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MELAG
competence in hygiene

User Manual

MELAseal® 100+

Sealing device



EN

Dear customer,

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 EN ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE

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1 General guidelines

Read this user manual carefully before commissioning the device. The user manual includes important safety information. The functionality and value-retention of this device depends on the care accorded to it. Store this user manual carefully and in close proximity to your device. It represents a component of the product.

Should the user manual no longer be legible, damaged or lost, obtain a new copy from MELAG. State the device type and your address in an e-mail.

The device type is specified on the type plate on the rear of the device.

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.

MELAconnect App

The MELAconnect app provides the following functions for MELAG sealing devices integrated in your practice network from any location in the practice.

- Access to user manuals and video tutorials for using the device
- Performing quick paperless documentation of routine checks of MELAG sealing devices
- Contacting the service technician (contact data must be entered manually)

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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.

Qualified personnel

- Only competent and trained personnel may use the sealing device.

Set-up, installation and commissioning

- Check the device after unpacking for any damage suffered during transport.
- The device is not suitable for operation in explosive atmospheres.
- Install and operate the device in a frost-free environment.
- The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.

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 device housing. 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 MELAG-authorized technician.

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3 Description of the device

Intended use

This sealing device is designed for application in a medical context, e.g. clinics and medical and dental practices. It was developed especially for the heat sealing of instruments in sterilization packaging and complies with the standard EN ISO 11607-2 and the German standard DIN 58953-7[1].

The bar sealing device MELAseal 100+ is not a medical device as defined by the Medical Device Regulation.

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, please consult your stockist or contact MELAG directly.

Unsuitable materials

Sterilization packaging that is not compatible with the requirements of DIN EN 868-5, is incompatible with this device:

- Pure hose film (double-sided film), as these tends to become adhere to the sealing rail, and can restrict the functionality of the sealing device.
- Polyethylene 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.

- Comply with the manufacturer's recommendations for the sealing temperatures suitable for each type of packaging material.

Scope of delivery

Please check the scope of delivery before setting up and connecting the device.

Standard scope of delivery

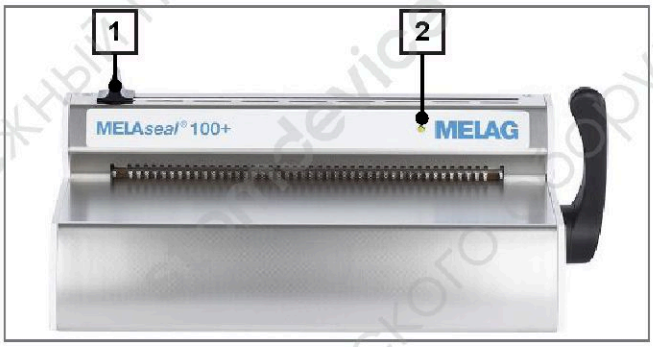
- MELAseal 100+ sealing device
- User manual
- Declaration of conformity
- Warranty certificate
- Power cable
- Sealing lever

[1] DIN = Deutsches Institut für Normung

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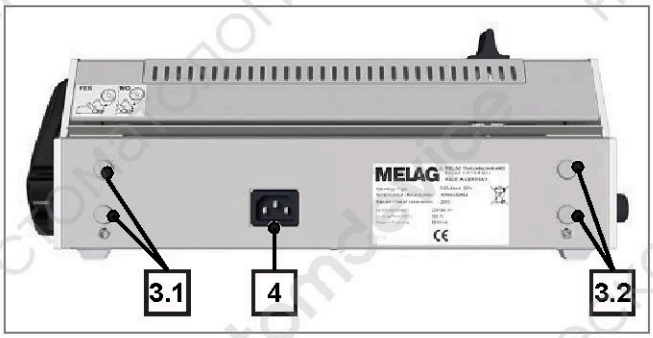
Views of the device

View from front



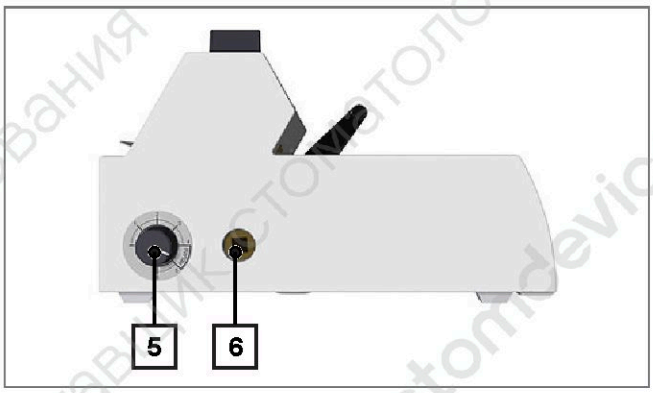
1 Knife handle
2 Control lamp

View from rear



3.1 Brackets for roll dispenser left
3.2 Brackets for roll dispenser right
4 Power cable connection

View from the left

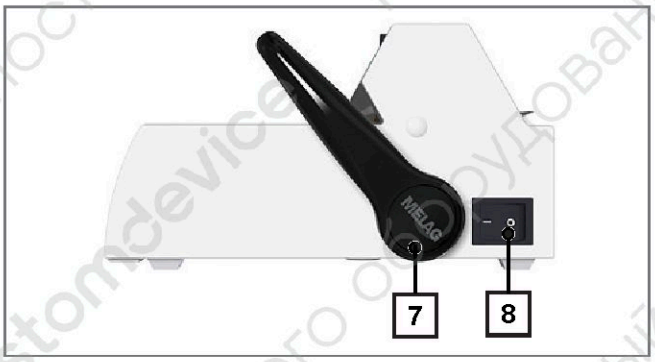


5 Rotary knob for temperature setting
6 Square hole for sealing lever (on both sides)

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View from the right



7 Sealing lever
8 Power switch (On/Off)

Symbols on the device


Manufacturer of the product


Date of manufacture of the product



Product serial number from the manufacturer



Article number of the product


Electrical connection of the device: AC current


The user manual includes important safety information. Failure to comply with these instructions can result in injury and material damage.


Please read this user manual carefully before commissioning the device.


In affixing the CE mark, the manufacturer declares that this product fulfils the corresponding EU requirements.


The device may not be disposed as domestic waste. The vendor is responsible for appropriate disposal of the device - it must be delivered to the vendor to be disposed of.

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Status display and acoustic signal

	Control lamp / acoustic signals	Possible cause	Measure
	LED illuminates orange	The sealing device is in the heating or cooling phase.	Wait until the pre-set sealing temperature has been reached.
	LED flashes red, warning signal sounds	▪ The sealing lever is depressed during the heating phase. ▪ The sealing temperature has not yet been achieved.	Wait until the LED is continuously illuminated green.
	LED illuminates green	▪ The sealing device has reached the pre-set sealing temperature and is ready for operation. ▪ The pre-set sealing duration (4 s) has been reached. The sealing procedure has been completed.	Raise the sealing lever and remove the packaging.
	LED flashes green	The sealing procedure runs when the sealing lever is depressed (4 s).	Wait until the LED is continuously illuminated green.
	LED illuminates red, warning signal sounds (malfunction)	The sealing lever has been raised early, despite the required sealing duration not having been reached.	Keep the sealing lever depressed until the green LED is continuously illuminated.
		The sealing lever has not been raised, despite the required sealing duration having been completed.	Lift the sealing lever as soon as the sealing duration has been reached so that the film is not burnt.
		Device malfunction: The heating phase takes too long (> 5 min). The sealing device does not reach the pre-set sealing temperature.	Upon repeated incidence, contact an authorized customer services or stockist technician.

PLEASE NOTE

Should further status displays or acoustic signals be issued, contact an authorized customer services or stockist technician.

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4 Commissioning

Requirements of the installation location

CAUTION

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

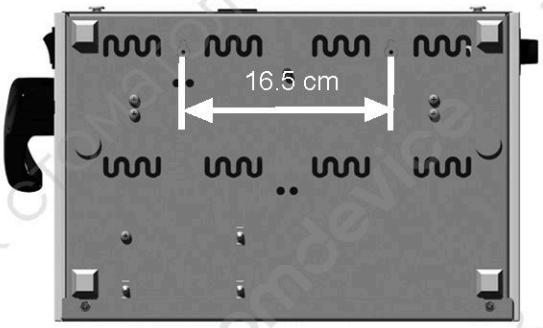
- Comply with all the specifications of this chapter for initial commissioning.

- The device is not suitable for operation in explosive atmospheres.
- The device is only intended for use in interior spaces.
- The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away 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 sealing device is located away from direct sunshine and outside the range of other sources of heat.
- Set-up the device protected against blows or vibrations.

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 (Ø 3.5 x 45 mm) in the boreholes.
4. Hang the sealing device on the screws.

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Connecting the sealing device

✓ *The sealing device has been switched off.*

✓ *Use the power cable included in the scope of delivery.*

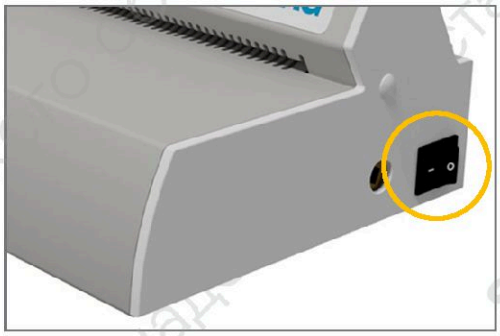
1. Connect the rubber connector of the power cable to the rear side of the sealing device and connect the power plug in the mains socket.

2. Insert the sealing lever in the square hole on the right or left 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

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.

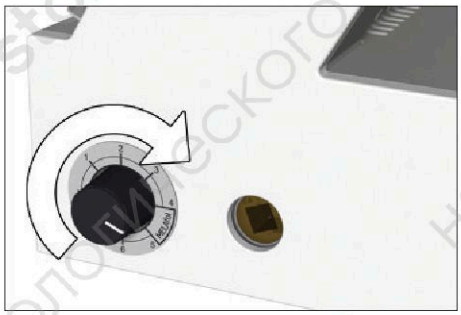
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5 Sealing

Sealing temperature

Infinitely variable temperature control is performed via 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, turn the rotary knob to point to the middle of the area marked with “MELAfol” (corresponds to 180 °C).



To reduce the sealing temperature, turn the rotary knob anti-clockwise. To increase the sealing temperature, turn the rotary knob clockwise.

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 sealing rail and in the area of the rear and fore paper guide directly.

NOTICE

Inserting the packaging inverted can result in the adhesion of film residue to the sealing rail.

The film side of the packaging must always face upwards.

PLEASE NOTE

When sealing MELAfol bags with a side gusset, ensure compliance with the manufacturer’s specifications (e.g. the operating manual of MELAfol) especially when wishing to seal cassettes.

In order to perform a sealing procedure with a prefabricated film bag, proceed as follows:

1. Lead the packaging (the film side facing upwards) from the front into the paper guide between the pressure and sealing rail. Ensure maintenance of the correct clearance between the instrument and seal seam (see Standard specifications [▶ page 21]).



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2. Press the sealing lever down until it latches.



3. Leave the sealing lever depressed until the control lamp flashes green in short intervals (approx. 4 s).
4. When the control lamp is continuously illuminated green again, return the sealing lever upwards to its starting position.
5. Perform a visual inspection of the film after every successful sealing procedure.

PLEASE NOTE

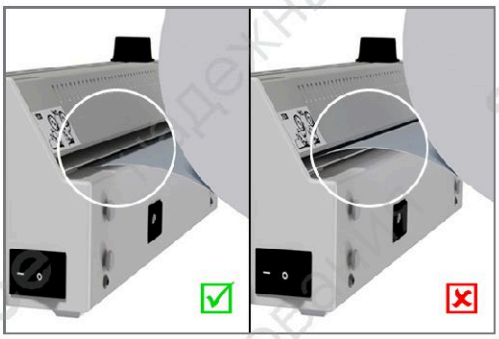
With bags with side gussets, perform weekly controls of the seal seam using an ink test (e.g. MELAink test).

Sealing procedure for film rolls

Produce film bag

To package instruments in transparent sterilization packaging bags from the roll, proceed as follows:

1. Guide the end of the film roll along the device rear panel into the lower paper guide with the paper side facing downwards (**lower slit**). Slide the film forwards and between the pressure and sealing rail to the desired length.



2. Press the sealing lever down until it latches.

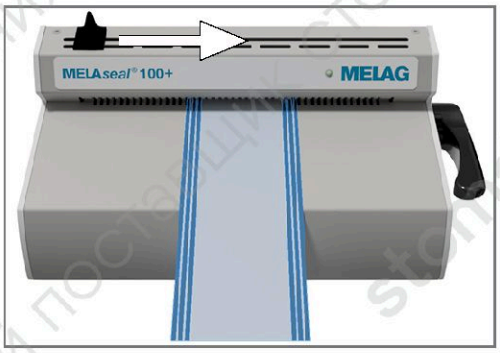


3. Leave the sealing lever depressed until the control lamp flashes green in short intervals (approx. 4 s).

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



5. As soon as the LED control lamp is continuously illuminated green, raise the sealing lever and remove the film bag thus produced.

Sealing film bags

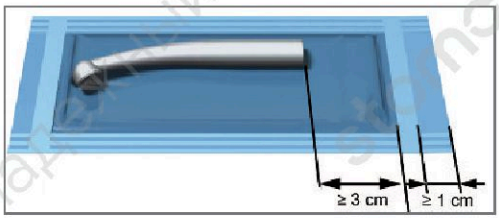
NOTICE

Inserting the packaging inverted can result in the adhesion of film residue to the sealing rail.

The film side of the packaging must always face upwards.

To seal the film bag cut to the corresponding length, proceed as follows:

1. Place the instruments to be sterilized in the film bag. Ensure maintenance of the correct clearance between the instrument and seal seam (see Standard specifications [▸ page 21]).



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



3. Press the sealing lever down until it latches.



4. Leave the sealing lever depressed until the control lamp flashes green in short intervals (approx. 4 s).
5. When the control lamp is continuously illuminated green again, return the sealing lever upwards to its starting position.
6. Perform a visual inspection of the film after every successful sealing procedure.

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6 Maintenance

Cleaning and regular controls

Comply with the following information when cleaning:

- Switch off the sealing device at the power switch and remove the power plug 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.

Frequency	Measure
When necessary and every 6 months	Clean the exterior of the sealing device with a dry or damp, non-fuzzing cloth and where necessary with a neutral fluid cleaner or spirit. Only at persistent soiling, use a mild stainless steel cleaning agent with a pH value between 5 and 8.

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7 Pause times

Pause times

The sealing device can remain switched on over longer operating pauses of many hours. MELAG recommends switching off the device during long operating pauses to save energy.

Transport and storage

NOTICE

Damage to the housing and the device interior as a result of using unsuitable transport packaging.

- Only transport the device in its original packaging or other suitable packaging.

- Store and transport the device frost-free.
- Avoid strong shocks/vibrations.
- Store the device in a fashion protected against moisture.

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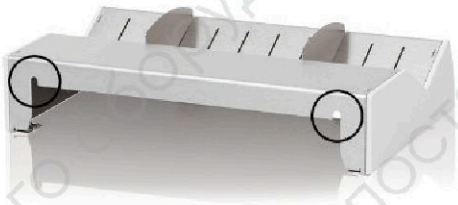
8 Optional accessories

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.



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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.



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9 Manufacturer's recommendation for routine operation

Video tutorial

See also “Manufacturer’s Recommendation for Routine Operation”.

Frequency	Check:	Measures
Daily before operation	Making and checking a test seal seam	**Visual check:** ▪ The seal seam should be distinct and even and not contain any creases or defects. ▪ The colour of the seal seam should be identical with the works seal seam (industrial seam). ▪ The seal seam may not be too light or brown (too light: Sealing temperature and/or contact pressure (sealing force) too low; brown sealing temperature too high or sealing duration too long). **Mechanical check:** ▪ Tear-resistance check: the strength required to open the seal seam must be exactly equal to that required to open the works-side seam, i.e. industrial seam, see Performing the peel test [▸ page 20]. ▪ During peeling, the paper should free itself from the film, leaving almost no residue.
Following every sterilization	Batch-related seal seam check	▪ Control the entire packaging for dryness and integrity. ▪ Clearance after sterilization, documentation within the scope of process approval. ▪ Check for dryness and integrity once again, before using the instruments.
Weekly	Check the seal seam with resources	Perform a visual control using MELAG Seal Check and document the results (e.g. using the MELAconnect app) – for criteria and further information, see the MELAG Seal Check operating manual.
Annually	Check the seal seam for tear-resistance in accordance with DIN EN 868-5, Appendix D	See MELAG seal seam stability test [▸ page 20]
Upon malfunction messages or obviously faulty seals	Remedying the malfunction	Do not operate a defective sealing device. Inform an authorized customer services.

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Performing the peel test

1. Seal a transparent sterilization packaging in the sealing device.
2. Place the sealed transparent sterilization packaging in a sterilization cycle.
3. Working by hand, pull the seal seam apart slowly along the direction of peeling. Perform a visual check to verify whether the seal seam extends consistently along its entire width and length. No more than 10 mm paper fraying is permitted on the seal seams.
4. Document the results.

MELAG seal seam stability test

For validating your sealing processes MELAG provides a seal seam stability test for a cost price of 125.00 € plus V.A.T. (state 01/2020). After the film test strips have been tested successfully, 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 stability test application form. The application form can be downloaded from the MELAG homepage (Service/Download Center).

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10 Standard specifications

Explanation of terms

Term	Explanation
Sterile barrier system	EN ISO 11607-2 replaces the terms “packaging”, “final packaging” and “primary packaging” with the single term “sterile barrier system”. A sterile barrier system is the minimum level of packaging which prevents the penetration of micro-organisms and permits aseptic provision of the product at the location of use. 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

Comply with the following during packaging and sealing:

- Choose packaging of a sufficient size
- Packaging made of porous materials and plastic composite film should be filled to a max. of 3/4 of its volume (DIN 58953-7).
- In packaging made of porous materials and plastic composite film, a minimum of 30 mm must remain free between the sterilization material and the seam to be sealed (DIN 58953-7).
- 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).
- Press together to remove all air before sealing.

Seal seam width

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

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

Distance between the seal seam and the cutting edge

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

Seal seam stability

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

Storage duration for sterile medical devices

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

- 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.

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Guidelines for the storage duration of sterile medical devices in accordance with DIN 58953-8

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

Storage duration for sterile medical devices

Packaging type	**Storage duration**	
Sterile barrier system	**Unprotected storage*)**	**Protected storage**
Paper bag in accordance with DIN EN 868-4 and heatable, self-sealing transparent bag and tubing of paper and plastic composite film in accordance with DIN EN 868-5, or other equivalent packaging.	Serves supply for immediate use**). 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 protective packaging)	5 years, as far as the manufacturer has not determined an alternative expiry date.	
*) On shelves in rooms which do not correspond with room class II as defined by DIN 1946-4. **) Immediate use means application or use of the product within a maximum of two days or 48 hours.		

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11 Technical Data

Device type	MELAseal 100+
Device dimensions (W x D x H)	41.5 x 24 x 15 cm
Weight	5.4 kg
Electrical connection	
Power supply	220-240 V, 50/60 Hz | 100-110 V, 50/60 Hz[2)]
Electrical power	max. 300 W, average 100 W
Fuses	--
Overheat control	> 240 °C
Length of the power cable	2 m
Ambient conditions	
Max. altitude	2000 m
Ambient temperature	5-40 °C
Relative humidity	max. 80 % at 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)
Sealing characteristics	
Seal temperature range	100-210 °C
Sealing force	~100 N (factory settings, fix)
Sealing duration	min. 4 s (factory settings, fix)
Seal seam width	10 mm
Seal length	max. 27.5 cm

[2)] See type plate

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12 Accessories and spare parts

You can obtain the specified articles and an overview of further accessories from your stockist.

	Article	Art. no.
Accessories	Roll dispenser “standard”	10117
	Roll dispenser “comfort”	10111
	Roll dispenser “Deluxe”	10108
	Wall-mounted roll dispenser	00106
	Spacer washer (1 pcs.) for wall-mounted roll dispenser	13330
	Spacer washer (1 pcs.) for roll dispenser “Deluxe” and “comfort”	89740
	Distance plate for roll dispenser “standard” (2 pcs.)	72335
	MELAG Seal Check	01079
	MELAink Test	01089
Spare parts	Lever, black (sealing lever)	77000

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Original instructions

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