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OPERATOR MANUAL Millseal Plus

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1. FOREWORD

Dear Customer,

thank you for choosing this product. We hope that you will find it completely satisfactory. This manual describes all procedures for the correct use of the device and instructions for deriving the full benefit from its features. In any case, we will be available to provide explanations and to receive any suggestions you may have for improving our products or services.

Note, warning, and danger symbols used in the manual

-  *Attention: indications concerning installation, use and maintenance procedures*
-  **Potential danger to property. Follow the instructions in the manual to prevent potential damage to materials, equipment and/or other property.**
-  **Potential danger to persons. Follow the procedures described in the manual in order to prevent possible damage to users and/or others.**
-  **Potential danger due to high temperature.**

Symbols on the device

-  Potential danger due to high temperature.
-  Device complying with applicable directives.
-  Disposal symbol in accordance with Directive 2012/19/EU.
-  Refer to the user manual.

1.1. RELEVANT EUROPEAN DIRECTIVES

The product described in this manual is manufactured in accordance with the highest safety standards and doesn't represent any danger for the operator if used according to the following instructions. The product is **complying** with the following **European Directives as applicable**:

2014/35/EC
2014/30/EC
2011/65/EU (Rohs II)

1.2. INTENDED USE

The unit is meant for professional use and can only be employed for the purpose it was designed for, that is heat-sealing and cutting of paper/polypropylene laminate rolls for sterilisation.

-  *The device must not be used with rolls of material other than those indicated above.*
-  **The device can be used by qualified personnel only. Under no circumstances it can be used or handled by unskilled and/or unauthorised persons.**
-  **The information contained in this manual is subject to change without notice.**
The manufacturer is not responsible for direct, indirect, accidental or consequential damage or any other damage relating to the provision/ use of this information.
This document may not be reproduced, adapted or translated, in part or in full, without the prior written permission of the manufacturer. For the correct interpretation of the instructions contained in this manual, the Italian version shall be valid as original text.

1.3. PURPOSE OF THE MANUAL

The purpose of this manual is to provide instructions for:

- Becoming generally familiar with the product;
- Correct installation;
- Its safe, efficient use;
- The treatment of instruments and/or materials to subject to sterilisation.

Its appendixes also provide:

- Product technical specifications;
- Maintenance operations;
- Troubleshooting;
- Other documentation.

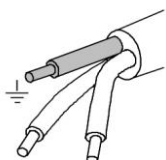
1.4. GENERAL WARNINGS

When using this product, **always** follow the instructions in the manual and never use it for anything other than its intended purpose.

 **The user is responsible for all legal requirements related to the installation and use of this product. The manufacturer will not be held responsible for any breakage, malfunction, property damage or injury to people in the event that the product is not installed or used correctly, or proper maintenance is not carried out.**

Please observe the following precautions in order to avoid injury or property damage; in particular:

- Use **only** recommended cleaning detergents;
- **Do not** pour water or other liquids or inflammable substances on the device;
- **Do not** use the device in the presence of gas or explosive vapours;



Before carrying out any maintenance operation, always disconnect the power cable plug from the power socket.

- Make sure the electrical system is **grounded** according to current laws and/or standards;
- **Do not** remove any label or nameplate from the device; request new ones, if necessary;
- Use **only original spare parts**.



Failure to comply with the above exempts the manufacturer from all liability.

2. PACKAGE CONTENT



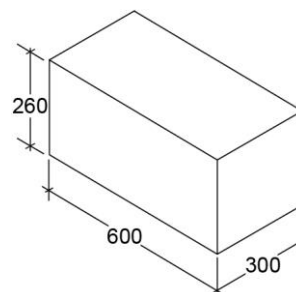
Check the integrity of the product package upon receipt.

Once the package is opened, check that:

- the supply matches the specifications of the order (see the delivery note);
- there is no visible damage to the product.

2.1. DIMENSIONS AND WEIGHT

Dimensions and weight	
Height	260 mm
Width	600 mm
Depth	300 mm
Total weight	6 kg



In case of wrong delivery, missing parts or any type of damage, inform immediately and in detail the reseller and the carrier that made the delivery.



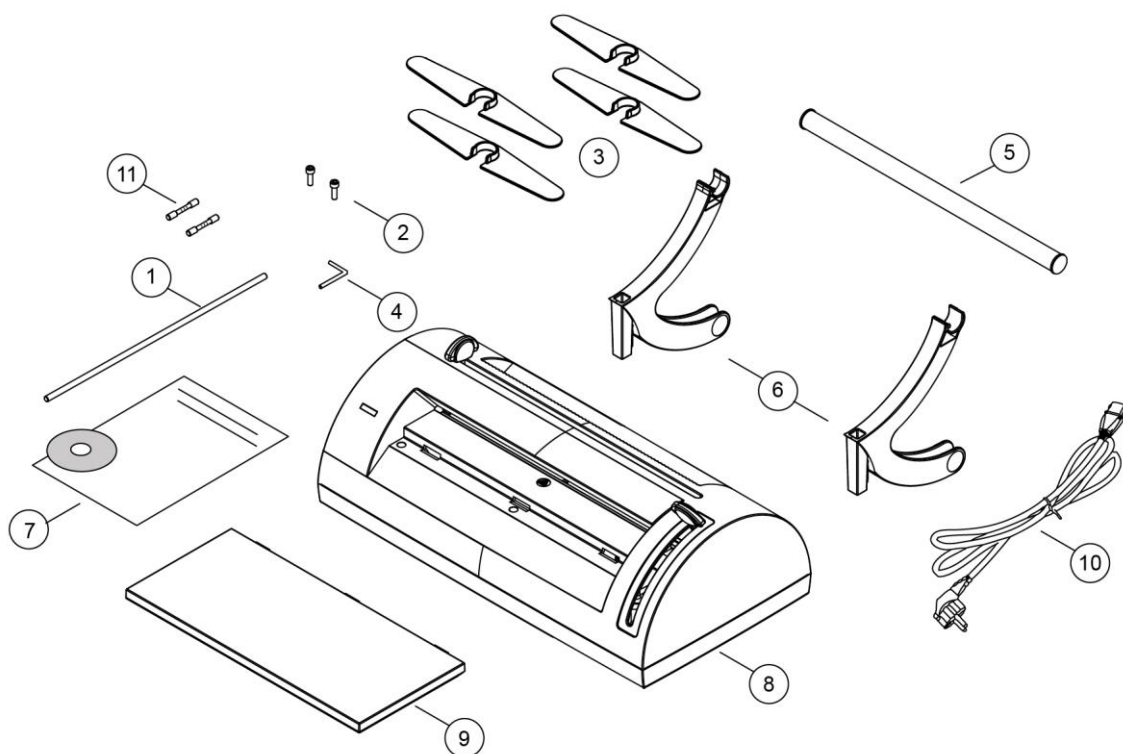
Keep the original packaging and use it whenever the device is to be transported. The use of different packaging could damage the product during shipment.

2.2. DESCRIPTION OF THE CONTENT

- 1 Paper stop bar
- 2 No. 2 screws
- 3 No. 4 centring devices
- 4 Allen key
- 5 Roll holder tube
- 6 No. 2 roll supports
- 7 Operator documentation
- 8 Heat sealer Millseal Plus
- 9 Resting surface
- 10 Power cable
- 11 No. 2 fuses



The customer must keep the warranty certificate together with the purchase invoice of the product.



3. PRODUCT PRESENTATION

Millseal Plus is a heat sealer designed as a natural complement to our range of steam sterilisers. It is an elegant, space-saving equipment that is both user-friendly and reliable, even with heavy use. Millseal Plus is therefore a useful option for all those users who require professional equipment with excellent performance/price/quality ratio.

3.1. MAIN PERFORMANCES

Millseal Plus is an electronically-controlled heat sealer that produces a multiple sealing strip of 12 mm, suitable to withstand the sterilisation processes of modern autoclaves that work with fractionated pre-vacuum, and guarantees package sterility over time.

Efficient heat control in the sealing area is achieved thanks to the automatic temperature adjustment, ensuring high and constant performance.

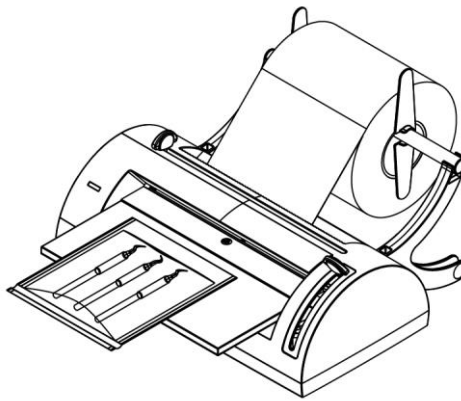
The solid structure in plastic and steel, as well as the ergonomic and essential shape, allows maintaining a high level of hygiene, reduced weight and dimensions and excellent stability during use.

All this with the objective of offering a product suitable for the daily needs in the medical area.



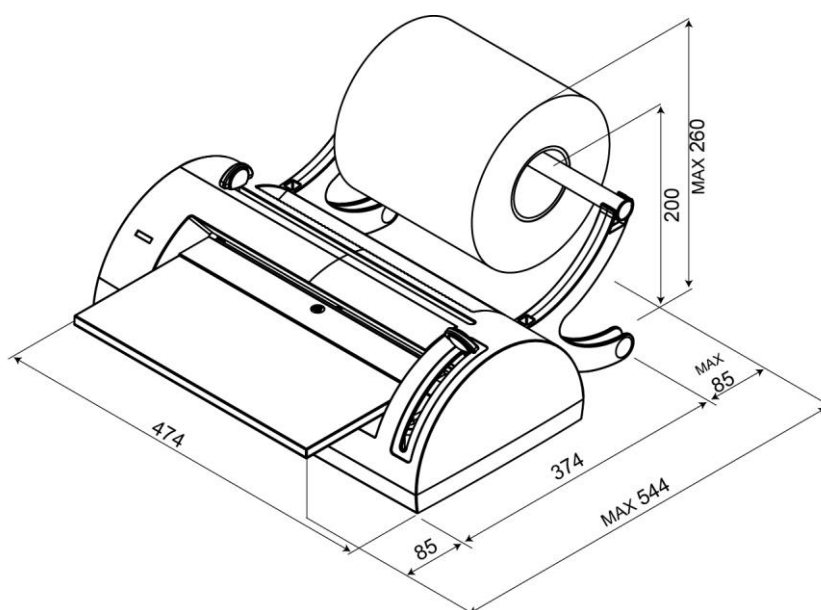
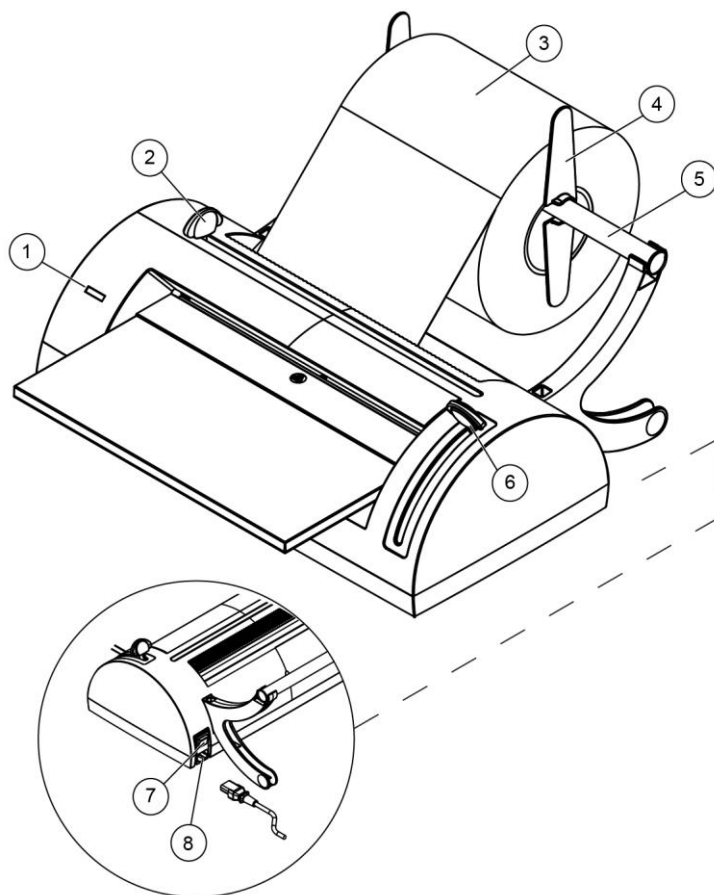
For the description of safety devices, refer to the appendix under technical characteristics.

For a good operation of the heat sealer the first and essential task is its correct installation; in this way possible malfunctions or damage to the unit will be avoided.



3.2. VIEWS WITH DIMENSIONS

1. Signalling LEDs
2. Cutting knob
3. Paper roll for autoclave
4. Centring device
5. Roll holder
6. Sealing lever
7. Switch
8. Power cable socket with fuse holder



4. SETTING UP THE DEVICE

Please read carefully the warnings mentioned in the rest of this chapter.



The technical assistance service is at your disposal for further information or any doubt you may have.



The electric system must be provided with ground connection.

4.1. GENERAL PRECAUTIONS

- Install the heat sealer on a flat surface, leaving enough room for its operation and adequate ventilation;
- check that the support surface is sufficiently robust to support the weight of the machine (about 15 kg);
- do not install near sinks to avoid contact with water or liquids that could cause short circuits or situations potentially dangerous for the operator;
- do not install in humid or poorly ventilated environments;
- do not install in environments with the presence of inflammable and/or explosive gases or vapours;
- install the unit so that the power supply cable is not bent or pressed along its path up to the power socket.

4.2. ELECTRICAL CONNECTIONS

In compliance with the standing regulations, the unit must be connected to a mains socket of the electrical system with power rating suitable for the unit consumption and provided with ground connection.

The socket must be suitably protected upstream by an electric panel provided with magneto-thermal and residual-current circuit breaker.

Connect the supplied power cable to the mains socket on the rear of the device.



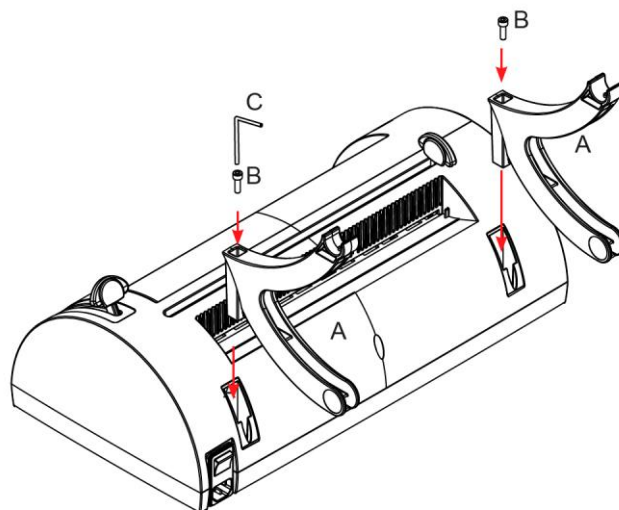
Use only the power cable supplied with the equipment; any replacement of the plug is the sole responsibility of the user.

Connect the power cable directly to the power outlet.

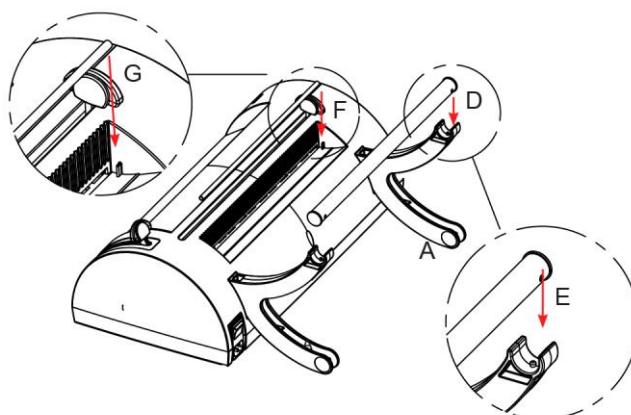
Do not use extensions, adapters or other accessories.

4.3. PRODUCT PREPARATION

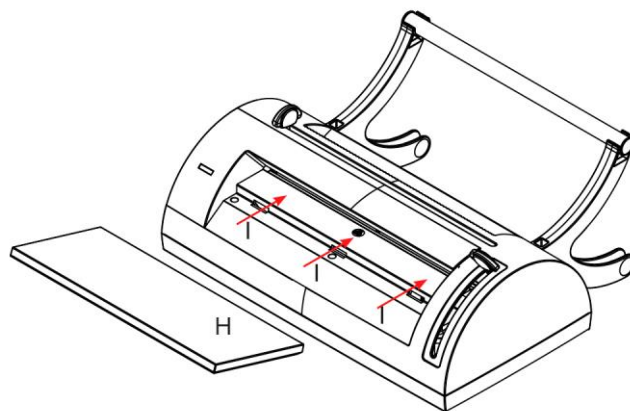
- 1 Carefully remove the material from the packaging.
- 2 Insert the roll supports (A) into the appropriate housings. Tighten the two screws (B) using the Allen key (C) supplied.



- 3 Insert the roll holder tube (D) into the supports (A), checking that the holes at the end of the tube engage correctly in the teeth (E) on the supports (A). Place the paper stop bar (F) in the housings provided (G).



- 4 Insert the support surface (H) into the relevant slots (I).



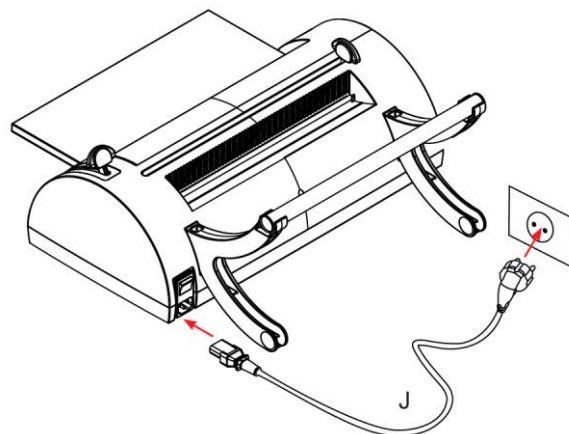
- 5 Connect the power cable (J).



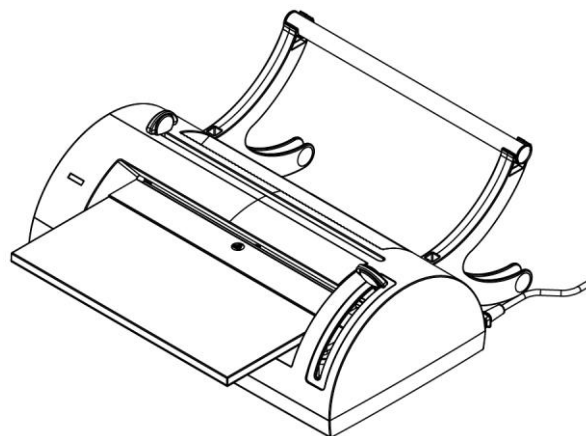
Position the machine in such a way that the ends of the cable are easily accessible.



During periods of inactivity, always switch off the heat sealer via the switch

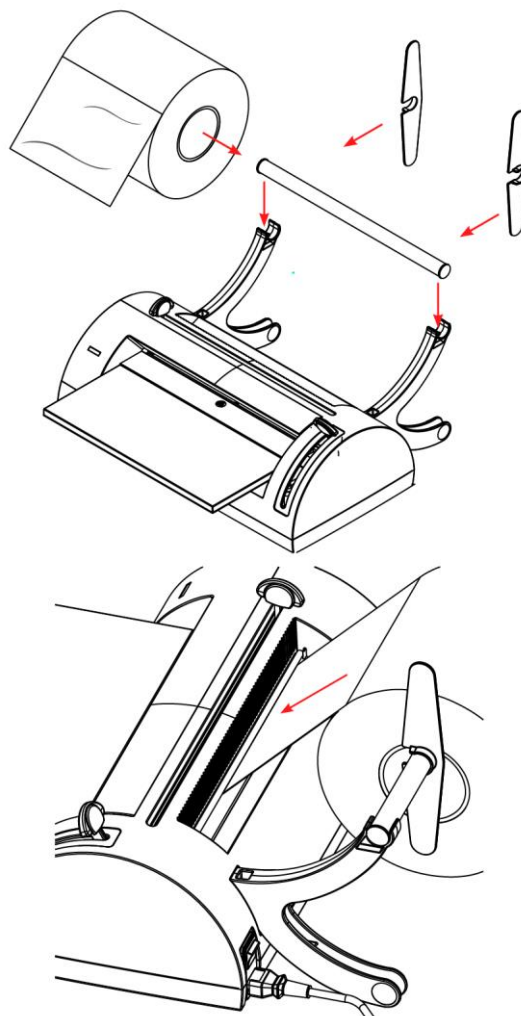


- 6 The heat sealer is now ready for use.

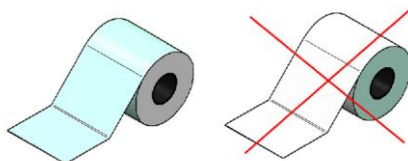


4.4. PAPER ROLL INSTALLATION

- Place the paper roll on the roll holder tube;
- install the roll/roll holder assembly on the arm housings (as described in the previous paragraph), aimed so that the paper tape unrolls from above and with the polypropylene thread visible, taking care to route the sheet under the paper stop bar;
- finally, install the centring devices.



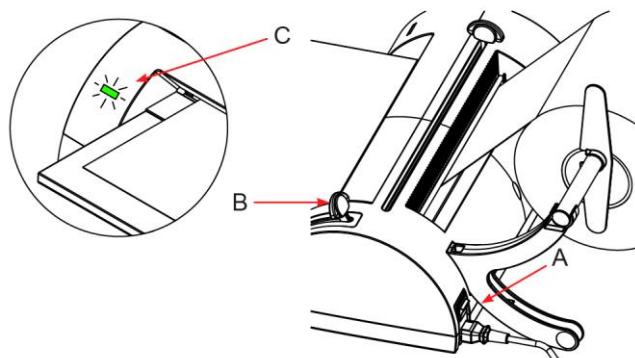
 Only use laminate rolls wound with the plastic part on the outer side (visible) see figure.



5. FUNCTIONING

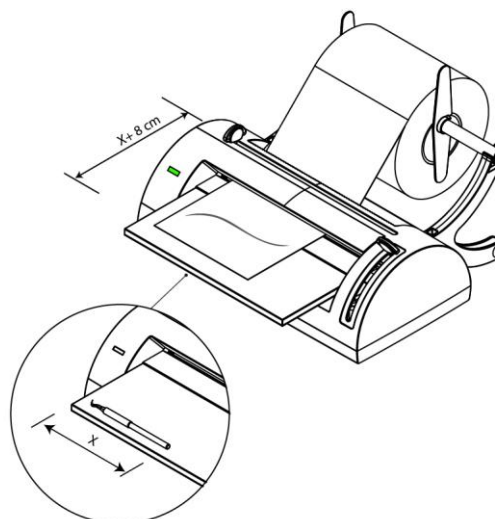
5.1. PREPARATION

- Check that the sealing lever (**B**) is positioned at the upper end of the guide.
 - Turn on the machine with the switch (**A**) on the rear side.
 - The green front LED (**C**) flashes.
 - The heating element is energised and the temperature gradually increases.
- When it reaches the optimum value for correct sealing, the green front LED remains steady on, emitting a sound.



5.2. PAPER INSERTION

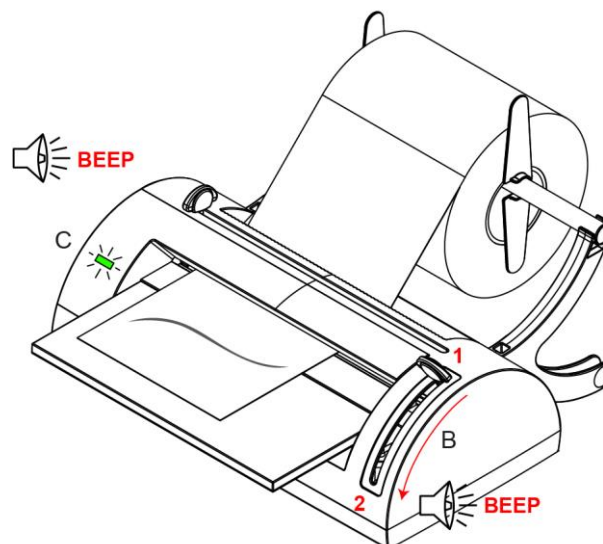
- Route the paper tape under the paper stop bar and insert it into the rear slot; then pull it out from the front by the desired length. (see paragraph 5.3);
- It is recommended to pull out the paper by the length of the instrument plus 8 cm in order to allow for proper sealing of the edge.



It is not recommended to make bags shorter than 7 cm.

5.3. SEALING OF ONE END AND CUTTING

- Lower the lever (**B**) from position 1 to position 2, the green LED (**C**) will flash quickly until the end of the sealing process, which is notified with a sound;



- Slide the cutting lever (**D**) to the opposite end.
- Lift lever (**B**) from position 2 to the original position 1.
- The front LED turns steady **green** again and the sound stops. The bag is now sealed at one end;

 If the lever is not lifted after the first sound, the sealing machine will emit a further sound and the LED will turn flashing red.



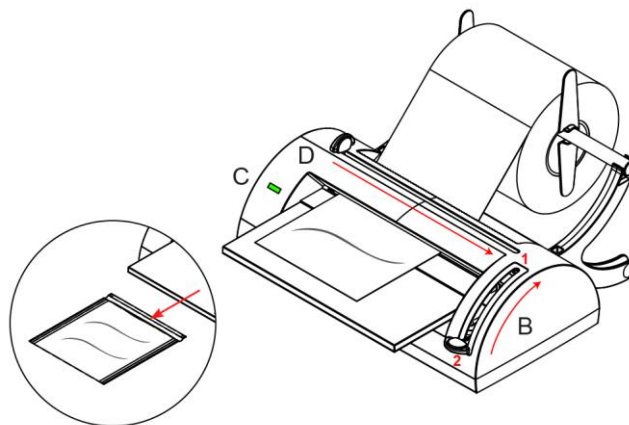
Do not insert your fingers into the sealing area when the machine is switched on and immediately after it has been switched off.



Never insert your fingers into the slot of the cutting lever.



Do not leave the paper threaded in the sealing area without using the machine.



5.4. BAG RECOVERY AND FINISHING

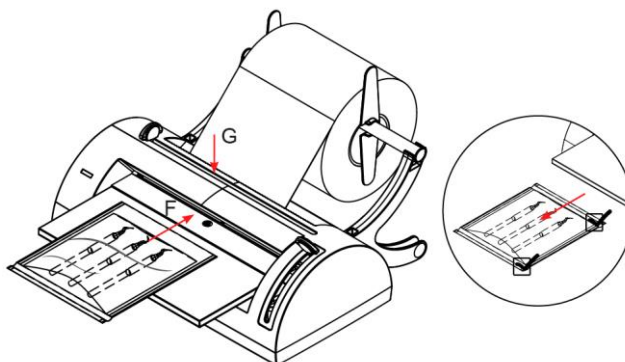
- Insert the instruments from the open side of the bag, following the instructions in the chapter "Preparing the material" (see next page).
- Insert the unsealed end of the bag into the front slot (**F**) for a few centimetres until the end of the bag is aligned with the top slot (**G**).
- Lower the lever (**B**) from position 1 to position 2, the green LED (**C**) will flash quickly until the end of the sealing process, which is notified with a sound.

 Do not slide the cutting lever to avoid paper residues falling into the heat sealer.

 When the machine has not been used for 30 minutes, it goes into standby mode, switching off the heating element. The stand-by state is indicated by the periodic double flashing of the green LED.

To resume machine operation, lower and raise the sealing lever. The machine re-activates the heating element (green LED flashing); wait until the machine has reached optimum temperature again (green LED steady on) before resuming use.

 During periods of inactivity, always switch off the heat sealer via the switch.



6. PREPARATION OF THE MATERIAL

The sterilisation process can be considered as effective, reliable and repeatable on condition that the instruments and the materials in general are first properly treated and subsequently correctly positioned inside the sterilization chamber.

This precaution is even more required when we consider packed objects.

It must be stressed that organic residue or deposit of substances used in the medical practice inevitably become receptacle of micro-organisms and can hamper the steam sterilisation process.

An improper arrangement of the load makes difficult and sometimes impossible the circulation of water steam on the material and/or inside its cavities, with the consequences that can be imagined.

Therefore we provide a few basic indications concerning these aspects, leaving the customers with the task of improving their knowledge on the matter in the best fashion.

6.1. MOVING THE MATERIAL

When handling and moving contaminated material, it is good practice to take the following precautions:

- always wear rubber gloves with adequate thickness;
- clean with a germicide detergent the hands protected with the gloves;
- always carry the instruments on a tray;
- never carry the instruments directly in your hands;
- pay attention to any sharp or cutting parts to avoid the risk of infections;
- separate the objects that must not undergo a sterilisation or cannot stand the process;
- when you have finished handling the material, carefully wash your hands still gloved.

6.2. CLEANING THE TOOLS

All materials and/or instruments to be sterilised must be perfectly cleaned and without trace of any kind of residue (organic and inorganic materials, paper fragments, cotton or gauze swabs, scale, etc.).

Otherwise, the sterilisation process could turn out to be not effective, and the sterilizer and the instruments themselves undergo irreversible damage.

For an effective cleaning:

- after use, immediately rinse the instruments with a jet of running water;
- separate instruments by type of material (carbon steel, stainless steel, brass, aluminium, chromium, etc.), to avoid electrolytic oxidation-reduction;
- wash with an ultrasonic cleaner containing a mix of water and germicide solution, carefully following the manufacturer's recommendations;
- carefully rinse and check that the cleaning is complete; if necessary repeat the washing cycle or clean manually;
- dry perfectly.

Before the sterilisation, check the indications provided by the manufacturer of the instrument/material, checking any incompatibility.

Follow meticulously the use procedures for detergent or disinfectant products and the instructions for the instrument washing and automatic lubrication equipment.

6.3. PACKING AND POSITIONING THE LOAD

The use of autoclave paper bags allows both an optimal sterilisation and maintaining the sterility condition over time.

Follow these general indications:

- bag the instruments one by one or make sure that they are made of the same material;
- close the bag with the heat sealer;
- do not use metal points, pins or similar since they do not warrant sterility;
- arrange the bags so as to avoid the creation of air pockets that prevent the correct penetration and the removal of the steam;
- if possible, arrange the bags vertically using a suitable support;
- never stack bags one on top of the other.

7. APPENDIX A - TECHNICAL SPECIFICATIONS

7.1. SUMMARY TABLE

Device	HEAT SEALER
	Millseal Plus
Manufacturer	CEFLA s.c. Headquarters Via Selice Provinciale 23/A – 40026 Imola (BO) IT
Input voltage	220-240 V~
Network frequency	50-60Hz
Network fuses (5 x 20 mm)	T 3.15 A - 250V
Nominal power	150 W
Insulation class	Class I
Installation category (IEC 61010-1)	Cat. II
Environment of use (IEC 61010-1)	Indoor use
Environmental operating conditions	Temperature: +15°C ÷ +35°C
	Relative humidity: 80% (max), without condensation
External dimensions (without roll) (L x W x H)	474 x 374 x 200 mm
Net weight	5 kg
Type of sealing	Continuous-cycle and constant temperature
Nominal operating temperature of the heating resistor	180 °C
Height of sealing band	12 mm
Sealing maximum width	300 mm
Material that can be sealed	Paper/polypropylene laminates
Roll maximum diameter	200 mm
Roll maximum width	300 mm
Paper/polypropylene laminate orientation	Polypropylene film facing upwards

The label bearing rated values is on the bottom of the machine.

7.2. SAFETY DEVICES

The heat sealer is equipped with the following safety devices, of which we enclose a short description along with their function:

- **Network fuses** (see data in summary table)
Equipment protection from internal electrical faults.
Action: power supply interruption.
- **Automatic switch-off of the heating circuit.**
After sealing, if the lever is not raised, the heating circuit is automatically switched off.
The intervention is signalled by an intermittent sound and red LED.
- **Finger anti-crushing design.**
Protection against accidentally crushing your fingers during lever activation.
- **Automatic stand-by system.**
When the machine has not been used for 30 minutes, it goes into standby mode, switching off the heating element.
This device protects from the risk of overheating caused by not switching off the machine at the end of use, and allowing at the same time significant energy saving.
- **Protected cutting knife.**
Unique design with cutting blade completely inaccessible from the outside.

8. APPENDIX B - MAINTENANCE

8.1. GENERAL INFORMATION

The device does not need any special care; it is only recommended that the user clean it periodically.

In all cases, strictly follow the procedures given in this manual.

In case of replacement of components of the device, request and use ONLY ORIGINAL SPARE PARTS.



Before carrying out any maintenance operation, always disconnect the power cable plug from the power socket.



Make sure that the machine has cooled down before any maintenance operation.

8.2. CLEANING

Clean the equipment externally with a clean cloth dampened with water and neutral detergent.



- Do not use products containing isopropyl alcohol (2-propanol, iso-propanol);
- Do not use products containing sodium hypochlorite (bleach);
- Do not use cleaners containing phenols.

Perfectly dry the surfaces and remove any remaining resistant residue.

Always keep in mind the following general warnings:

- Do not subject the unit to direct water jets, under pressure or sprinkling. Any infiltration on the internal electrical components could irretrievably damage its operation.
- Do not use abrasive sponges, metal brushes (or other aggressive materials) or products for cleaning metals, both solid and liquid.

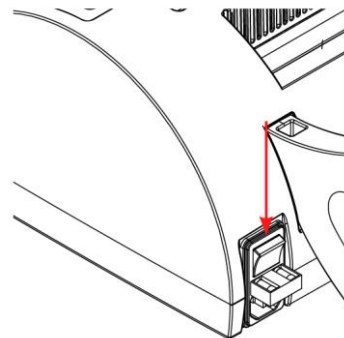
8.3. CUTTING BLADE REPLACEMENT

Replace the blade periodically, or whenever cutting the paper proves difficult.
Contact the technical service.

8.4. FUSES REPLACEMENT

The fuses are housed in the fuse box above the power cable socket.

- Remove the power cable plug;
- pull out the fuse box using a screwdriver;
- replace the fuse with one of the same type (see Appendix A).



8.5. DISPOSING THE EQUIPMENT WHEN NO LONGER USED

In compliance with Directive 2012/19/EU regarding restriction of the use of certain hazardous substances in electrical and electronic equipment along with waste electrical and electronic equipment, it is forbidden to dispose of this equipment in the municipal waste stream as unsorted municipal waste. When purchasing a new device of an equivalent type, one for one, the device that has come to the end of its lifetime should be returned to the dealer for disposal. As regards reuse, recycling and other forms of recovery of waste electrical and electronic equipment, the Manufacturer carries out the functions defined by current local laws.

Appropriate differentiated waste collection for subsequent recycling treatment and environmentally friendly disposal contributes to preventing possible negative effects on the environment and health and encourages recycling of the materials of which the device is made up. The symbol indicating separate collection for electrical and electronic equipment consists of the crossed out bin marked on the equipment.



Improper disposal of the product may result in the application of sanctions which are defined by individual national laws.

9. APPENDIX C - TROUBLESHOOTING

If your heat sealer does not work correctly, carry out the following checks before contacting the Technical Service:

PROBLEM	POSSIBLE CAUSE	SUGGESTED SOLUTION
The heat sealer does not switch on.	The plug of the power supply cable is not inserted in the outlet.	Plug it in.
	Lack of power at the power supply socket.	Check the possible cause of power failure and try to solve it.
	The system magneto-thermal and/or residual-current circuit breaker are OFF.	Set the switches to ON position.
	Network fuses blown.	Replace the fuses. (see Appendix B - Maintenance)
Upon switching on the heat sealer the LED does not flash.	The LED does not work.	Contact the Technical Service Department.
	Electronic board faulty.	
Bag sealing takes place but the LED remains green and not flashing (instead of red) and no sounds can be heard.	Faulty limit microswitch.	Contact the Technical Service Department.
Inappropriate sealing of the bag.	Insufficient pressure in the sealing area.	Contact the Technical Service Department.
	Damaged silicone rubber profile.	
	Heating element does not reach the operating temperature.	
Cutting the bag proves difficult.	Worn blade.	Contact the Technical Service Department.



Should the problem persist, contact the technical service network indicating the model and serial number of the heat sealer. These data can be found on the factory nameplate located under the unit.

Warning to the operator

INDICATORS	CAUSE	ACTION
The LED is green and flashing	The machine is warming up.	Wait for the machine to warm up.
The LED is steady green	The machine is now ready to be used.	-
The LED is green and flashing fast	The sealing lever has been lowered and the machine is in use.	Wait for the sound, raise the lever and pull out the bag.
The green LED flashes very briefly every 5 seconds	The machine has entered the stand-by state after a period of inactivity of 30 minutes.	Lower and raise the lever to restore normal operation.
The red and green LEDs flash simultaneously	The machine indicates the presence of a fault in the heating system.	Turn the machine off and try using it again. If the signal is recurrent, please contact the Technical Service Department.
The LED is steady red and the machine emits a sound	The sealing operation has been completed.	Raise the lever and pull out the bag.
	The machine was switched on with the sealing lever down.	Raise the lever.
	The sealing lever was lowered before the correct operating temperature was reached.	



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