Miltenyi Biotec

MACS® TubeSealer

User Manual

The CliniMACS System components, including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer, are designed, manufactured and tested under a quality system certified to ISO 13485. In the EU, the CliniMACS System components are available as CE-marked medical devices for their respective intended use, unless otherwise stated. In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Set TS and CliniMACS Tubing Set LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved as a Humanitarian Use Device (HUD), authorized by U.S. Federal law for use in the treatment of patients with acute myeloid leukemia (AML) in first complete remission. The effectiveness of the device for this indication has not been demonstrated. All other products of the CliniMACS Product Line are available for use only under an approved Investigational New Drug (IND) application or Investigational Device Exemption (IDE). In Australia, the following components of the CliniMACS Prodigy System are included in the Australian Register of Therapeutic Goods (ARTG) and are therefore approved for supply: CliniMACS Prodigy, CliniMACS CD34 Reagent, CliniMACS Prodigy Tubing Sets, and CliniMACS PBS/EDTA Buffer. Only those products which are included in the ARTG may be used in Australia. CliniMACS MicroBeads are for research use only and not for human therapeutic or diagnostic use.

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use.

MACS® TubeSealer

User Manual

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Essential information

This user manual provides instructions, warnings, precautions, and other important information for the use of the MACS® TubeSealer which is an accessory to the CliniMACS Prodigy®. For information on the use of the CliniMACS Prodigy, specific applications run on the CliniMACS Prodigy, or further information, warnings, and precautions regarding the operation of the CliniMACS Prodigy System, refer to the respective CliniMACS Prodigy User Manual.

⚠ WARNING

The operation of the CliniMACS Prodigy System must be performed by trained operators only. Before putting the system into operation, carefully read and understand the safety information, warnings, precautions, and instructions for proper operation of the MACS TubeSealer provided in the instructions for use of the CliniMACS Prodigy System components (including, without limitation, the safety information in this user manual, chapter 3 "Important safety information") and in any safety-related recommendations issued by Miltenyi Biotec. The operator must adhere to all instructions and procedures at all times during the operation of the heat sealer, confirming that all safety information, warnings, precautions, and instructions are observed. Failure to follow the safety information, warnings, precautions, and instructions contained in the instructions for use could result in heat sealer malfunction, property damage, personal injury, and/or death. Equipment safety may be compromised if the heat sealer is not used according to the manufacturer's instruction.

Retain the instructions for use for future reference. They should be kept accessible and readily available, together with all other safety and operating documentation, during the entire life cycle of the heat sealer for all personnel responsible for installation, operation, and maintenance.

Table of contents

Table of contents (continued)

1 Introduction

1.1 General information

The MACS TubeSealer is a fully automatic accessory for sealing PVC and EVA tubing. The hand unit is connected to the CliniMACS Prodigy by a cable. The sealing takes place in the hand unit when the trigger is pressed. All CliniMACS Prodigy Tubing Sets as well as different types and sizes of tubing can be used and the necessary sealing time is self-adaptive to fit the tubing used.

1.2 Technical support

For information or support, contact Miltenyi Biotec Technical Support:

Miltenyi Biotec B.V. & Co. KG
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2
Glossary

2.1 Graphical depiction

The following chart depicts the panels used in this user manual to inform the user about potential risks if the outlined warnings and precautions are not followed. The hazard level classifies the hazard, as described below. The level, type, and source of the hazard, as well as potential consequences, prohibitions, and measures are indicated as follows. Icons on the left side specify the risk.

⚠ WARNING

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

Addresses practices or information not related to personal injury but may lead to property damage.

IMPORTANT

Advises the user of important practices or information not related to personal injury nor property damage.

2.2 Glossary of symbols and terms

An overview of symbols and terms used for the MACS TubeSealer is provided in the CliniMACS Prodigy User Manual (Instrument). The glossary of symbols depicts the symbols used for labeling of the CliniMACS Products.

3

Important safety information

⚠ WARNING

The operation of the CliniMACS Prodigy System must be performed by trained operators only. Before putting the system into operation, carefully read and understand the safety information, warnings, precautions, and instructions for proper operation of the MACS TubeSealer provided in the instructions for use of the CliniMACS Prodigy System components (including, without limitation, the safety information in this user manual, chapter 3 "Important safety information") and in any safety-related recommendations issued by Miltenyi Biotec. The operator must adhere to all instructions and procedures at all times during the operation of the heat sealer, confirming that all safety information, warnings, precautions, and instructions are observed. Failure to follow the safety information, warnings, precautions, and instructions contained in the instructions for use could result in heat sealer malfunction, property damage, personal injury, and/or death. Equipment safety may be compromised if the heat sealer is not used according to the manufacturer's instruction.

Retain the instructions for use for future reference. They should be kept accessible and readily available, together with all other safety and operating documentation, during the entire life cycle of the heat sealer for all personnel responsible for installation, operation, and maintenance.

⚠ WARNING

Hazards to users, instrument damage, and/or malfunction, unpredictable results, premature wear and tear, and/or reduced life time of the heat sealer if the following safety information, warnings, precautions, and instructions are not observed at all times when using the heat sealer.

- Always operate, handle, use, and maintain the heat sealer in accordance with the safety information, warnings, precautions, instructions, and recommended procedures provided in the user manual and other written instructions issued by Miltenyi Biotec. Do not deviate from these operating instructions and procedures.

- Always ensure that the heat sealer is operated, handled, used, and maintained only by appropriately skilled and trained personnel familiar with the construction, operation, and hazards involved with the heat sealer. The heat sealer is intended for the use in the professional facility healthcare environment. The heat sealer is not intended to be used near active HF surgical equipment. The customer or user should assure that it is used in such an environment.

- Always operate, handle, use, and maintain the heat sealer in compliance with all applicable laws, rules, regulations and administrative provisions, including, without limitation, all regulations regarding health and safety at work and, as appropriate, the safety of medical devices, as applicable at the location where the heat sealer is operated.

- Always use the heat sealer for its designated purpose (in accordance with the product documentation and within its performance limits), and not in any other manner or for any other purpose.

- Never use the heat sealer with consumables, accessories, transducers, and/or cables other than those approved by Miltenyi Biotec to ensure safe and proper operation of the heat sealer. **Note:** The use of consumables, accessories, transducers, and/or cables not expressly approved by Miltenyi Biotec could void the warranty and/or invalidate the authority to operate this heat sealer under applicable regulations.

- Always follow the maintenance recommendations of Miltenyi Biotec and appropriate product standards. **Note:** Initial installation, maintenance, and service of the heat sealer must only be performed by authorized local Miltenyi Biotec Service Provider.

- Defects should be addressed immediately. If there is any doubt regarding the proper functioning of the heat sealer, **do not** use the heat sealer and contact the authorized local Miltenyi Biotec Service Provider or Miltenyi Biotec Technical Support as soon as possible.

- Never change or modify the heat sealer except with Miltenyi Biotec's prior written approval. **Note:** Changes or modifications to the heat sealer not expressly approved by Miltenyi Biotec could void the warranty and/or invalidate theoperator's authority to operate the heat sealer under applicable regulations.

Failure to comply with the safety information, warnings, precautions, and instructions in the user manual (and in other safety related publications issued by Miltenyi Biotec for use with the heat sealer) could lead to improper or incorrect use, handling or care of the product and cause a hazard, and could result in death, serious personal injury, and/or property damage, heat sealer malfunction, or damage, premature wear and tear, and reduced heat sealer life time, and may void the warranty and/or invalidate the authority to operate the heat sealer under applicable regulations. Miltenyi Biotec accepts no liability for consequences arising from failure to comply with the safety information, warnings, precautions, and instructions provided herein.

If concerned about the safe use of the heat sealer or additional safety information regarding the CliniMACS Prodigy System is required, contact the authorized local Miltenyi Biotec Service Provider or Miltenyi Biotec Technical Support.

Always follow local working area safety instructions and laboratory policies, as well as standards for health, safety, and prevention of accidents. Contact the local authority governing electrical power supply, building constructions, maintenance, or safety for more information about the safe installation and operation of the heat sealer.

⚠ WARNING

Electrical hazard. The heat sealer is intended for indoor use only. Water ingress may lead to an electrical short and could result in electric shock or spread of fire.

Do not use the heat sealer in a wet or damp location or if it has been exposed to moisture. Avoid high humidity or condensation and protect the heat sealer from contact with water. Do not allow fluids to enter the interior of the heat sealer. Do not operate the heat sealer if liquids have spilled into the heat sealer. Fluid containers must be handled with caution when in the area of the heat sealer.

After moving the heat sealer from a cold environment, such as a cold room at +4 °C (+39 °F), to room temperature, condensing liquid droplets may form inside the heat sealer. It is necessary to wait for the heat sealer to dehumidify before operating the heat sealer.

Unplug the heat sealer from the power outlet before cleaning. Do not use liquid or aerosol cleaning agents; always use a damp cloth.

The heat sealer must be used in compliance with all specifications (see Table 4.1) and operational procedures listed in this manual.

The heat sealer must be used by trained operators only. Operator training will be provided by a Miltenyi Biotec Sales representative.

Follow the operating instructions while operating the heat sealer.

The heat sealer is used in the same environment as laboratory equipment.

The heat sealer is intended for use with the CliniMACS Prodigy. Do not use with or connect to instruments other than the CliniMACS Prodigy. If adjacent use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

If any of the components of the heat sealer are exposed to blood or biohazardous material, they must be cleaned with an appropriate disinfectant solution (see section 4.6).

ELECTROMAGNETIC INTERFERENCE REGULATIONS:
The heat sealer emits a low level of electromagnetic (non-ionizing) radiation during sealing. It should not be used near high-frequency sensitive electronic equipment.

The heat sealer uses radio frequency (RF) energy to generate heat for sealing. Never place an object other than the PVC or the EVA tubing between the electrodes.

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information. Portable and mobile RF communications equipment can affect medical electrical equipment. For information on electromagnetic compatibility refer to the appendix.

Inspect all parts of the heat sealer for the appearance of defects before use.

To guarantee safe use, only accessories delivered with the heat sealer may be used.

If multiple seals are made along a length of tubing, the seals should be at least 1 cm (1/2 inch) apart. Multiple seals made closer than the recommended distance may result in rupture of the sealed tubing segment. Make three separate seals in the tubing and cut at the middle seal. Disconnect the heat sealer from the power source before performing any maintenance and cleaning procedure.

In case of sealer malfunction (for example, intermittent operation, poor quality seals, sealing time seems too long or too short), use a different heat sealer and/or call Miltenyi Biotec Technical Support for assistance.

Periodically check the pattern of the sealing visually (see section 4.5 “Operating instructions”).

4

MACS® TubeSealer

4.1 Regulatory information

Intended purpose

As an accessory of the CliniMACS Prodigy, the MACS® TubeSealer is intended to seal PVC and EVA tubes of CliniMACS Prodigy Tubing Sets installed on the CliniMACS Prodigy. The MACS TubeSealer must only be used in combination with the CliniMACS Prodigy.

The MACS TubeSealer conforms to the Medical Device Regulation MDR (EU) 2017/745:

MD CE

The MACS TubeSealer complies with the following standards:

- IEC 60601-1 and
- IEC 60601-1-2.

For the applied standard version, refer to the respective Certificate of Conformance.

The MACS TubeSealer is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

IMPORTANT

Any serious incident that has occurred in relation to this product should be reported to Miltenyi Biotec B.V. & Co. KG – using the contact information provided – and the competent authority of the member state in which the user of this product is established.

4.2 Technical data

⚠ WARNING

Safety and performance of the MACS TubeSealer may be compromised. Safety and performance of the heat sealer may be compromised if it is used outside its specifications. Do not use the heat sealer outside its specifications.

The technical data of the heat sealer are listed in Table 4.1.

Technical data	
Model	MACS TubeSealer
Weight	0.35 kg
Power supply	30.5 VDC 8.3 A
RF Output	Max. 80 W / 50 Ω / 40.68 MHz
Tubing specification	PVC and EVA @20 °C The heat sealer is suitable for sealing of tubing of the CliniMACS Prodigy Tubing Sets.
Sealing time	Max. 6 s depending on tubing size and type
Mode of operation	Operation: 25% Intermittens: 75%
Seal procedures	100 per hour
Continuous seal capacity	20
Operation conditions	Temperature: +15 °C (+59 °F) to +25 °C (+77 °F) Humidity: 10 to 90% Rh (non-condensing) Altitude: max. 2,000 meters above sea level
Storage conditions	Room temperature Avoid condensing conditions.

Table 4.1: Technical data of the MACS TubeSealer

Note: The emissions characteristics of this heat sealer make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) the heat sealer might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the heat sealer.

Changes or modifications of the heat sealer, unless expressly approved by Miltenyi Biotec, may void the authority to operate the heat sealer pursuant to FCC 47 CFR.

4.3 Components of the MACS® TubeSealer

The MACS® TubeSealer is comprised of the hand unit with a cable and a connector (see Figure 4.1). The hand unit consists of a RF-generator with intelligent sense control, ergonomic handgrip with trigger, a mobile electrode which can be removed for cleaning, and a cable with a connector. The hand unit uses no power between sealing.

⚠ WARNING

Read chapter 3 "Important safety information" before installation and use of the heat sealer.

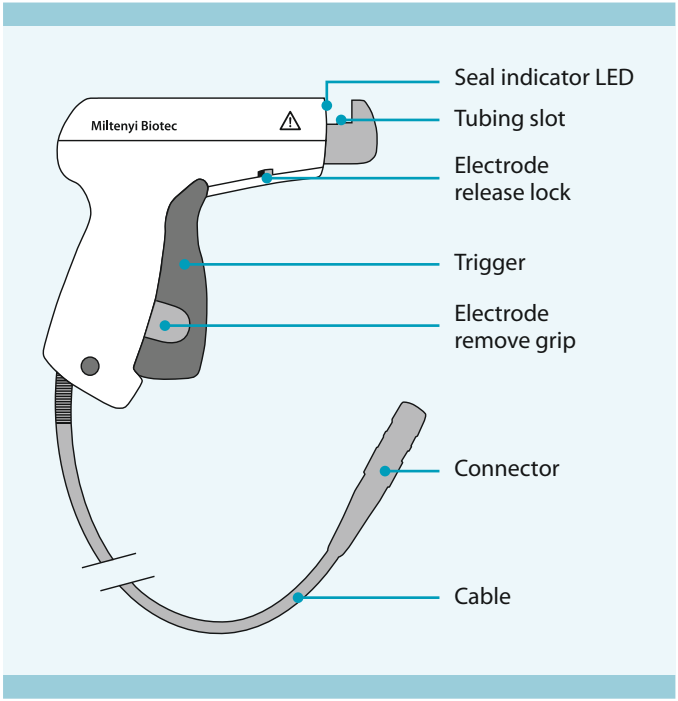

Figure 4.1: The MACS TubeSealer hand unit with cable and connector

4.4 Unpacking and installation

⚠ CAUTION

RIsk of damage to the MACS TubeSealer. Risk of damage to the heat sealer if it is unpacked or installed by unauthorized persons. Unpacking and initial installation of the MACS TubeSealer must only be performed by an authorized local Miltenyi Biotec Service Provider. Read chapter 3 "Important safety information" before use of the heat sealer. Visually inspect and note any significant damage to the package. Damage may require inspection by a representative of the shipping company.

4.4.1 Unpacking and inspection of spare part

⚠ CAUTION

Risk of damage to the MACS TubeSealer. In the event replacement is required, the heat sealer is shipped in a cardboard box. Visually inspect and note any significant damage to the package. In case of any damage, do not use the heat sealer and contact the authorized local Miltenyi Biotec Service Provider.

1. Lift the heat sealer out of the cardboard box and place it on a flat surface.

2. If parts of the heat sealer are damaged, immediately report it.

3. Connect the hand unit to the TubeSealer port (AUX 5 pin connector) on the rear of the CliniMACS Prodigy. Confirm the connector snaps in secured position.

4.5 Operating instructions

Regarding product specific electromagnetic emissions and immunity, refer to the appendix.

NOTICE

Never place an object other than the PVC or EVA tubing between the electrodes.

4.5.1 Description of sealing

The MACS TubeSealer has several safety functions that identify whether it is possible to seal the tubing before sealing is attempted. If the heat sealer does not start, see chapter 5 “Troubleshooting” for further information. The sealing process is based on radio frequency technology. Active sealing and sealing completion are indicated by a yellow light. The sealing process stops automatically when a proper seal is achieved. Temperature adjustments are not required.

The indicator on the hand unit shows different light indications depending on the status of the heat sealer (see Table 4.2).

Indicator	Description
Yellow light	RF-energy is being applied to the sealing electrode. Light turns off when sealing is completed.
Red flashes	Overheating, sealing function is blocked.
Red light for one second	In case of short circuit, sealing function is blocked.

Table 4.2: Indicator lights of the hand unit

NOTICE

The tubing must be dry on the outside.

1. Place the tubing to be sealed down in the bottom of the slot of the hand unit. Check that the tubing is placed between the electrodes in the slot.

2. Press the grey trigger on the hand unit to bring the two electrodes closer together until the light on top of the hand unit illuminates. The sealing procedure will commence automatically. The sealing time is normally 0.5 to 1.5 seconds; after a maximum of 6 seconds, the RF is turned off.

   Throughout the sealing process, a yellow light on the front of the hand unit is switched on. When this light goes out, the grey trigger may be released and the sealing is complete. The intelligent sense control in the hand unit detects, controls, and adjusts the sealing process to provide the best sealing quality for the type of tubing used. See Table 4.2 for the light indications on the hand unit, in case of problems.

3. When the light turns off, sealing is finished. Release the trigger and remove the tubing. **Note:** If the seal trigger is released, the sealing process stops.

4. The center of the seal pattern is very thin and pulling both sides will divide the tubing into two pieces.

5. Check the tubing for leakage. In case of sealer malfunction (intermittent operation, poor seals quality), call Miltenyi Biotec Technical Support for assistance.

⚠ CAUTION

Risk of loss of cell product. Multiple seals made closer than the recommended distance may result in rupture of the sealed tubing segment. If multiple seals are made along a length of tubing, they should be at least 1 cm (½ inch) apart.

4.5.2 Environmental requirements

⚠ WARNING

Safety and performance of the MACS TubeSealer may be compromised. Safety and performance of the heat sealer may be compromised if it is used outside its specifications. Do not use the heat sealer outside its specifications.

To optimize the performance of the heat sealer, refer to the operation conditions described in Table 4.1 and observe the following:

- When not in use, the heat sealer should be placed in the holder next to the CliniMACS Prodigy, free from vibrations and risk of shocks, dust, solvents, and acidic vapor.

- Handle the heat sealer with care in a clean environment.

4.6 Cleaning and disinfection

The MACS TubeSealer requires minimal maintenance for efficient operation. Follow the cleaning and disinfection procedure described below.

⚠ WARNING

Risk of electric shock or damage to the heat sealer. For safety reasons, always disconnect the hand unit from the CliniMACS Prodigy. Biohazardous material must be treated as potentially infectious at all times. In the event of spill, appropriate protective clothing should be worn during cleanup procedures. After removing residual biological material, surfaces which have been in contact with biohazardous material must be disinfected.

The surface of the heat sealer is compatible with the following disinfectants:

- Aldehyde up to 3%, e.g. Melsitt®[1] 3% or Kohrsolin®[2] FF 3%,
- Amphotenside up to 2%, e.g. Tensodur 2% (MFH Marienfelde GmbH, Hamburg) or
- Ethanol up to 80%.

Alternatively, a freshly prepared solution of diluted sodium hypochlorite (household bleach) may be used to disinfect surfaces which will not be harmed by the solution. Diluted solutions from one part bleach to ten parts water may be used. Regardless of the "sterilant" or disinfection solution used, remember to remove any residue to ensure that the surfaces of the heat sealer are not subject to corrosion or discoloration. Discard all materials in contact with biohazardous material according to institutional policies regarding the disposal of biohazardous materials.

⚠ CAUTION

Do not disinfect or sterilize any part of the heat sealer through autoclave or with ethylene oxide gas. To do so, will render the heat sealer unusable and void the warranty. Do not dip the unit in liquid, as it is not waterproof. Intruding liquid will result in malfunctions, tiny arcs, and void the warranty.

Cleaning the hand unit is required if biohazerdous material spillage occurs. Otherwise cleaning of the hand unit is recommended once per week.

1 Melsitt is a registered trademark of B. Braun Melsungen AG, Melsungen, Germany.
2 Kohrsolin is a registered trademark of Bode Chemie GmbH, Hamburg, Germany.

For cleaning the electrodes, remove the mobile electrode.

1. Pull the gray trigger till “click” to release the front electrode. Then push electrode release lock forward (see Figure 4.2).

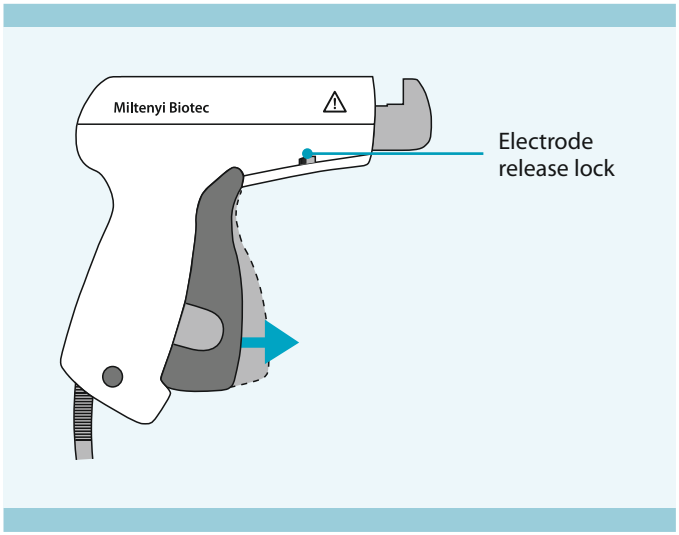

Figure 4.2: Pull the gray trigger.

2. First push the electrode inward and then pull out the electrode (see Figure 4.3).

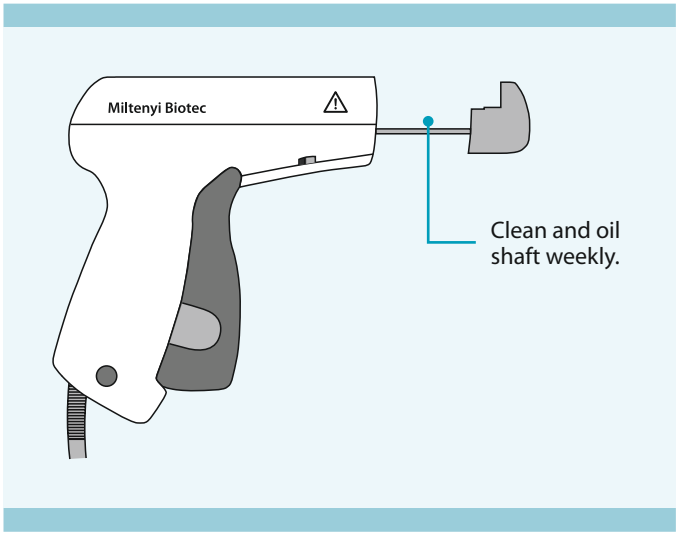

Figure 4.3: Pulled out electrode

Clean the handle and both electrodes with a soft lint-free cloth moistened with mild detergent. Dry carefully and ensure that the electrodes are completely dry to prevent sparks. To clean the electrode shaft, use a dry cotton swab.

⚠ CAUTION

For proper function, add a drip of light machine oil on the electrode shaft after each cleaning. After cleaning, inspect the electrodes for mechanical damage or wear out. Do not use if the heat sealer is damaged.

Assemble the parts in reverse order. Confirm the trigger and spring lock is in full forward position before electrode insertion. Insert the mobile electrode, ensuring that it is positioned parallel with the fixed electrode. Press the trigger twice and check that the mobile electrode moves smoothly, is in position, and not loose.

Note: It is recommended to perform some sealing tests before resuming use.

4.7 Disposal

The MACS TubeSealer must be separately collected according to the European directive of waste of electrical and electronic equipment (WEEE). For final disposal, the heat sealer must be returned to the manufacturer. Clean the heat sealer according to the instructions given in section 4.6. The heat sealer should be transported with care in packaging specified by Miltenyi Biotec. Contact Miltenyi Biotec Technical Support for final disposal.

5

Troubleshooting

This section is intended to cover common problems and offers recommended solutions for the MACS TubeSealer. For information not covered in Table 5.1, contact Miltenyi Biotec Technical Support or the authorized local Miltenyi Biotec Service Provider.

Symptom	Probable cause	Recommended action
The sealing does not start.	Wet electrodes	Dry the electrodes (see section 4.6).
	Dirty electrodes	Clean the electrodes (see section 4.6).
	Wet tubing	Dry the tubing and electrodes and try again (see section 4.6).
	Tiny arcs between the electrodes	Dry the electrodes and try again (see section 4.6).
	No "click" when pulling the trigger	Contact Miltenyi Biotec Technical Support to replace the heat sealer.
	Overheated (red blinking light)	Let the heat sealer cool down.
	Cable not connected correctly to the power source in the CliniMACS Prodigy.	Check that the connector has snapped into place.
	Cable broken	Contact Miltenyi Biotec Technical Support.
	Other cause	Contact Miltenyi Biotec Technical Support.

Symptom	Probable cause	Recommended action
Bad sealing	Mobile electrode doesn't move smoothly in handle.	Clean and oil electrode shaft (see section 4.6).
	Wet electrodes	Dry the electrodes and try again (see section 4.6).
	Dirty electrodes	Clean the electrodes (see section 4.6).
	Mobile electrode out of position	Contact Miltenyi Biotec Technical Support.
	Other cause	Contact Miltenyi Biotec Technical Support.
Intermittent sealing	Cable broken	Contact Miltenyi Biotec Technical Support.
Hard to divide tubing after seal	Rim on moving electrode damaged	Contact Miltenyi Biotec Technical Support.
	Mobile electrode does not move smoothly in handle.	Clean and oil electrode shaft (see section 4.6).
	Wet electrodes	Dry the electrodes and try again (see section 4.6).
	Dirty electrodes	Clean the electrodes (see section 4.6).
	Other cause	Contact Miltenyi Biotec Technical Support.
Seal lamp still lit after seal trigger has been released.	Seal switch is broken.	Contact Miltenyi Biotec Technical Support.
Seal lamp does not light.	Hand unit defective	Contact Miltenyi Biotec Technical Support to replace the heat sealer.
Seal lamp flickers	Cable broken	Contact Miltenyi Biotec Technical Support.
	Other cause	Contact Miltenyi Biotec Technical Support.

Table 5.1: Problems and solutions for user-level maintenance

6 Legal notes

6.1 Limited warranty

Except as stated in a specific warranty statement, which may accompany this Miltenyi Biotec product, or unless otherwise agreed in writing by a duly authorized Miltenyi Biotec representative, Miltenyi Biotec's warranty for products purchased directly from Miltenyi Biotec shall be subject to the terms and conditions of sale under which it was provided to you by the respective Miltenyi Biotec sales organization. These terms and conditions are available on request or at www.miltenyibiotec.com. The applicable terms and conditions of sale may vary by country and region. Nothing herein should be construed as constituting an additional warranty.

For products purchased from third-party retailers or resellers (e.g. purchased from an Authorized Distributor of Miltenyi Biotec), different terms and conditions may apply.

To determine the warranty that came with your product, see your packing slip, invoice, receipt or other sales documentation. Some components of a product combination you purchased may have a shorter warranty than that listed on your packing slip, invoice, receipt or other sales documentation (e.g. goods subject to shelf life and obsolescence).

Miltenyi Biotec's warranty for this product only covers product issues caused by defects in material or workmanship during normal use. It does not cover product issues caused by any other reason, including but not limited to product issues due to use of the product in a manner other than specifically described in this manual, for example: inappropriate or improper use; incorrect assembly or installation by an operator or a third party; reasonable wear and tear; negligent or incorrect operation, handling, storage, servicing, or maintenance; non-adherence to the operating instructions; unauthorized modification of or to any

part of this product; or use of inappropriate consumables, accessories, or work materials.

Miltenyi Biotec's warranty does not cover products sold AS IS or WITH ALL FAULTS or consumables. Nothing herein should be construed as constituting an additional warranty.

Miltenyi Biotec must be informed immediately, if a claim is made under such warranty. If a material or manufacturing defect occurs within the warranty period, Miltenyi Biotec will take the appropriate steps to restore the full usability of the instrument.

Limitation on damages
Miltenyi Biotec shall not be liable for any incidental or consequential damages for breach of any express or implied warranty or condition on this product.

Some countries/states or jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This warranty statement gives you specific legal rights and you may have other rights, which vary from state to state or jurisdiction to jurisdiction.

6.2 Trademarks

CliniMACS, CliniMACS Prodigy, MACS, and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec B.V. & Co. KG and/or its affiliates in various countries worldwide. All other company, product and service names, logos, and brands used herein are property of their respective owners and are for identification purposes only.

APPENDIX

Guidance and manufacturer's declaration on electromagnetic compatibility

MACS® TubeSealer manufactured until 2018

EMC compliance with IEC 60601-1-2:2007 (Third Edition) has been attested. The MACS® TubeSealer generates RF energy. While most modern electronic equipment and instruments feature proper shielding against RF energy, improperly shielded devices could be affected if close to the heat sealer. If electromagnetic interference with other devices is suspected, appropriate electronic shielding, a larger distance between the devices to the RF instrument or the operation in separate circuits may be required.

Guidance and manufacturer's declaration – Electromagnetic emissions

The MACS TubeSealer is intended for use in the electromagnetic environment specified below. The customer or the user of the heat sealer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF Emissions CISPR 11	Group 2	The heat sealer emits electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The heat sealer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Table A.1: Guidance and manufacturer's declaration – Electromagnetic emissions (manufactured until 2018)

⚠ WARNING

The heat sealer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the heat sealer should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – Electromagnetic immunity

The MACS TubeSealer is intended for use in the electromagnetic environment specified below. The customer or the user of the heat sealer should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines n/a	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the heat sealer requires continued operation during power mains interruptions, it is recommended that the heat sealer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Table A.2: Guidance and manufacturer's declaration – Electromagnetic immunity (manufactured until 2018)

Guidance and manufacturer's declaration – Electromagnetic immunity

The MACS TubeSealer is intended for use in the electromagnetic environment specified below. The customer or the user of the heat sealer should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the heat sealer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the heat sealer is used exceeds the applicable RF compliance level above, the heat sealer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the heat sealer.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6.3: Guidance and manufacturer's declaration – Electromagnetic immunity (manufactured until 2018)

Recommended separation distances between portable and mobile RF communications equipment and the MACS TubeSealer

The MACS TubeSealer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the heat sealer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters), and the heat sealer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 6.4: Recommended separation distances (manufactured until 2018)

MACS® TubeSealer manufactured as of 2019

EMC compliance with 60601-1-2:2014 (Edition 4) has been attested. The MACS® TubeSealer generates RF energy. While most modern electronic equipment and instruments feature proper shielding against RF energy, improperly shielded devices could be affected if close to the heat sealer. If electromagnetic interference with other devices is suspected, appropriate electronic shielding, a larger distance between the devices to the RF instrument or the operation in separate circuits may be required.

Guidance and manufacturer's declaration – Electromagnetic emissions

The MACS TubeSealer is intended for use in the electromagnetic environment specified below. The customer or the user of the heat sealer should assure that it is used in such an environment.

Emissions test	Compliance
RF Emissions CISPR 11	Group 2
RF Emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies

Table 6.5: Guidance and manufacturer's declaration – Electromagnetic emissions (manufactured as of 2019)

⚠ WARNING

Use of this heat sealer adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Based on technical limitations of the internal power supply voltage, interruptions on power supply input lines for longer than 10 ms may lead to cessation of the sealing process (power failure). The sealing process cannot be resumed after a power failure. It is recommended that the heat sealer is powered from an uninterruptible power supply or a battery that starts within 10 ms.

Guidance and manufacturer's declaration – Electromagnetic immunity

The MACS TubeSealer is intended for use in the electromagnetic environment specified below. The customer or the user of the heat sealer should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±2kV, ±4kV, ±8kV, ±15kV air discharge	±8 kV contact discharge ±2kV, ±4kV, ±8kV, ±15kV air discharge
Electrical fast transients (Bursts) IEC 61000-4-4	±2 kV 100kHz repetition frequency Power supply lines ±1 kV 100kHz repetition frequency Input/output lines	±2 kV 100kHz repetition frequency Power supply lines ±1 kV 100kHz repetition frequency Input/output lines
Surges IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground
Voltage dips, interruptions, and variations IEC 61000-4-11	0% U_T during 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T during 1 cycle and 70% U_T during 25/30 cycles (single phase) @ 0° 0% U_T during 250/300 cycle	0% U_T during 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T during 1 cycle and 70% U_T during 25/30 cycles (single phase) @ 0°
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz
Conducted disturbances induced by RF fields IEC 1000-4-6	3 V (0.15 MHz to 80 MHz) 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM @ 1kHz	3 V (0.15 MHz to 80 MHz) 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM @ 1kHz
Radiated RF EM fields IEC 61000-4-3	3 V/m (80 MHz–2.7 GHz) 80% AM @ 1kHz	3 V/m (80 MHz–2.7 GHz) 80% AM @ 1kHz
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See table below: Specifications for immunity to RF wireless communication equipment	See table below: Specifications for immunity to RF wireless communication equipment

Table A.6: Guidance and manufacturer's declaration – Electromagnetic immunity (manufactured as of 2019)

Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment							
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
385	380 – 390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27	27
450	430 – 470	GMRS460, FRS460	FM ±5kHz deviation 1kHz sine	2	0.3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 217 Hz	2	0.3	28	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28	28
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9

Table A.7: Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment (manufactured as of 2019)

⚠ WARNING

Degradation of the performance of the heat sealer. Degradation of the performance of this equipment if portable RF communications equipment is used in close proximity to any part of the heat sealer. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the heat sealer, including cables specified by the manufacturer.

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