Dear Doctor:

Thank you very much for the trust which you have shown by purchasing this package sealing device.

For more than 55 years now, MELAG — a medium-sized family-owned and -operated business — has specialized in the production of sterilization equipment for medical practice. During this period, 420,000 MELAG units sold throughout the world testify to the exceptional quality of our sterilizers.

This package sealing device has also been produced and tested in accordance with the strictest quality criteria. Please read the operating Instructions. Careful use and maintenance will ensure that our product has a long working life and maintains its value.

The staff and management of MELAG
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1 Installation

1.1 Overview of appliance

Illustration 1: Overview of appliance

1 Cutter
2 Handle
3 Main switch
4 Signal lamp
5 Knob for temperature regulation
6 Paper guide
7 Upper rear enclosure hood
8 Upper enclosure front

1.2 Power cable and pressure lever

The power cable should be plugged into a 230 V (or only for device variant 110V), 50/60 Hz safety socket with earthing.

Then switch the power on (Illustration 1 item 3). The MELAseal®100 will now warm up for about 3 minutes, and is ready for use when the signal lamp (Illustration 1 item 4) is no longer illuminated.

The pressure handle (Illustration 1 item 2) can be inserted at either the bottom right or bottom left side of the appliance.

1.3 Sealing temperature

The MELAseal®100 has a very precise regulation system for the sealing temperature, which is adjusted by turning the temperature knob (Illustration 1, item 5). With the transparent packaging material such as MELAfol® most commonly used in autoclaves by doctors and dentists (one side paper and one side foil, as described in DIN 58953 Part 4) the temperature knob (Illustration 1 item 5) should be set to the first third of the area marked with "MELAFOL". Turning the knob anti-clockwise lowers the heating power, and turning clockwise increases it. As long as the same packaging material is being used, it is then not necessary to adjust the sealing temperature again during the sealing operations.

With use of see-through sterilization packaging, the MELAseal®100 Package Sealing Device always produces uniform sealing seams with a width of 10 mm (DIN 58953 requires at least 8 mm). This requires, however, that the operator place the paper side downward onto the sealing rail. Tubular film materials should not be used, because they tend to adhere to the sealing rail.
1.4 Wall mounting

The MELAseal®100 "economic" has been prepared for installation on the wall. Use the prepared holes in the bottom, which you can open by breaking out the metal parts. Use a screw, for example, to break out the metal plugs toward the outside (see Illustration 3), by gently moving them back and forth at the already perforated places (Illustration 2, no. 9 + 10). The interval between the holes on the wall is 16.4 cm. Caution: Be sure to place the device only on walls that are strong enough to support the weight of the unit – and make sure to use 6 mm wall anchor plugs in the holes, as well as round-head screws (Ø 3.5 mm × 45 mm).

Illustration 2: Bottom of the unit
Illustration 3: Mounting on the wall

2 Every-day use

2.1 Sealing procedure

When the signal lamp (Illustration 1 item 4) is no longer illuminated you can begin to produce seals. Warning: The sealing rail is always hot! Feed in the transparent sterilisation packaging with the paper side downwards. Place the sterilization package, with the paper side down, under the rear paper guide. Then move the package toward the front between the pressure bar (top) and the sealing rail (bottom). The sealing pressure is generated by pressing down the handle (Illustration 4 item 2) until it engages. This ensures that the sealing pressure is maintained automatically. Warning: If the handle (Illustration 4 item 2) is not pressed down far enough, sealing pressure may not be adequate and the quality of the seal can suffer. The handle (Illustration 4 item 2) should not be released while the seal is being produced, which takes about 4 seconds. The process is terminated by returning the lever to the vertical starting position, and sealing can be repeated as required, if the main switch is not switched off.

2.2 Packaging cutter

The cutting blade (Illustration 8 item 14) must be dragged quickly and with light pressure across the foil using the black cutter handle (Illustration 4 item 1), and with the switch handle (Illustration 4 item 2) pressed as far as it will go. If the blade is moved too slowly then the sterilisation packaging will not be cut properly but will only wrinkle up. The cutting blade functions when moved to the right and to the left.
2.3 Working with packaging rolls

As shown in Illustration 4, slide the rolls onto the roll mounting rod, position them with the side guides (Illustration 4 item 20), move the packaging under the rear angled paper guide (Illustration 1 item 6), and guide them through toward the front, between the sealing rail and the pressure bar. The paper side must be downward: i.e., it must lie on the sealing rail (down). Then pull the packaging in the required length toward the front, seal the package, and then cut it off.

Place the objects to be sterilized in the package that you have now made. Guide the open end from the front between the sealing rail and the pressure bar, and seal the package. The width of the sealing rail enables you to work with packages up to a width of 250 mm.

Illustration 4: Working with packaging rolls

3 Accessories

3.1 Unit-mounted reel dispenser "comfort"

The "Comfort" unit-mounted roll-holder (Illustration 4 & Illustration 5) - MELAG item number. 111 - can be used to save space by mounting the rolls of sterilisation pack directly onto the MELAseal®100 Package Sealing Device. The roll-holders come with four side guides (Illustration 4, item 20), which ensure good guidance of the sterilization packaging rolls. The roll-holder is attached to the rear side of the sealing device with keyhole borings and brackets (Illustration 5 and Illustration 8 item 13 & 19).

Illustration 5: Fastening the unit-mounted reel dispenser "comfort"
3.2 Wall-mounted reel dispenser

If the MELAseal®100 Package Sealing Device is placed against the wall, or if it is mounted directly on the wall, then it is best to have a wall-mounted reel dispenser - MELAG item number. 106, (Illustration 6) - positioned directly above it. The wall-mounted roll-holder can also be installed in a wall cupboard above the package sealing device, and the packaging foil fed through a slit in the base of the cupboard.

Four (4) side guides are provided for each reel dispenser, to ensure proper positioning of the rolls of sterilization packaging.

Illustration 6  Wall-mounted reel dispenser

3.3 Reel dispenser “standard”

The reel dispenser "standard" – MELAG item number 110 – can be used to hold the packaging role directly on the MELAseal®100 Package Sealing Device. This reel dispenser is fixed on the two mounting points on the rear side of the package sealer (Illustration 7 and Illustration 8 item 13).

Illustration 7  MELAseal®100 reel dispenser "standard"

4 Servicing

4.1 Exchanging the pressure rail

Note: Let the appliance cool down first to avoid risk of burns. Then disconnect the appliance from the mains power supply. This is important for all repairs, maintenance and servicing work.

Loosen the four Phillips screws at the top (Illustration 8 item 11 & 12), and completely remove only the two screws at the rear (item 12).

Now lightly lift the upper enclosure front (Illustration 1 item 8) and remove the upper rear enclosure hood (Illustration 1 item 7) toward the rear.

Danger! The cutting blade is very sharp! (Illustration 8 item 14)

Take off the blade holder by unscrewing the two Phillips screws (Illustration 8 item 18) from the blade handle. The pressure rail (Illustration 8 item 15) is now visible. Now remove the right and the left sides of the enclosure (they are attached by Velcro-type closures). Unscrew the right and the left studs on the end of the pressure rail (Illustration 8 item 16), and pull the pressure rail out of the unit to the rear.

Replace the pressure rail, and install it by following the above steps in reverse order.
Install the blade holder and the upper rear enclosure hood again. Be sure to slide the front enclosure hood (Illustration 8 item 17) in the direction of the arrow. Make sure that the axis of the cutter carriage runs free and easily in the slot of the cover.

Illustration 8  Views of the unit for Service

4.2 Exchanging or turning the cutting blade

Note: Let the appliance cool down first to avoid risks of burns. Then disconnect the appliance from the mains power supply. This is important for all repairs, maintenance and servicing work.

Loosen the four Phillips screws at the top (Illustration 8 items 11 & 12), and completely remove only the two screws at the rear (item 12).

Now lightly lift the upper enclosure front (Illustration 1 item 8) and remove the upper rear enclosure hood (Illustration 1 item 7) toward the rear.

Danger! The cutting blade is very sharp! (Illustration 8 item 14)

Remove the screw that holds the cutting blade (Illustration 8 item 14). Turn or replace the blade, and fasten it tightly in place with the screw.

Install the upper rear enclosure hood again. Be sure to slide the front enclosure hood (Illustration 8 item 17) in the direction of the arrow. Make sure that the axis of the cutter carriage runs free and easily in the slot of the cover.

5  German DIN regulations

5.1 Width of sealed seams and clear space

Width of sealed seams

German Standard DIN 58953 Part 7 requires that sealed seams in transparent packaging material should have a width of at least 8 mm. With a width of 10 mm for its sealed seams, the MELAseal®100 is considerably better than this minimum requirement.

DIN 58953 Part 7 specifies that a clear space of at least 30 mm be left below the sealing border between the sterilisation goods and the seam in order to ensure a perfect seal without wrinkles. This applies both for bags and transparent material from the roll.

General:
- Do not select packages that are too small.
- Before sealing the packages, make sure to press them together to remove as much air as possible.
- If you wish to seal entire standard tray cassettes, the length of the film package should be at least twice as long as the standard tray cassette (also see DIN 58953, Part 7). This also applies to the sterilization of textiles in standard tray cassettes.
5.2 Storage life

Guidelines for the length of storage for sterile medical products

<table>
<thead>
<tr>
<th>Sterile goods packaging</th>
<th>Type of packaging</th>
<th>Length of storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper bags in accordance with DIN 58 953 Part 4 and heat resistant and self-sealing transparent packaging or hoses made of paper or plastic in accordance with DIN 58953 Part 5 or other equivalent packaging</td>
<td>Sterile goods in single packaging or two-stage packaging</td>
<td>Storage unprotected 1)</td>
</tr>
<tr>
<td></td>
<td>Serves as supply for immediate usage. Avoid this way of storage.</td>
<td>Storage protected 2)</td>
</tr>
<tr>
<td></td>
<td>6 months 3)</td>
<td></td>
</tr>
<tr>
<td>Sterile-goods store packaging not opened or opened and closed again</td>
<td>Sterile-goods store packaging not opened or opened and closed again</td>
<td>5 years 4)</td>
</tr>
</tbody>
</table>

1) in accordance with 4.3 a) in DIN 58953-8: 1993-02
2) in accordance with 4.3 b) in DIN 58953-8: 1993-02
3) Exceeding the length of storage for this type of packaging is not recommended for practical and economical reasons
4) provided that no other maturity was defined by the manufacturer

A comment on the table in Section 8.2 of the DIN standard says:
“The information in the table only represents standard values. These do not mean that longer storage periods are not possible under particularly favourable storage conditions, or that a longer duration of storage necessarily leads to the pack contents being re-contaminated during storage, but signify that if these periods are observed, recontamination of the contents when they are opened and correctly removed is extremely unlikely.”

An additional explanatory note goes into further detail:
“The risk in storing sterile goods is not that micro-organisms may penetrate the sterile goods packaging, provided that dry storage conditions are ensured and the packaging material has the required germ-proof qualities, but that when the sterile goods packaging is opened after storage, micro-organisms contained in dust particles may be stirred up and could re-contaminate the sterile objects when these are removed. “The extent of dust loading depends upon the dust content of the air and on the duration of storage. For these reasons the storage period should be kept as short as possible.”

5.3 VDE regulations

In accordance with current VDE regulations, this appliance is not suitable for use in areas at risk of explosion.
It should only be serviced by the manufacturer or a specially authorised agent (dealer or customer service).

6 Spare parts

<table>
<thead>
<tr>
<th>Article</th>
<th>Description</th>
<th>Article</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10115</td>
<td>Pressure rail</td>
<td>45615</td>
<td>Blade holder</td>
</tr>
<tr>
<td>12630</td>
<td>Overheating protection switch</td>
<td>45605</td>
<td>Handle for cutter</td>
</tr>
<tr>
<td>31190</td>
<td>Heating cartridge (up to SN 04100N1620)</td>
<td>59610</td>
<td>Temperature regulation</td>
</tr>
<tr>
<td>13680</td>
<td>Heating cartridge (since SN 04100N1621)</td>
<td>14405</td>
<td>Knob for temperature regulation</td>
</tr>
<tr>
<td>33730</td>
<td>Main switch</td>
<td>24130</td>
<td>Signal lamp</td>
</tr>
<tr>
<td>17780</td>
<td>Cutting blade</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>