (sealing force) is too low; brown → sealing temperature is too high/sealing time too long. **Mechanical check:** ▪ Tear-resistance check: the strength required to open the seam must be exactly equal to that required to open the factory-produced seam → Peel test[1)] ▪ When peeled off, the paper should free itself from the film when peeling, leaving almost no residue.
Following every sterilization	Batch-related check of the seal seam	▪ Control the entire packaging for dryness and integrity. ▪ Clearance after sterilization, documentation within the scope of process clearance ▪ Check for dryness and integrity once again, before using the instruments.
Weekly	Checking the seal seam with aids	▪ Perform a visual control using MELAG seal check and document the results - for criteria and further information, see the MELAG seal check operation manual
Annually	Check the seal seam for tear-resistance in accordance with DIN EN 868-5, Appendix D.	▪ See the supplementary instructions of the MELAG seal seam strength test
After 50,000 cycles or 2 years (MELAseal 200, MELAseal Pro)	Maintenance	▪ Perform the maintenance in accordance with the MEALG maintenance instructions, including the replacement of wear parts.
Upon malfunction messages or obviously faulty seals	Remedying the fault	▪ Do not operate a defective sealing device. Inform an authorized customer services.

1) Performing the peel test:

1. Seal a sterilization package in the sealing device.
2. Place the sealed sterilization package in a sterilization cycle.
3. Working by hand, pull the seal seam along the direction of peeling slowly. Perform a visual check to verify whether the sealing seam extends consistently along the whole width and length of the sterilization package just sterilized. No paper residue greater than 10 mm is permitted on the seal seam.
4. Document the results.

MELAG seal seam strength test

For validating your sealing processes MELAG provides a seal strength test for a cost price of 85.00 € (D) or 125.00 € (AT, CH) plus V.A.T. (state 01/2017). After the film test strips have been tested, MELAG will issue a certificate. This certificate confirms conformity of the seal seam with the standard DIN EN 868-5, Appendix D. Use the MELAG seal seam strength test application form. The application form can be downloaded from the MELAG homepage (service/download center).

10 DIN Specifications

Explanation of terms

Term	Explanation
Sterile barrier system	DIN EN ISO 11607-2:2006 replaces the terms "packaging" "end packaging" and primary packaging" with the single term "sterile barrier system." A sterile barrier system is the minimum level of packaging facilitating successful sterilization, serving as a micro-biological barrier and permitting aseptic provision. This includes transparent sterilization packaging, a sterilization bag, reusable containers etc.
Protective packaging	The protective packaging is designed to provide the sterile barrier system with protection up until its final application.
Packaging system	The sterile barrier system and protective packaging combine to form the packaging system.
Peel test	A procedure to determine the peeling characteristics of paper/plastic composite material in accordance with DIN EN 868-5, Appendix E.

General information regarding the packaging and sealing procedure

Please observe the following during packaging and sealing:

- Choose packaging of a sufficient size
- Packaging made of porous materials and plastic composite film should be filled with a max. of up to 3/4 of its volume (DIN 58953-7:2010).
- When using transparent sterilization packaging from a roll, the removal side must have an overlap of min. 1 cm between the cutting edge and the seal seam, enabling an aseptic removal (DIN 58953-7:2010).
- Pressing together should remove all air before sealing.

Seal seam width

- The recommended nominal size for the width of the seal seam in the German standard DIN 58953 part 7 is 6 mm. Section 4.3.2 of DIN EN 868-5 requires a min. total seal width of 6 mm. The sum of the individual seams should amount to min. 6 mm.

This sealing device produces homogeneous seal seams of 10 mm in width with every sealing procedure.

Clearance of the seal seam to the cutting edge

- Maintain the clearance between seal seam and cutting edge as prescribed in the standard: The German standard DIN 58953, part 7 requires the maintenance of a sufficient overhang between the seal seam and the cutting edge when working with transparent bags on the removal edge. This ensures aseptic removal. We recommend a minimum overhang of 10mm.

Strength of seal seam

When using MELAfol transparent sterilization packaging, the sealing device guarantees a seal seam strength in accordance with EN 868-5.

Storage length for sterile medical products

The following requirements apply to the storage of sterile medical products:

- The rooms must be dry, cool and easy to clean.
- The rooms must not be accessible to everyday activity.
- We recommend protected storage in cupboards or drawers.

Guidelines for the storage period of sterile medical products according to DIN 58953-8

This standard applies to the delivery, storage, commissioning, transport and provision (including the packaging and marking of all sterile medical products to be used in healthcare institutions such as

hospitals and dental and medical practices. This standard applies to all medical products delivered in a sterile state and which are to be handled in such a manner so as that their quality is maintained until coming to aseptic application. According to DIN 58953-8 section 7.1.1, responsibility for compliance with the specified storage requirements and period is lies with the operator of the institution. According to section 7.2, loss of sterility is dependent less on the length of the storage time as from external influences during storage, as well as transport and handling. An ideal storage time can thus not be generally specified. The following table only makes recommendations regarding the storage length of sterile medical products.

Table 2: Storage length for sterile medical products

Packaging type	**Storage period**	
Sterile barrier system	**Unprotected storage**[1)]	**Protected storage**
Paper bag in accordance with DIN EN 868-4 and heatable, self-sealing transparent bag and hosing of paper and plastic composite film in accordance with DIN EN 868-5, or other equivalent packaging.	Serves provision for immediate use[2)]. Should be avoided as a method of storage.	6 months, although no longer than expiry date
Packaging system (a combination of a sterile barrier system and sterile packaging)	5 years, as far as the manufacturer has not determined an alternative expiry date.	
1) On shelves in rooms which do not correspond with room class II as defined by DIN 1946-4:2008-12. 2) Immediate use means application / use of the product within a maximum of 2 days / 48 hours.		

11 Accessories and spare parts

	Article	Art. no.
Accessories	Roll dispenser “standard”	00117
	Roll dispenser “comfort”	00111
	Roll dispenser "Deluxe“	00108
	Wall-mounted roll dispenser	00106
	Spacer washers (1 pcs.) for roll dispenser "comfort“ or wall-mounted roll dispenser	13330
	Spacer washers (1 pcs.) for roll dispenser "Deluxe"	88110
	Distance plate for roll dispenser "standard" (2 pcs.)	72335
	MELAG seal check	01079
Replacement parts	Lever, black	77000

12 Technical Data

Device type	MELAseal 100+
Device dimensions (WxDxH)	40.5 x 24 x 15 cm
Weight	5.4 kg
Electrical connection	220-240 V~, 50/60 Hz | 100-110 V~, 50/60 Hz*
Electrical power	300 W
Fuses	--
Max. altitude	2000 m
Ambient temperature	5-40 °C
Relative humidity	80 % at 31 °C, decreasing in a linear fashion up to a relative humidity of 50 % at 40 °C
Sealing temperature	160-200 °C
Sealing force	~100 N (factory settings, fix)
Sealing duration	3.0 sec. (factory settings, fix)
Seal seam width	10 mm
Seal length	max. 27.5 cm
Overheat control	> 240 °C

* refer to the type plate

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Responsible for content: MELAG Medizintechnik oHG
We reserve the right to technical alterations

Your stockist

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