Operating Manual

MELA*seal*®100+

Bar sealer

Dear Dr.

We should like to extend our thanks for the expression of trust in our company which you have displayed through 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 systems 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 conducted by the certification agency BSI. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

General Guidelines

Please read these operating instructions carefully before commissioning the sealing device. The instructions include important safety information. The functionality and value-retention of this autoclave depend on the care accorded to it.

Make sure to keep the Operating Manual near to the device. It represents a component of the product.

User Group

This manual is targeted at doctors, medical assistants and service.

Symbols used

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

Formatting rules

Symbol	Explanation
OPEN	Words or phrases appearing on the display of the sealing device are marked as display text.
see **Chapter 2**	Reference to another text section within this manual.
Fig. 1/(3)	Reference to a detail in a figure – in the example, to part no. 3 in figure 1.

Contents

Chapter 1 – Performance Specifications 5
Proper use 5
Chapter 2 – Device Description 6
Views of the device 6
Control lamp status display and acoustic signals 7
Chapter 3 – Initial Commissioning 8
Transport and storage 8
Conditions of storage and installation 8
Requirements of the set-up location 8
Wall mounting 8
Connecting the sealing device 9
Commissioning 10
Simple sealing procedure 10
Sealing procedure for rollstock 11
Seal seam width 13
Sealing temperature 13
Chapter 4 – Optional Accessories 14
Reel dispenser “standard” 14
Reel dispenser “Comfort” and “Deluxe” 14
Wall-mounted reel dispenser 15
Chapter 5 – Maintenance 16
Cleaning and regular controls 16
Replacing the blade 16
Manufacturer's Recommendation for Routine Operation 18
DIN Specifications 20
Terms 20
General information regarding the packaging and sealing procedure 20
Seal seam width 20
Strength of seal seam 20
Accessories and Replacement Parts 21
Technical Data 21

⚠Safety Instructions

When operating the sealing device, please ensure that you observe the following safety instructions as well as those contained in following chapters.

Power cable and mains socket

- Only the power cable included in the scope of delivery may be connected to the sealing device.
- Liquids may not be permitted to reach the interior of the sealing device. This could result in an electrical shock or short circuiting.

Repair

- Never open the housing of the sealing 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 sealing device is opened by anyone other than a member of a MELAG-authorized technical customer service.

Chapter 1 – Performance Specifications

Proper 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 transparent sterilization packaging according to DIN EN 868-5 such as e.g. MELA*fol*.

Should you wish to use packaging materials other than those specified above, please consult your stockist first or contact MELAG directly.

Unsuitable foils and materials

- Tubular film (double-sided film) is not suitable for use in this sealing device as these types tend to become glued together on the sealing rail, thus restricting the functionality of the sealing device.
- Polyethylene film
- Soft PVC film
- Hard PVC film
- Polyamide film
- Polypropylene film

PLEASE NOTE

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.

Chapter 2 – Device Description

Scope of delivery

Please check scope of delivery before connecting the sealing device.

Standard scope of delivery

- MELA*seal*®100+ sealing device
- Power cable
- Operating Manual
- Certificate of Conformity
- Warranty certificate
- Lever
- Torx key for housing screws

Views of the device

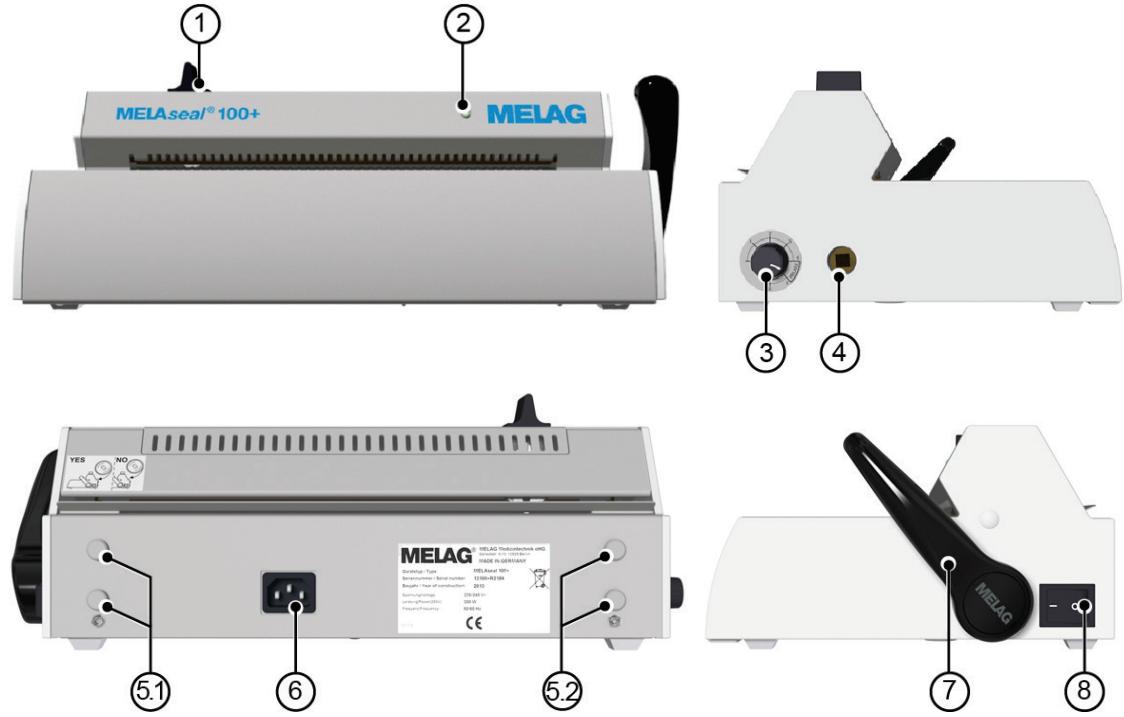


Fig. 1: Views of the device

(1) Knife handle
(2) Control lamp
(3) Rotary knob for temperature adjustment
(4) Square hole for lever (double-sided)
(5.1/5.2) Reel dispenser “comfort”
(6) Power cable socket
(7) Lever
(8) Power switch (ON/OFF)

Control lamp status display and acoustic signals

Table 1: Explanation of the warning lights and the acoustic signals

Warning lights/acoustic signals	Possible cause	Risk management
illuminated yellow	The sealing device is currently warming up or cooling down	Please wait until the pre-set sealing temperature has been reached.
Flashes red, warning signal	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.
Illuminated 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.
Flashes green	The sealing procedure is running (3 sec) and the lever has been depressed.	Please wait until the LED is constantly illuminated green.
illuminates red, warning signal (malfunction)	The lever has been raised early, despite the required sealing time not having been reached. The lever has not been raised, despite the required sealing time having been completed. The heating phase is taking too long (> 5 min.); the sealing device cannot reach the pre-set sealing temperature.	Please keep the lever depressed until the green LED is constantly illuminated. Lift the lever as soon as the sealing time has been reached so that the film is not burnt.

Chapter 3 – Initial Commissioning

Transport and storage

WARNING

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

- The sealing 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.

Conditions of storage and installation

- In accordance with current VDE specifications, the sealing device is unsuitable for operation in areas exposed to the danger of explosion.
- The sealing device is conceived for use outside patient surroundings. The device should be located at least 1.5 m away (radius) from the treatment area.
- Observe all the information contained in this chapter during commissioning.

DANGER

Damages to the sealing device and/or injuries can occur in case the installation conditions are not observed.

Requirements of the set-up location

Observe the following requirements:

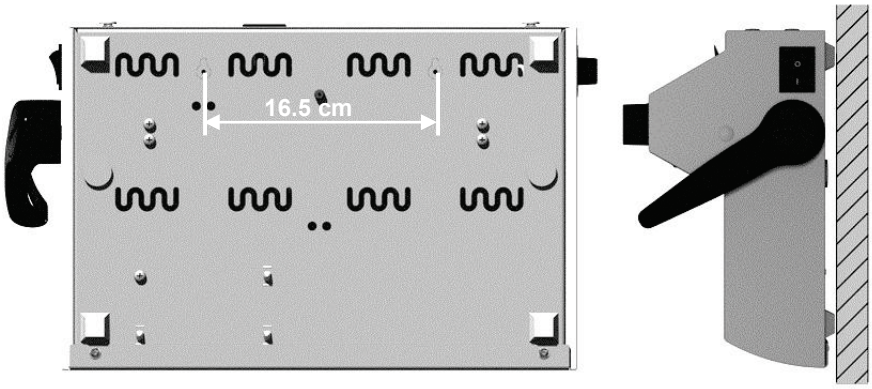
- ✓ *The site of setup is dry and dust-protected.*
- ✓ *Sufficient clearance to the surrounding surfaces is available in order to ensure sufficient ventilation.*
- ✓ *The sealing device is located away from direct sunshine and outside the range of other sources of heat*
- ✓ *The sealing device is protected 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 (6mm) with round-head screws (Ø3.5 x 45 mm) in the bore holes.
4. Hang the sealing device on the screws.

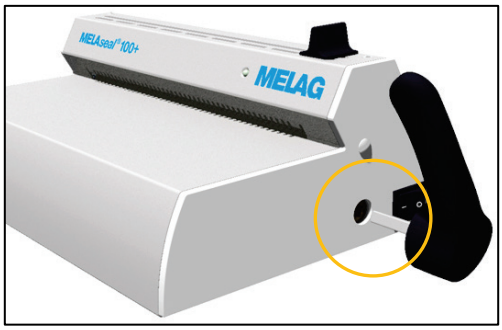
Connecting the sealing device

Connecting the sealing device

Check the following before connecting the sealing device:

- ✓ *The device power switch is off.*
- ✓ *The power cable included in the scope of delivery is used for connecting.*

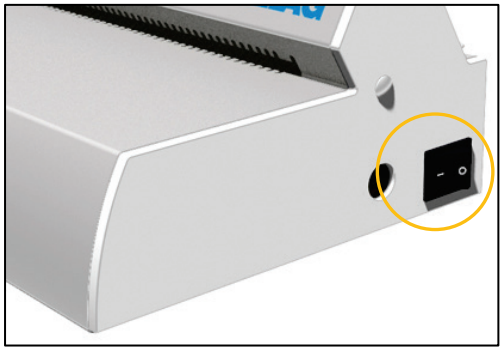
1. Connect the one end of the power cable with the port on the rear of the sealing device and the other end with a mains socket with an approved voltage supply (in accordance with the name plate on the rear of the sealing device).
2. Insert the lever in the square hole on the left or right-hand side of the device as required (Fig. 1/(4)).



Commissioning

Switching on the sealing device

Activate the sealing device at the power switch.



The LED at the front of the sealing device (Fig. 1/(2)) 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.

Simple sealing procedure

DANGER

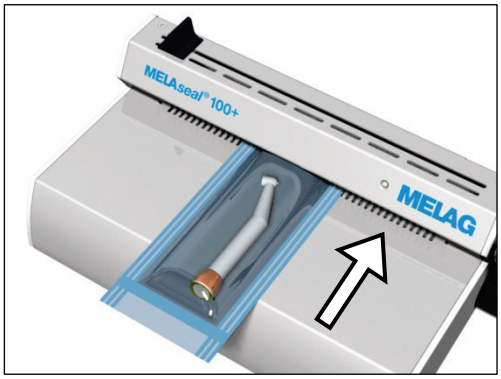
The sealing bar is heated continuously after the sealing device has been switched on. The surrounding metal components are hot!

Touching the hot metal surfaces can cause burns.

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

In order to perform a simple sealing procedure, proceed as follows:

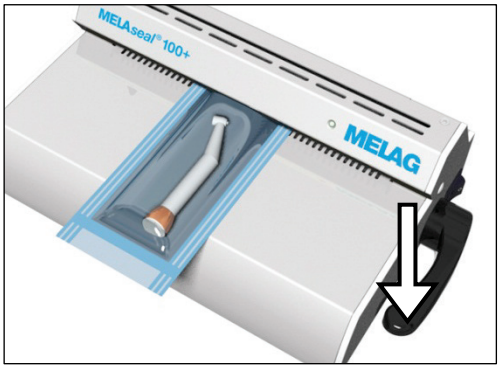
1. Introduce the packaging in the paper guide with the foil side facing upwards and push the packaging through the pressure bar and sealing bar. Ensure maintenance of the correct clearance between instrument and seal seam (consult the relevant section of the **DIN Specifications**).



WARNING

The film side of the packaging must always face upwards. Should the packaging be inserted incorrectly, this could result in the deposit of film residue on the sealing rail.

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



3. Leave the lever depressed as long as the control lamp flashes green in short intervals (for 3 seconds).
4. When the control lamp is continually illuminated green again, return the leaver to its starting position.
5. The sealing procedure has been completed successfully.
6. After every successful sealing process carry out a visual inspection of the film.

Sealing procedure for rollstock

DANGER

The sealing bar is heated continuously after the sealing device has been switched on. The surrounding metal components are hot!

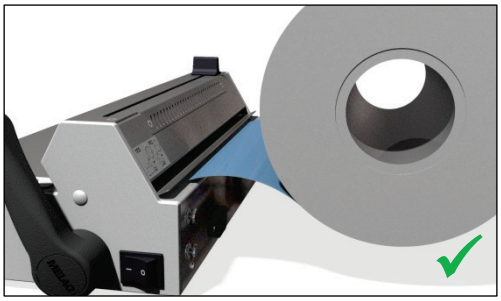
Touching the hot metal surfaces can cause burns.

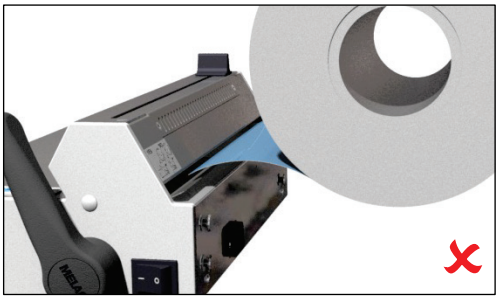
- Never touch the metal surface on the cutting bar and on the rear and fore paper guide directly.

Cutting the film

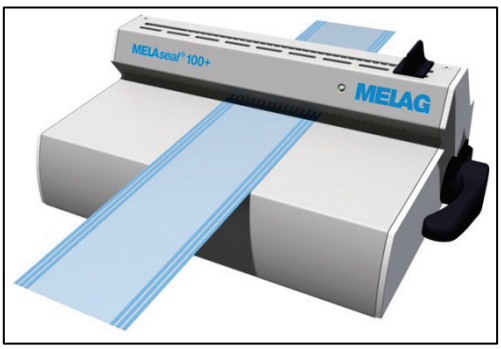
If the instruments are packaged from the roll in transparent sterilization packaging bags, proceed as follows:

1. Introduce the film in the paper guide (**lower slot**) **from the rear** with the paper side facing downwards and push the packaging forward through the pressure bar and sealing bar until reaching the desired length.

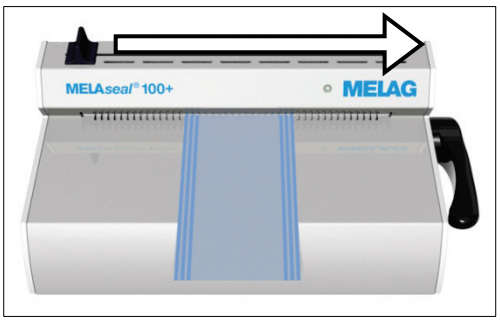




2. Press the lever forwards to its fullest extent until it clicks.



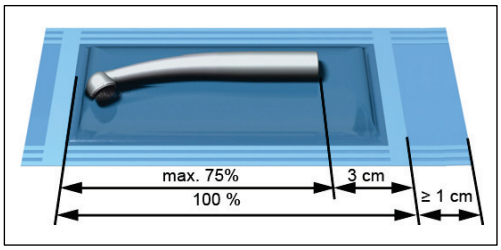
3. Leave the lever depressed as long as the control lamp flashes green in short intervals (for 3 seconds).
4. To cut the film during the sealing process, move the knife handle to the other end of the sealing device quickly. The lever should remain depressed. Do not return the knife handle.



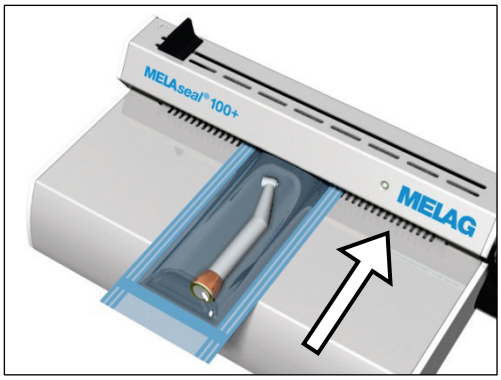
Sealing film bags

In order to seal the cut to length film bag, proceed as follows:

1. Place the instruments to be sterilized in the bag thus produced. Ensure maintenance of the correct clearance between instrument and seal seam (consult the relevant section of the (**DIN Specifications**).

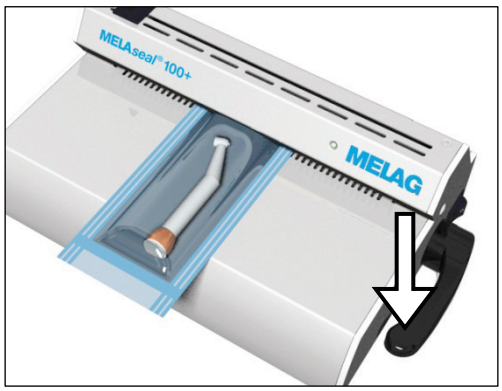


2. Slide the open side of the bag from the front into the paper guide.



WARNING
The film side of the packaging must always face upwards. Should the packaging be inserted incorrectly, this could result in the deposit of film residue on the sealing rail.

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



4. Leave the lever depressed as long as the control lamp flashes green in short intervals (for approx. 3 seconds).
5. When the control lamp is continually illuminated green again, return the leaver to its starting position.
6. The sealing procedure has been completed successfully.

PLEASE NOTE
When sealing MELAfol sealing bags with lateral creases, please observe and comply with the special information contained in the sealing bag operating manual regarding sealing cassettes.

Seal seam width

The sealing device produces homogenous 10 mm wide seal seams with every sealing procedure.

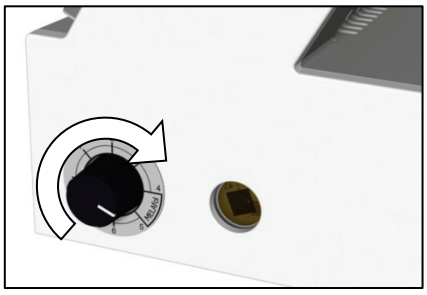
The recommended nominal size for the width of the seal seam in the German standard DIN 58953 part 7 is only 6 mm.

> ***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.***

Sealing temperature

Continuously variable temperature regulation is performed using the rotary knob (Fig. 1/(3)) on the left-hand side of the sealing device. The sealing temperature is determined by the type of sterilization packaging.

When using MELA*fol* transparent sterilization packaging as provided by MELAG, the rotary knob should point to the middle area marked with “MELAFOL” (corresponds to 180°C).



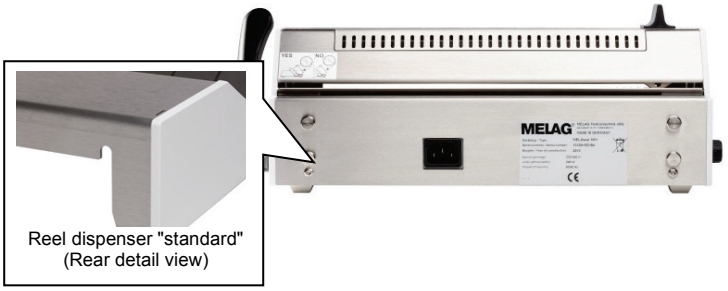
To reduce the sealing temperature, turn the knob leftwards in an anti-clockwise direction.
To increase the sealing temperature, turn the rotary knob rightwards in a clockwise direction.

Chapter 4 – Optional Accessories

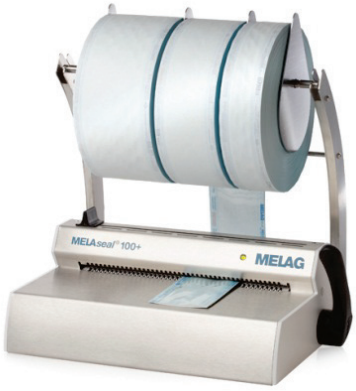
Reel dispenser “standard”

The reel 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.

The reel dispenser “standard“ is hooked onto the brackets on the rear of the sealing device.



Reel dispenser "standard"
(Rear detail view)



Reel dispenser “Comfort” and “Deluxe”

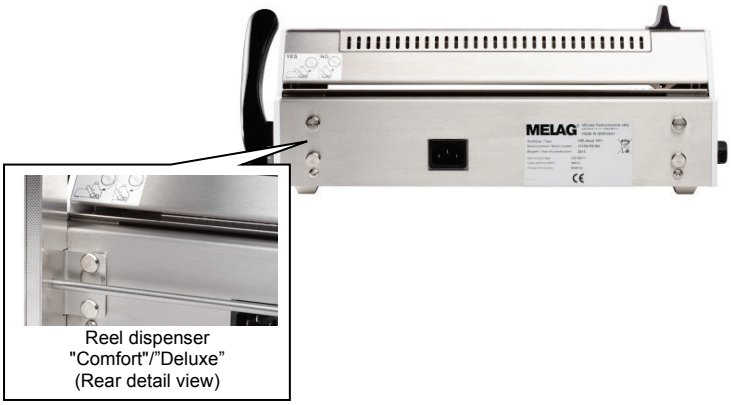
The reel dispenser “Comfort“ enables space-saving storage of the film rolls over the sealing device.

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 and turning as well.

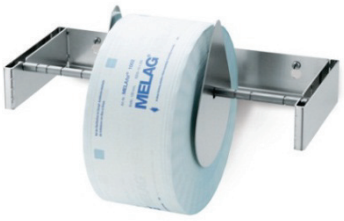
In the roll dispenser "deluxe", the film rolls are stored above the sealing device, thus saving space.

The integrated feeding device enables easy feeding of the film via a hand wheel.

The reel dispensers “Comfort“ and “Deluxe” are hooked onto the brackets on the rear of the sealing device.



Reel dispenser
"Comfort"/"Deluxe"
(Rear detail view)



Wall-mounted reel dispenser

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

Chapter 5 – Maintenance

Cleaning and regular controls

The outside of the sealing device should be cleaned at least twice a year. Only use a lint-free damp cloth stainless steel-cleaning agent suitable for use with medical products. It should not deposit any oily residue.

Observe the following instructions when cleaning:

- Before every cleaning switch off the sealing device at the power switch and remove the power plug.
- The cleaning cloth may never be allowed to become entirely wet in order to prevent water from entering the interior of the sealing device.

Replacing the blade

DANGER

Failure to observe this provision can result in a short circuit and/or an electric shock.

- Switch off the sealing device at the mains and remove the cable.

DANGER

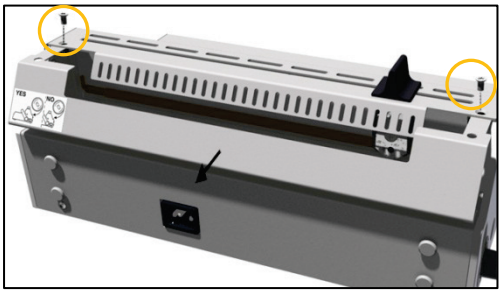
Metal surfaces of the sealing device become hot during operation.

Touching the hot metal surfaces can cause burns.

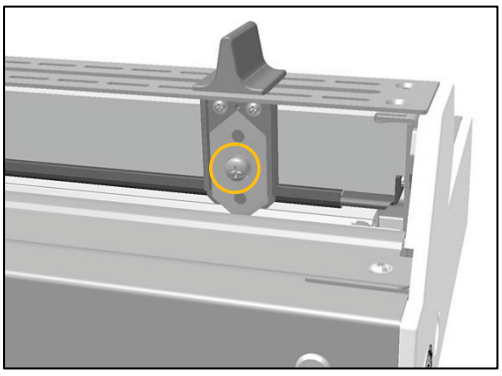
- Allow the sealing device to cool before opening.

Proceed as follows to replace the blade:

1. Remove the 2 TORX screws (Torx 20) from the upper side of the sealing device on the cutting bar using the TORX screwdriver included in the scope of delivery.
2. Remove the upper rear housing cover rearwards.



3. Loosen the screws on the blade.
4. Turn the blade 180° in order to use the other side of the blade or replace it entirely.



5. Return the screws.
6. Replace the unit housing and secure with the Torx screws.
   Press the fore housing cover against the rear housing cover in order to return the Torx screws.

PLEASE NOTE
When assembling the sealing device, ensure that the blade is able to move freely from side to side.

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. If the sealing seam is too light, → the sealing temperature and/or the contact pressure (sealing force) is too low; If the sealing seam is brown, → the sealing temperature is too high or the sealing duration 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, leaving almost no residue
Following every sterilization	Batch-related check of the 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 (MELA*seal* 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. Notify the authorized customer services

[1)] Performing the peel test:
1. Seal the sterilization packaging in the sealing device.
2. Place a sealed sterilization packaging in a sterilization cycle.
3. Slowly pull apart (by hand) the sealing seam in the direction of peeling. The visual check is to verify whether the sealing seam extends along the whole width and length. No paper residue greater than 10 mm is permitted on the seal seam. Document the results.

MELAG seal seam strength 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 01/2015)

After the film test strips have been tested, MELAG will issue verification of testing and if successful, 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 (http://www.melag.de/en/service/download-center/recommendations).

DIN Specifications

Terms

Sterile barrier system

DIN EN ISO 11607-2:2006 replaces the terms "packaging" "final packaging" and immediate 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 bags, 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:

- Do not select undersized packaging.
- 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

Maintain the seal seam width stipulated in the standard:

- The width of the seal seam for sterilization packaging e.g. transparent sterilization packaging should amount to a min. 6 mm. With grooved seal seams, the sum of the individual seams should amount to min. 6 mm (DIN EN 868-5:2009).

Strength of seal seam

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

Accessories and Replacement Parts

	Article	Article no.
Accessories	Reel dispenser “standard”	00117
	Reel dispenser “Comfort”	00111
	Reel dispenser “Deluxe”	00108
	Wall-mounted reel dispenser	00106
	Distance plate (1 pcs) for reel dispenser "Comfort" or wall-mounted reel dispenser	13330
	Distance plate (1 pcs) for reel dispenser "Deluxe"	88110
	Distance plate for reel dispenser "standard" (2 pcs.)	72330
	MELAG seal check	01079
Replacement parts	Knife blade	17781
	Knife holder black (without blade)	45610
	knife handle black	45600

Technical Data

Model name	**MELA*seal*® 100+**
Device dimensions (WxDxH)	41.5 x 24 x 15 cm
Weight	5.4 kg
Electrical connection	220 - 240 V 50/60 Hz 100 – 110 V 50/60 Hz
Power input	300 W
Seal temperature range	160 - 200°C
Seal seam width	10 mm
Seal seam length	max. 27.5 cm
Sealing time	3.0 sec. (factory settings, fix)
Sealing force	~100 N (factory settings, fix)
Overheating protection	>240°C

MELAG Medizintechnik oHG
Geneststraße 6-10
10829 Berlin
Germany
E-Mail: info@melag.de
Web: www.melag.de

Responsible for content: Technical Office

Your stockist: