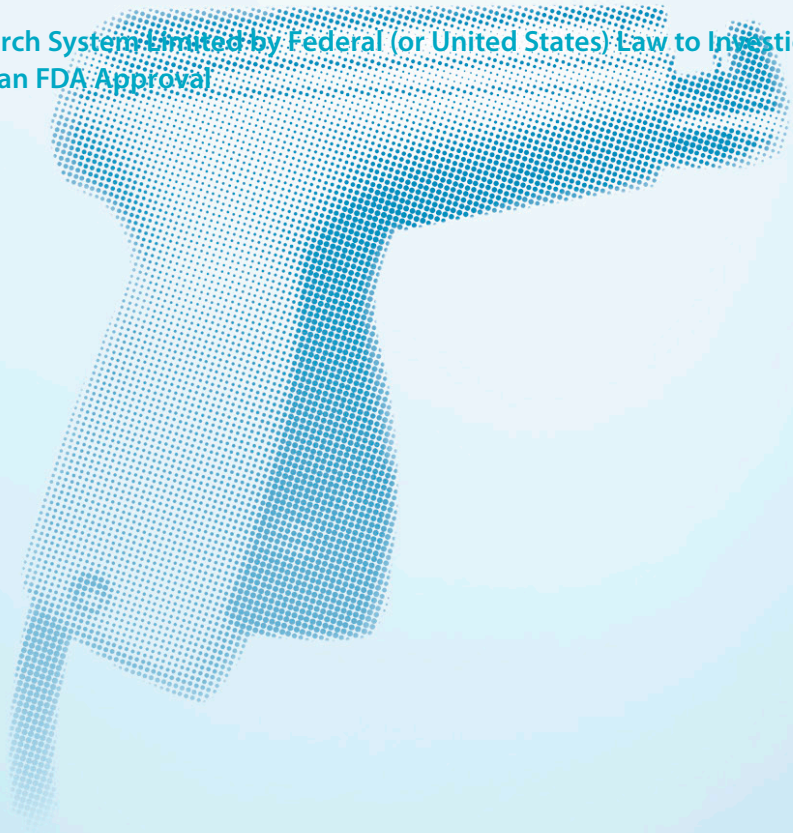
Miltenyi Biotec

MACS® TubeSealer

User manual

CAUTION:
Clinical Research System Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval



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.

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MACS® TubeSealer

User manual

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APPENDIX

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1

About this user manual

This user manual provides instructions, warnings, precautions, and other important information for the use of the MACS TubeSealer. For information on the use of the specific applications, or further information, warnings, and precautions regarding the operation of the CliniMACS instruments, refer to the respective CliniMACS instrument user manual.

1.1 Essential information

⚠ WARNING

The operation must be performed by trained operators only. Before putting the product 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 system components (including, without limitation, the safety information in this user manual, chapter 4 ´Safety information´) and in any safety-related recommendations issued by Miltenyi Biotec. Adhere to all instructions and procedures at all times during the operation of the product, confirming that all safety information, warnings, precautions, and instructions are observed. Failure to observe the safety information, warnings, precautions, and instructions contained in the instructions for use could result in product malfunction, property damage, personal injury, and/or death. Equipment safety may be compromised if the product 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 product for all personnel responsible for installation, operation, and maintenance.

1.2 Presentational conventions

The following formatting styles are used to indicate specific information types in this user manual.

1.2.1 Text styles

• Bullet point list item with text	Indicates a list item
1. Numbered list item with text	Indicates a list item of a step-by-step instruction
A Capital letter list item with text	Indicates an optional list item
Bold <colored> text	Indicates software elements, for example, a button or a tab of the user interface
Bold ‹**black**› text	Indicates software elements, for example, a certain part of the user interface
See section 1.2.1 ´Text styles´	References to the section with the number 1.2.1 and the heading ´Text styles´
See Figure 2.1/Screen 2.1/Table 2.1	References to the first figure/screen/table in the second chapter.

1.2.2 Screens and figures

IMPORTANT

The screens and the figures in this manual are only representative screens and may differ slightly from those shown on the instrument.

1.2.3 Warning messages

The color and signal word of a warning message depend on the hazard level (see chapter 4 ´Safety information´). The following examples show the layout of warning messages at the beginning of a chapter/section where a hazard can occur.

⚠ WARNING

Type and source of hazard. Consequences of non-compliance.

- Measures to avoid the hazard.

⚠ CAUTION

Type and source of hazard. Consequences of non-compliance.

- Measures to avoid the hazard.

NOTICE

Type and source of hazard. Consequences of non-compliance.

- Measures to avoid the hazard.

The following example shows the layout of warning messages before an instructional step.

WARNING! Type and source of hazard. Consequences of non-compliance. Measures to avoid the hazard. Instructional text.

2 Introduction

2.1 General information

The MACS TubeSealer is a fully automatic accessory for sealing PVC and EVA tubing. The hand unit is connected to the CliniMACS instruments by a cable. The sealing takes place in the hand unit when the trigger is pressed. All CliniMACS 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.

3 Glossary

3.1 Glossary of symbols and terms

An overview of symbols and terms used for the MACS TubeSealer is provided in the respective CliniMACS instrument user manual. The glossary of symbols depicts the symbols used for labeling of the CliniMACS Products.

4

Safety information

4.1 Hazards

4.2 Hazard levels

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 that, if not avoided, could result in death or serious injury.

CAUTION

indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

indicates a hazardous situation that, if not avoided, could result in property damage. This does not indicate a risk of personal injury.

IMPORTANT

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

4.3 General safety notes

⚠ WARNING

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

- Always operate, handle, use, and maintain the product in accordance with the safety information, warnings, precautions, instructions, and recommended procedures provided in the user manuals and other written instructions issued by Miltenyi Biotec.
- Always ensure that the product is operated, handled, used, and maintained only by appropriately skilled and trained personnel familiar with the construction, operation, and hazards involved with the product. The product is intended for the use in the professional facility healthcare environment. The product is not intended to be used near active HF surgical equipment.
- Always operate, handle, use, and maintain the product 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 product is operated.
- Always use the product 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 product with consumables, accessories, transducers, and/or cables other than those approved by Miltenyi Biotec to ensure safe and proper operation of the product.
- 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 product under applicable regulations.
- Always follow the maintenance recommendations of Miltenyi Biotec and appropriate product standards. Only authorized local Miltenyi Biotec service provider should install, maintain, or service the product.
- Report any defects immediatetly. If there is any doubt regarding the proper functioning of the product, do not use the product and contact the authorized local Miltenyi Biotec service provider or Miltenyi Biotec Technical Support.
- Only make changes to the product with written permission from Miltenyi Biotec. Unauthorized modifications may void the warranty and your operating authority under applicable regulations.

4.3.1 Electrical hazards

⚠ WARNING

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

Environment

- The product is intended for use with the CliniMACS instruments. Do not use with or connect to any other instrument. 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. Do not use the instrument in a wet or damp location or if it has been exposed to moisture.
- Avoid ingress of any liquid into the instrument.
- Do not operate the instrument if liquids have spilled into the instrument.
- Avoid condensation. After moving the product from a cold environment, such as a cold room at +4 °C (+39 °F), to room temperature, condensing liquid droplets may form inside the product. Wait for the instrument to dehumidify before operating the product.

Cleaning

- Only clean the instrument when it is switched off and the power cord is unplugged.
- Do not use liquid or aerosol cleaning agents; always use a damp cloth.

ELECTROMAGNETIC INTERFERENCE REGULATIONS:

The product emits a low level of electromagnetic (non-ionizing) radiation during sealing. It should not be used near high-frequency sensitive electronic equipment.

The product 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´ on page 31.

Inspect all parts of the product for the appearance of defects before use.

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

Disconnect the product 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 product and/or call Miltenyi Biotec Technical Support for assistance.

Periodically check the pattern of the sealing visually (see section 5.5 ´Operation´ on page 20).

5 MACS TubeSealer

5.1 Regulatory information

Intended purpose

As an accessory of the CliniMACS instruments, the MACS TubeSealer is intended to seal PVC and EVA tubes. The MACS TubeSealer must only be used in combination with CliniMACS instruments.

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

MD

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.

5.2 Technical data

⚠ WARNING

Safety and performance of the MACS TubeSealer may be compromised. Safety and performance of the product may be compromised if it is used outside its specifications.

- Do not use the product outside its specifications.

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 at 20 °C The product is suitable for sealing of tubing of the CliniMACS 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 5.1: Technical data of the MACS TubeSealer

Note: The emissions characteristics of this product 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 product might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the product.

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

5.3 Components of the MACS TubeSealer

The MACS TubeSealer is comprised of the hand unit with a cable and a connector (see Figure 5.1). 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.

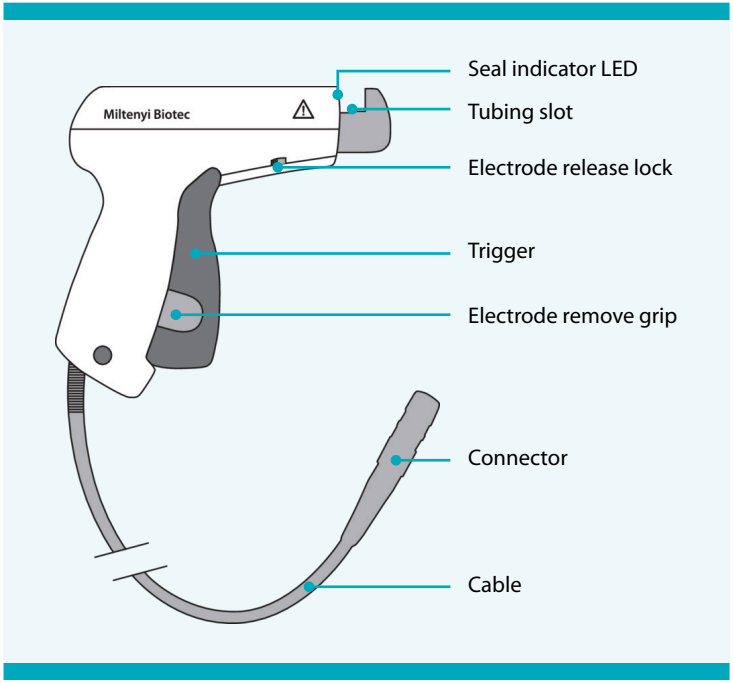


Figure 5.1: The MACS TubeSealer hand unit with cable and connector

5.4 Unpacking and installation

⚠ CAUTION

Risk of damage to the MACS TubeSealer. Risk of damage to the product 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 4 ´Safety information´ on page 13 before use of the product.
- Visually inspect and note any significant damage to the package.
- Damage may require inspection by a representative of the shipping company.

5.4.1 Unpacking and inspection of spare part

⚠ CAUTION

Risk of damage to the MACS TubeSealer. In the event replacement is required, the product 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 product and contact the authorized local Miltenyi Biotec service provider.

1. Lift the product out of the cardboard box and place it on a flat surface.
2. If parts of the product are damaged, immediately report it.
3. Connect the hand unit to the TubeSealer port on the rear of the CliniMACS instrument. Confirm the connector snaps in secured position.

5.5 Operation

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

⚠ CAUTION

Risk of delay of cell preparation. Improper use may lead to damage to the product.

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

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 product has several safety functions that identify whether it is possible to seal the tubing before sealing is attempted. If the product does not start, see chapter 6 ´Troubleshooting´ on page 27 for further information.

5.5.1 Indicator lights

The indicator on the hand unit shows different light indications depending on the status (see Table 5.2)

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 5.2: Indicator lights of the hand unit

5.5.2 Operating instructions

⚠ CAUTION

Risk of delay of cell preparation. Improper function may lead to delay of cell separation.

- Only use the product when the tubing is 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 gray 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 gray 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. If the light is not yellow, see Table 5.2
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 Milteny 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.

5.5.3 Environmental requirements

⚠ WARNING

Safety and performance may be compromised. Safety and performance may be compromised if the product is used outside its specifications.

- Do not use the product outside its specifications.

To optimize the performance of the product, refer to the operation conditions described in Table 5.1 and observe the following:

- When not in use, the product should be placed in the holder next to the CliniMACS instrument, free from vibrations and risk of shocks, dust, solvents, and acidic vapor.
- Handle the product with care in a clean environment.

5.6 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 product. Disregarding the safety instructions can lead to electric shock or product damage.

- Always disconnect the hand unit from the CliniMACS instrument. 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 product is compatible with the following disinfectants:

• Aldehyde up to 3%

• Amphotenside up to 2% or

• Ethanol up to 80%.

Regardless of the "sterilant" or disinfection solution used, remember to remove any residue to ensure that the surfaces of the product 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

Risk of instrument damage. Liquids inside the instrument or sterilization through autoclave or with ethylene oxide gas can damage the instrument and void the warranty.

- Do not autoclave, sterilize with ethylene oxide gas, or dip the unit in liquid

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

For cleaning the electrodes, remove the mobile electrode.

1. Pull the gray trigger until "click" to release the front electrode. Then push electrode release lock forward (see Figure 5.2).

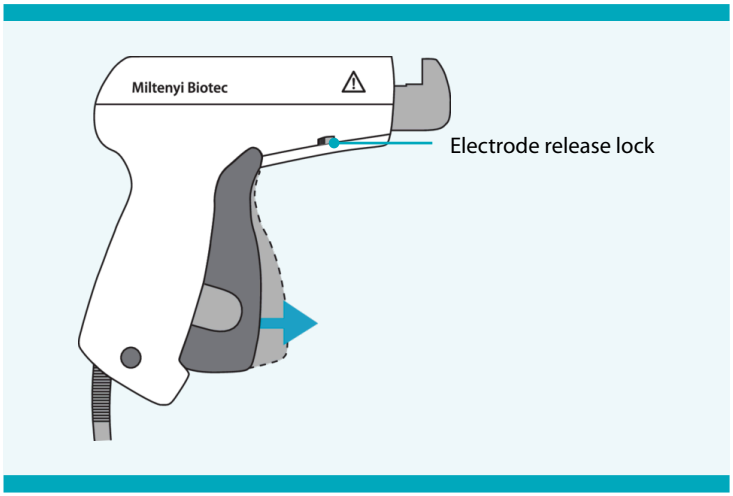


Figure 5.2: Pull the gray trigger.

2. First push the electrode inward and then pull out the electrode (see Figure 5.3).

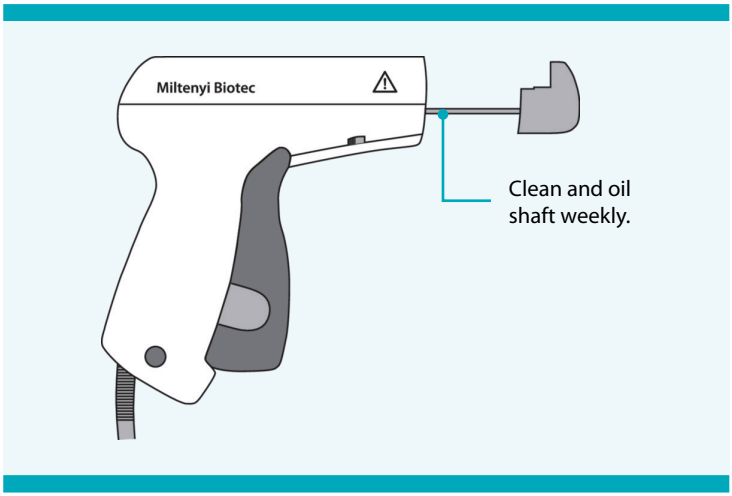


Figure 5.3: Pulled out electrode

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

Risk of delay of cell preparation. Improper function may lead to delay of cell separation.

- 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 product 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.

⚠ WARNING

Biological hazard. Depending on the biological material used, contact may lead to severe personal injury or death.

- If any component is exposed to blood or biohazardous material, clean the product with appropriate disinfectant solution.

5.7 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 product must be returned to the manufacturer. Clean the product according to the instructions given in section 5.6 ´Cleaning and disinfection´. The product should be transported with care in packaging specified by Miltenyi Biotec. Contact Miltenyi Biotec Technical Support for final disposal.

6

Troubleshooting

This section is intended to cover common problems and offers recommended solutions.
For information not covered in Table 6.1 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 5.6 ´Cleaning and disinfection´ on page 22).
	Dirty electrodes	Clean the electrodes (see section 5.6 ´Cleaning and disinfection´ on page 22)..
	Wet tubing	Dry the tubing and electrodes and try again (see see section 5.6 ´Cleaning and disinfection´ on page 22).
	Tiny arcs between the electrodes	Dry the electrodes and try again (see section 5.6 ´Cleaning and disinfection´ on page 22).
	No "click" when pulling the trigger	Contact Miltenyi Biotec Technical Support to replace the product.
	Overheated (red blinking light)	Let the product cool down.
	Cable not connected correctly to the power source in the CliniMACS instrument.	Check that the connector has snapped into place.
	Cable broken	Contact Miltenyi Biotec Technical Support.
	Other cause	Contact Miltenyi Biotec Technical Support.
Bad sealing	Mobile electrode does not move smoothly in handle.	Clean and oil electrode shaft (see section 5.6 ´Cleaning and disinfection´ on page 22).
	Wet electrodes	Dry the electrodes and try again (see section 5.6 ´Cleaning and disinfection´ on page 22).
	Dirty electrodes	Clean the electrodes (see section 5.6 ´Cleaning and disinfection´ on page 22).

Symptom	Probable cause	Recommended action
	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 5.6 ´Cleaning and disinfection´ on page 22).
	Wet electrodes	Dry the electrodes and try again (see section 5.6 ´Cleaning and disinfection´ on page 22).
	Dirty electrodes	Clean the electrodes (see section 5.6 ´Cleaning and disinfection´ on page 22).
	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 product.
Seal lamp flickers	Cable broken	Contact Miltenyi Biotec Technical Support.
	Other cause	Contact Miltenyi Biotec Technical Support.

Table 6.1: Problems and solutions for user-level maintenance

7 Legal notes

7.1 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.

7.2 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 trademarks mentioned in this document are the property of their respective owners and are used for identification purposes only.

APPENDIX

Guidance and manufacturer's declaration on electromagnetic compatibility

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 product. 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 emmisions

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

Emissions test	Compliance
RF Emissions CISPR 11	Group 2
RF Emissions CISPR 11	Class B
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

⚠ WARNING

Risk of compromised safety or performance. Using the instrument while adjacent to or stacked with other equipment may compromise the safety or performance.

- Do not use the instrument if adjacent to or stacked with other equipment.
- If adjacent or stacked use is necessary, carefully observe the instrument to verify normal operation.

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 product 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 product 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge
Electrical fast transients (Bursts) IEC 61000-4-4	±2 kV 100 kHz repetition frequency Power supply lines ±1 kV 100kHz repetition frequency Input/output lines	±2 kV 100 kHz repetition frequency Power supply lines ±1 kV 100 kHz 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 at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T during 1 cycle and 70% U_T during 25/30 cycles (single phase) at 0° 0% U_T during 250/300 cycle	0% U_T during 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T during 1 cycle and 70% U_T during 25/30 cycles (single phase) at 0°
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V (0.15 MHz to 80 MHz) 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V (0.15 MHz to 80 MHz) 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF EM fields IEC 61000-4-3	3 V/m (80 MHz–2.7 GHz) 80% AM at 1 kHz	3 V/m (80 MHz–2.7 GHz) 80% AM at 1 kHz
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.2: Guidance and manufacturer's declaration – Electromagnetic immunity

Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment

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

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 18 Hz	1.8	0.3	27	27
450	430 – 470	GMR S460, FRS 460	FM ±5 kHz deviation 1 kHz 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.3: Guidance and manufacturer's declaration – Electromagnetic immunity to RF wireless communication equipment

⚠ WARNING

Degradation of the performance of this equipment. If portable RF communications equipment is used in close proximity to any part of the product, this can degrade the performance of this equipment

- 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 product, including cables specified by the manufacturer.

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