



Operating Manual

QuickSeal[®] Cutter

Large Diameter Cutter



Read and understand all of the instructions and safety information in this manual before operating or servicing this tool.

Contents

| | |
|---|----|
| 1 Introduction | 4 |
| 1.1 Description | 4 |
| 1.2 Safety | 4 |
| 1.3 Purpose of this Manual | 4 |
| 1.4 Symbols Used | 5 |
| 2 General Safety Rules | 6 |
| 3 Important Safety Information | 8 |
| 4 Overview | 11 |
| 5 Operation | 12 |
| 5.1 Charging the Battery | 12 |
| 5.2 LED Indicator (Red) | 12 |
| 5.3 Cutting the Collar | 13 |
| 6 Maintenance | 14 |
| 6.1 Each Operating Day | 14 |
| 6.2 Monthly | 14 |
| 6.3 Annually (or after 10,000 cuts) | 14 |
| 6.4 Preventative Maintenance | 15 |
| 6.5 LCD Display | 15 |
| 7 Correction of defects | 16 |
| 7.1 Before You Begin | 16 |
| 8 Technical Data | 17 |
| 8.1 Cutting Capacities | 17 |
| 8.2 Cutting Tool | 17 |
| 8.3 Battery | 17 |
| 9 Risk Assessment | 18 |
| 10 Appendix | 28 |
| 10.1 Service | 28 |
| 10.2 Decontamination Declaration | 28 |
| 10.3 CE Declaration of Conformity | 29 |
| 10.4 Service and Maintenance Request Form | 30 |

1 Introduction

1.1 Description

The QUICKSEAL® Large Diameter Cutter is a hand-held, self-contained cutting tool intended to cut the QUICKSEAL® collars.

1.2 Safety

Safety is essential in the use and maintenance of all tools and equipment. This manual and any markings on the tool provide information for avoiding hazards and unsafe practices related to the use of this tool. Observe all of the safety information provided.

1.3 Purpose of this Manual

This manual is intended to familiarize all personnel with the safe operation and maintenance procedures for the following tool:

QUICKSEAL® Large Diameter Cutter
Keep this manual available to all personnel.

Replacement manuals are available upon request. Please contact your sales representative for replacement.

This tool is protected by US Patent Nos:

- 6,276,186
- 6,401,515
- 6,718,870
- 7,086,979
- 7,254,982

All specifications are nominal and may change as design improvements occur. Sartorius Stedim Biotech and Sartorius AG shall not be liable for damages from misapplication or misuse.

Declaration of Conformity see page 29.

1.4 Symbols Used

As a means of instruction and direct warning of hazards, all important text statements in these installation instructions will be marked as follows:



This instruction denotes a possible danger with medium risk of death or severe injury if not avoided.



This symbol denotes a possible danger with moderate or minor risk of injury if not avoided.



This symbol denotes a danger with low risk of damage to property if not avoided.



This symbol:

- is an indication of a function or setting on the device,
- is an indication that caution should be exercised while working,
- identifies useful information.

The following presentations will also be used:

- Texts that use this mark are lists
- ▶ Texts that use this mark describe activities that must be carried out in the specified order
- ▷ Texts that use this mark describe the result of an action

2 General Safety Rules



Read all instructions. Failure to follow all instructions listed below may result in electric shock, fire and/or serious injury. The term "power tool" in all of the warnings listed below refers to your mains operated (corded) power tool or battery operated (cordless) power tool, also machines and electric units.

Save these instructions.

Work Environment

- Keep work area clean and organized. Cluttered and dark areas might trigger accidents.
- Do not operate power tools in explosive atmospheres, such as in the presence of flammable liquids, gases or dust. Power tools create sparks which may ignite the dust or fumes.
- Keep persons away while operating a power tool. Distractions can cause you to lose control.

Electrical Safety

- Power tool plugs must match the outlet. Never modify the plug in any way. Do not use any adapter plugs with earthed power tools. Unmodified plugs and matching outlets will reduce risk of electric shock.
- Avoid body contact with earthed surfaces such as pipes, radiators, ranges and refrigerators. There is an increased risk of electric shock if your body is earthed or grounded.
- Do not expose power tools to rain or humidity. Water penetrating a power tool will increase the risk of electric shock.
- Do not abuse the cord. Never use the cord for carrying, pulling or unplugging the power tool. Keep cord away from heat, oil, sharp edges or moving parts. Damaged or entangled cords increase the risk of electric shock.
- When operating a power tool outdoors, use an extension cord suitable for outdoor use. Use of a cord suitable for outdoor use reduces the risk of electric shock.

Personal Safety

- Stay alert, be aware what you are doing and use common sense when operating a power tool. Do not use a power tool while you are tired or under the influence of drugs, alcohol or medication. A moment of inattention while operating power tools may result in serious personal injury.
- Use safety gear and always wear eye protection. Safety equipment such as dust mask, anti-skid safety shoes, hard hat, or hearing protection used for appropriate conditions will reduce personal injuries.
- Avoid unintended starts. Make sure the switch is in the off position before plugging in.
Carrying power tools with your finger on the switch or plugging in power tools that have the switch on invites accidents. Do not manipulate the switch.
- Remove any adjusting key or wrench before turning the power tool on. A wrench or a key left attached to a rotating part of the power tool may result in personal injury.
- Keep proper footing and balance at all times.
This enables better control of the power tool in unexpected situations.

- If devices are provided for the connection of dust extraction and collection facilities, ensure these are connected and properly used. Use of these devices can reduce dust related hazards.

Care and Usage of Power Tools

- Do not overload the power tool. Use the correct power tool for your application. The correct power tool will do the job better and safer at the rate for which it was designed.
- Do not use a power tool with a defective switch. Any power tool that cannot be controlled with the switch is dangerous and must be repaired.
- Disconnect the plug from the power source before making any adjustments, changing accessories, or storing power tools. Such preventive safety measures reduce the risk of starting the power tool accidentally.
- Do not allow persons unfamiliar with the power tool or these instructions to operate the power tool. Power tools are dangerous in the hands of untrained users.
- Maintain power tools thoroughly. Check for functionality or jamming of moving parts, breakage of parts and any other condition that may affect the power tools' operation. Many accidents are caused by poorly maintained power tools.
- Keep cutting tools clean and free from debris or defects. Properly maintained cutting tools are less likely to jam and are easier to control.
- Use the power tool, accessories, dies and jaws etc., in accordance with these instructions and in the manner intended for the particular type of power tool, taking into account the working conditions and the work to be performed. Use of the power tool for operations different from those intended could result in a hazardous situation. All unauthorized modifications to the power tool are prohibited for safety reasons.

Service

- Have the power tool repaired by Sartorius Stedim Biotech before use.

3 Important Safety Information



Read and understand all of the instructions and safety information in this manual before operating or servicing this tool. Failure to observe this warning could result in severe injury or death.



This tool shall be used by qualified personnel who have read and understand this manual in its entirety.
Failure to observe this warning could result in severe injury or death.



Electric shock hazard.
This tool is not insulated. When using this unit near energized electrical lines, use proper personal protective equipment.
Failure to obey this warning could result in severe injury or death.



Wear eye protection when operating or servicing this tool.
Failure to wear eye protection could result in serious eye injury from flying debris or hydraulic oil.



Skin injection hazard: Do not use hands to check for oil leaks.
High pressure oil easily punctures skin causing serious injury, gangrene, or death. If injured, seek medical help immediately to remove oil.



Do not use solvents or flammable liquids to clean the cutting tool.
Solvents or flammable liquids could ignite and cause serious injury or property damage



Cutting Hazard: Keep hands away from the cutting head when cutting.
Failure to observe this warning could result in severe injury or death.



Do not dispose of batteries in a fire. They will vent fumes and may explode.
Failure to observe this warning could result in severe injury from harmful fumes or burns from flying debris.



Inspect tool and blades before use. A damaged or improperly assembled tool can break and strike nearby personnel. Contact Sartorius Stedim Biotech for necessary repairs.
Failure to observe this warning could result in severe injury or death.



This tool shall be used by only one person at a time. This tool shall not be used if more than one operator is required to operate the tool, support the tubing or otherwise be in close proximity (<12") to the tool.
Failure to observe this warning could result in severe injury or death.



Keep work area clean, organized and well lit. Cluttered, dark areas might trigger accidents.
Failure to observe this warning could result in severe injury or death.



Do not operate in explosive atmospheres, such as in the presence of flammable liquids, gases or dusts. Power tools create sparks which may ignite the dust or fumes.



Stay alert, be aware of what you are doing and use common sense when operating a power tool. Do not use a power tool while you are tired or under the influence of drugs, alcohol or medication. A moment of inattention while operating power tools may result in serious personal injury.



Dress properly. Use safety gear and always wear eye protection. Do not wear loose clothing or jewelry. Keep your hair, clothing and loose fitting gloves away from moving parts. Loose clothing, jewelry or long hair can be caught in moving parts.



Avoid unintended starts. Remove the battery when the tool is not in use. Carrying power tools with your finger on the switch or plugging in power tools that have the switch on invites accidents. Do not manipulate the switch.



Keep proper footing and balance at all times. This enables better control of the power tool in unexpected situations.



Disconnect the battery before making any adjustments or cleaning of the tool, and when the tool is in storage or not in use.



Store the tool out of the untrained persons.



Maintain the condition of the cutting tool and do not use if the tool is damaged or appears unfit for use.



Do not use the tool if the switch does not turn on or off. Do not use the tool if it is not working properly.



- Do not operate the tool without cutting blades. Damage to the ram or cutting head can result.
 - Do not twist work piece or tool during cutting operation. Blade failure could result.
 - This tool is not designed for continuous use. After 100 cutting cycles, allow the cutting tool to cool for 15 minutes.
 - Do not secure this tool in a vise. This tool is designed for hand-held operation.
 - This tool may be used in damp or wet environments; however, air-drying is recommended before use if the tool becomes soaked. Damage may result when the tool is operated prior to thorough drying when electrical components are soaked.
 - Use this tool for manufacturer's intended purpose only.
 - Do not store the tool when wet or damp.
 - This tool should be used only to cut the metallic collar of the QUICKSEAL® tubing assembly supplied by Sartorius Stedim. Cutting any other item is prohibited and can result in injury or damage to the cutting tool.
- Failure to observe these precautions may result in injury or property damage. Do not allow anything to contact the battery terminals.



- Do not immerse the batteries in liquid. Liquid may create a short circuit and damage the battery. If batteries are immersed, contact your service center for proper handling.
- Do not place battery into a pocket, tool pouch, or tool box with conductive objects. Conductive objects may create a short circuit and damage the battery.
- Do not place a battery on moist ground or grass. Moisture may create a short circuit and damage the battery.

Failure to observe these precautions may result in injury or property damage.



- Do not store the battery at more than 122°F (50°C) or less than -4°F (-20°C). Damage to the battery can result.
- Do not use another manufacturer's charger. Other manufacturers' chargers may overcharge and damage the battery.
- Do not attempt to open the battery. It contains no userserviceable parts.

Failure to observe these precautions may result in injury or property damage.

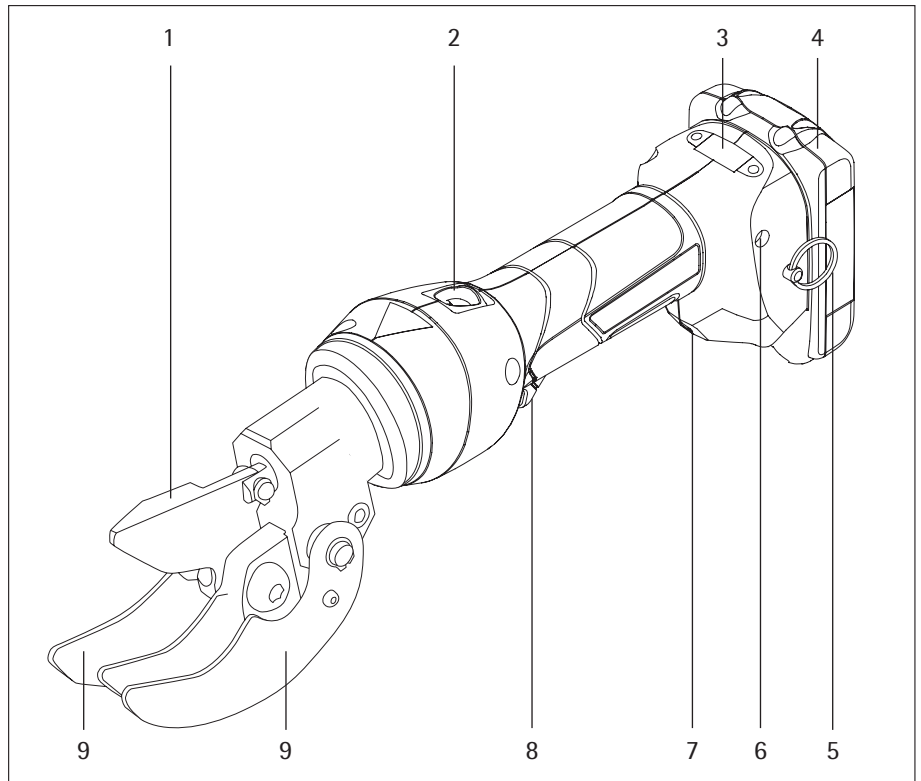


- Do not perform any service or maintenance other than as described in this manual. Injury or damage to the tool may result. Failure to observe these precautions may result in injury or property damage.



Keep all decals clean and legible, and replace when necessary.

4 Overview

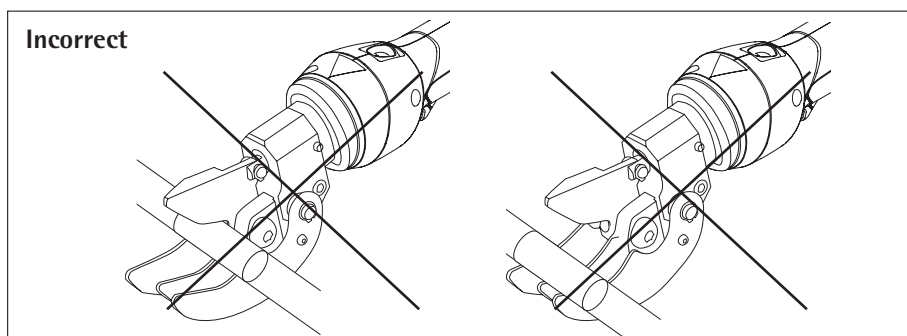
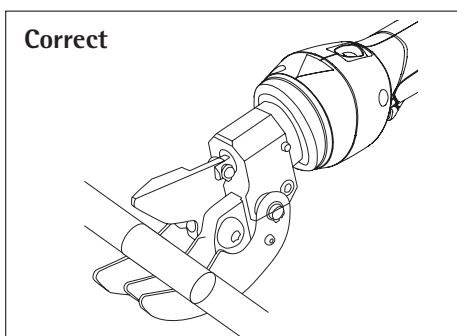


| Pos. | Description |
|------|-----------------------|
| 1 | Cutting Head |
| 2 | Retract Button |
| 3 | LCD Screen |
| 4 | Battery Cartridge |
| 5 | Lanyard Ring |
| 6 | LED Worklight (white) |
| 7 | Tube Guides |
| 8 | Trigger |
| 9 | Tube Guides |



5.3 Cutting the Collar

- ▶ Install the battery into the base of the QUICKSEAL® cutting tool. Be sure the trigger is not depressed during battery installation.
- ▶ The cutting head should be fully open. Push and hold the retract button until cutting head is fully open.
- ▶ Lay the metallic collar of QUICKSEAL® into the cutting head so that the tubing | collar is resting on the tube guides.
 - It is not necessary, and may result in malformed seal, to push the collar into the pivot point between the upper and lower blades of the cutting head
 - The guides present the collar to the cutting edge at a slight angle.



- ▶ Pull the trigger and make the cut between the 2 arrows on the collar.
- ▶ Hold the trigger down until the cutting tool achieves pressure relief which is accompanied by an audible "pop".
- ▶ The cutting tool returns automatically after the audible "pop". Use the retract button, if necessary to return the cutting head to the fully open position.
- ▶ Remove battery from cutting tool; clean and store properly.

IMPORTANT

The cutting process can be interrupted at any moment by releasing the trigger. If it is necessary to retract the ram before a cutting cycle is completed, push the retract button. Pushing the retract button will result in the complete retraction of the ram.

IMPORTANT

Lay QUICKSEAL® Collar in the trough of the cutting guides.

6 Maintenance

6.1 Each Operating Day

Before Use:

- ▶ Inspect blades for wear or damage such as cracks, gouges or chips.
- ▶ Inspect the tool for damage or leaks. If damage is detected, return the tool to Sartorius Stedim Biotech for inspection.



Skin injection hazard:

Do not use hands to check for oil leaks.

High pressure oil easily punctures skin causing serious injury, gangrene, or death. If injured, seek medical help immediately to remove oil.

After Use:

- ▶ Wipe all tool surfaces clean with a damp cloth and mild detergent.



Do not use solvents or flammable liquids to clean the cutting tool. Solvents or flammable liquids could ignite and cause serious injury or property damage.

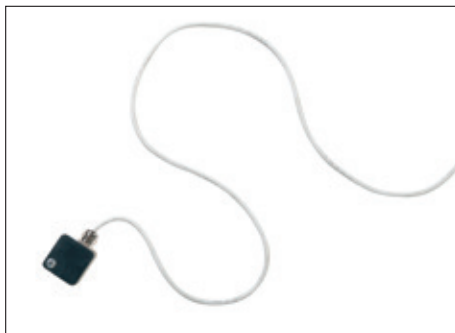
- ▶ Retract the ram putting the blades into the fully open position. Place the tool into the carrying case. Store in a cool, dry place.
- ▶ Charge the battery.

6.2 Monthly

Thoroughly clean all surfaces.

6.3 Annually (or after 10,000 cuts)

Return the tool to Sartorius Stedim Biotech for inspection (see also Chapter "10 Appendix", page 28).



6.4 Preventative Maintenance

Generate cutting tool data reports including number of cuts since last maintenance and more with i-press® App or software.

i-press® App

Connect the tool to a smartphone by Bluetooth®. Added features include project logs, adjust tool settings

QSCUTTERREADER

Fit adaptor over the light diode on the QUICKSEAL® cutter and depress the trigger to read data on the i-press® software.

- ▶ Download for i-press® free software:
<http://www.klauke.com/en/support/download/connectivity-software/>



i-press® is a registered trademark of Gustav Klauke GmbH
Bluetooth® is a registered trademark of Bluetooth Sig, Inc.
Google Play® is a registered trademark of Google, LLC
App Store® is a registered trademark of Apple, Inc.

- ▶ Download for i-press® app:
<https://itunes.apple.com/de/app/i-press/>
<https://play.google.com/store/apps/details?id=com.textron.klauke.iPress.Droid>

6.5 LCD Display

The LCD screen displays important information about the machine. Install battery, depress trigger and identify and error codes.

| Code | Description | Code | Description |
|------|--------------------------------|------|-----------------------------|
| 1 | Overcurrent fuse | 10 | Real-time clock battery low |
| 2 | Overcurrent comparator | 11 | Tool deactivated |
| 3 | Overheated circuit board | 12 | Service necessary |
| 4 | Overheated battery | 13 | Real-time clock not found |
| 5 | Battery empty; operation stops | 14 | Bluetooth® unit not found |
| 6 | Faulty cut; complete cycle | 15 | |
| 7 | Faulty cut; incomplete cycle | 16 | Pressure sensor not found |
| 8 | Low battery | 17 | Burst pressure exceeded |
| 9 | Battery empty; tool won't run | 18 | Battery temperature too low |

Adjust to preferences on LDC screen by pressing the buttons on either side of the LCD screen

| Code | Description |
|------|--|
| 1 | Bluetooth® status, battery charge, current pressure, max. pressure |
| 2 | Firmware, available firmware update, serial number |
| 3 | Current user. Press & hold both buttons to change user, select with right button, and confirm by jogging the tool. |
| 4 | |
| 5 | |
| 6 | Cycles until next service |
| 7 | Since manufacturing: operating hours, capacity, number of cycles |

IMPORTANT

Maintenance and Service must be performed by qualified personnel only. Return the tool to Sartorius Stedim Biotech for maintenance. Consult Sartorius Stedim Biotech for a maintenance schedule on high-frequency cutting.

7 Correction of defects

7.1 Before You Begin

- ▶ Make sure that the battery is charged. Re-check after several minutes to make sure the battery is holding its charge.
- ▶ Use a non-flammable contact cleaner or pencil eraser to clean electrical contacts on the battery and cutting tool.
- ▶ Reinstall the battery and check the tool again.

| Problem | Probable Cause | Probable Remedy |
|--------------------------------|---|---|
| Tool is inoperative | Dirt, contaminants, etc. in ram area of tool. | Clean tool |
| | Cutting tool battery contacts damaged | Reform contacts |
| | Tool components worn or damaged. | Return tool to Sartorius Stedim Biotech (see Chapter "10 Appendix", page 28) |
| Blades stop during operation | Oil level is low | Return tool to Sartorius Stedim Biotech (see Chapter "10 Appendix", page 28) |
| | Air in hydraulic system | Pull trigger and hold retract button simultaneously. Hold for approximately 10 seconds. |
| LED light glows for 20 seconds | Battery charge low | Charge or replace battery |
| Tool loses oil | Damaged internal seal | Return tool to Sartorius Stedim Biotech (see Chapter "10 Appendix", page 28) |

8 Technical Data

8.1 Cutting Capacities

| | | QUICKSEAL® | QUICKSEAL® |
|-------------------|---------------------|-----------------------|---------------|
| | Tube Size (o.d.) | Collar Size (o.d.) | Collar Length |
| 1/4" QUICKSEAL® | 1/4" | 0.281" | 1.500" |
| 3/8" QUICKSEAL® | 3/8" | 0.435" | 2.000" |
| 7/16" QUICKSEAL® | 7/16" | 0.498" | 2.125" |
| 1/2" QUICKSEAL® | 1/2" | 0.573" | 2.250" |
| 5/8" QUICKSEAL® | 5/8" | 0.700" | 2.500" |
| 3/4" QUICKSEAL® | 3/4" | 0.835" | 3.000" |
| 1" QUICKSEAL® | 1" | 1.091" | 3.500" |
| 1 1/8" QUICKSEAL® | 1 1/8" | 1.220" | 4.000" |

8.2 Cutting Tool

| | |
|------------------------------|------------------------|
| Length | 375 mm (14 - 3/4") |
| Width | 60 mm (2 - 3/8") |
| Depth | 108 mm (4 1/4") |
| Mass Weight (with battery) | 2.0 kg (4.4 lb) |
| Sound Level | <80 dB at 1 m |
| Vibration | < 2.5 m/s ² |
| Hydraulic Oil | 52057878 biodegradable |
| Average Cutting Time | 4 seconds |
| Average cuts per charge | approx. 300 |
| Closing Speed | 6 mm/sec |
| Cutting Force | 1.5 Tons |
| Operating Temperature | Range -15°C to 50°C |

8.3 Battery

| | |
|------------------|--------|
| Charging Voltage | 18 V |
| Charging Time | 20 min |

9 Risk Assessment

As referred in the CE Certificate the risk assessment considers the possible hazards when using the tool, the potential of the risk and safety measures to mitigate the risk.

| Position | Possible Risk according to EN 14121-1 | Risk | | Operational Step or Procedure | Body Part Place Persons and Property | Possible Cause according to EN 12100, Annex A |
|----------|---|------|---|-------------------------------|--|---|
| | | Y | N | | | |
| 1 | Mechanical hazards | | x | | | |
| | Machine parts | | x | | | |
| | – shape | x | | Cutting | Fingers | Closing of the blades |
| | – relative location | | x | | | |
| | – mass and stability | | x | | | |
| | – mass and velocity | | x | | | |
| | – mechanical strength | | x | | | |
| | Accumulation of energy | | x | | | |
| | – elastic elements | | x | | | |
| | – liquids under pressure | | x | | | |
| | – effect of vacuum | | x | | | |
| 1,1 | Crushing hazard | | x | | | |
| 1,2 | Shearing hazard | | x | | | |
| 1,3 | Cutting or severing hazard | x | | Cutting | Fingers | Closing of the jaws |
| 1,4 | Entanglement hazard | | x | | | |
| 1,5 | Drawing-in or trapping hazard | | x | | | |
| 1,6 | Impact hazard | | x | | | |
| 1,7 | Stabbing or puncture hazard | | x | | | |
| 1,8 | Friction or abrasion hazard | | x | | | |
| 1,9 | High pressure fluid injection or ejection hazard | | x | | | |
| 2 | Electrical hazard due to: | | x | | | |
| 2,1 | Contact of person with live parts, low voltage | | x | | | |
| 2,2 | Contact of person with parts which have become live under faulty conditions | | x | | | |
| 2,3 | Approach to live parts under high voltage | | x | | | |
| 2,4 | Electrostatic phenomena | | x | | | |

| Possible Consequences of Risk | Occurrence | Importance | Perception | Risk-factor | Safety Measures | Info to |
|-------------------------------|------------|------------|------------|----------------------------|---------------------------------|---------|
| | O | I | P | RF | | |
| | | | 0 | | | |
| | | | 0 | | | |
| Cuts and bruises | 2 | 3 | 1 | 21 | Decal on tool. Warning in IM | R&D2 |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | Closing speed < 10 mm/s | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| Cuts and bruises | 2 | 3 | 1 | 21 | Decal on tool. Warning in IM | R&D2 |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |
| | | | 0 | | | |

| Position | Possible Risk according to EN 14121-1 | Risk | | Operational Step or Procedure | Body Part Place Persons and Property | Possible Cause according to EN 12100, Annex A |
|----------|---|------|---|-------------------------------|--|---|
| | | Y | N | | | |
| 2,5 | Thermal radiation or other phenomena such as the projection of molten particles and chemical effects from short circuits, overloads, etc. | | x | | | |
| 3 | Thermal hazards, resulting in: | | x | | | |
| 3,1 | Burns and scalds | | x | | | |
| 3,2 | Hot Cold working environment | | x | | | |
| 4 | Hazards generated by noise, resulting in: | | x | | | |
| 4,1 | Hearing loss or other physiological disorders | | x | | | |
| 4,2 | Interference with speech | | x | | | |
| 5 | Hazard generated by vibration | | x | | | |
| 5,1 | Use of hand-held machines | | x | | | |
| 5,2 | Whole body vibration | | x | | | |
| 6 | Hazards generated by radiation | | x | | | |
| 6,1 | Radio frequency radiation | | x | | | |
| 6,2 | Infrared, visible and ultraviolet | | x | | | |
| 6,3 | X and gamma rays | | x | | | |
| 6,4 | Alpha, beta rays, electron to ion beams, neutrons | | x | | | |
| 6,5 | Lasers | | x | | | |
| 7 | Materials and Substances | | x | | | |
| 7,1 | Hazards from contact or inhalation of harmful fluids,gases, mist,fumes and dust | | x | | | |
| 7,2 | Fire and Explosion | | x | | | |
| 7,3 | Biological Microbiological | | x | | | |
| 8 | Hazards generated by neglecting ergonomic principles in machinery design as: | | x | | | |
| 8,1 | Unhealthy posture or excessive effort | | x | | | |
| 8,2 | Inadequate consideration of hand-arm or foot-leg anatomy | | x | | | |
| 8,3 | Neglected use of personal protection equipment | | x | | | |
| 8,4 | Inadequate local lighting | | x | | | |
| 8,5 | Metal overhead and underload, stress | | x | | | |
| 8,6 | Human error, human behavior | | x | | | |
| 8,7 | Inadequate design or location or identification of manual controls | | x | | | |

| Position | Possible Risk according to EN 14121-1 | Risk | | Operational Step or Procedure | Body Part Place Persons and Property | Possible Cause according to EN 12100, Annex A |
|-----------|--|------|---|-------------------------------|--|---|
| | | Y | N | | | |
| 8,8 | Inadequate design or location of visual display units | | x | | | |
| 9 | Combination of Hazards | | x | | | |
| 10 | Unexpected start-up, unexpected over-run over-speed | | x | | | |
| 10,1 | Failure disorder of the control system | | x | | | |
| 10,2 | Restoration of energy supply after an interruption | | x | | | |
| 10,3 | External influences on electrical equipment | | x | | | |
| 10,4 | Other external influences | | x | | | |
| 10,5 | Errors in software | | x | | | |
| 10,6 | Errors made by the operator | | x | | | |
| 11 | Impossibility of stopping the machine in the best possible conditions | | x | | | |
| 12 | Variations in the rotational speed of tools | | x | | | |
| 13 | Failure of power supply | | x | | | |
| 14 | Failure of control circuit | | x | | | |
| 15 | Errors of fitting | | x | | | |
| 16 | Break-up during operation | | x | | | |
| 17 | Falling or ejected objects or fluids | | x | | | |
| 18 | Loss of stability overturning of machinery | | x | | | |
| 19 | Slip, trip, fall of persons | | x | | | |
| 20 | Relating to traveling function | | x | | | |
| 20,1 | Movement when starting the engine | | x | | | |
| 20,2 | Movement without a driver at the driving position | | x | | | |
| 20,3 | Movement without all parts in a safe position | | x | | | |
| 20,4 | Excessive speed of pedestrian controlled machinery | | x | | | |
| 20,5 | Excessive oscillation when moving | | x | | | |
| 20,6 | Insufficient ability of machinery to be slowed down, stopped and immobilized | | x | | | |
| 21 | Linked to the work position | | x | | | |
| 21,1 | Fall of person during access to the work position | | x | | | |
| 21,2 | Exhaust gases lack of oxygen at the work position | | x | | | |
| 21,3 | Fire and Explosion | | x | | | |
| 22 | QuickSeal® Cutter | | | | | |

| Position | Possible Risk according to EN 14121-1 | Risk | | Operational Step or Procedure | Body Part Place Persons and Property | Possible Cause according to EN 12100, Annex A |
|-----------|--|------|---|-------------------------------|--|---|
| | | Y | N | | | |
| 21,4 | Mechanical hazards at the work position: | | x | | | |
| | a) contact with the wheels | | x | | | |
| | b) rollover | | x | | | |
| | c) fall of objects, penetration | | x | | | |
| | d) break-up of parts rotating at high speed | | x | | | |
| | e) contact of persons with machine parts or tools | | x | | | |
| 21,5 | Insufficient visibility from the work position | | x | | | |
| 21,6 | Inadequate lighting | | x | | | |
| 21,7 | Inadequate seating | | x | | | |
| 21,8 | Noise at work station | | x | | | |
| 21,9 | Vibration at work station | | x | | | |
| 21,10 | Insufficient means for evacuation emergency exit | | x | | | |
| 22 | Due to control system | | x | | | |
| 22,1 | Inadequate location for manual controls | | x | | | |
| 22,2 | Inadequate design of manual controls and their mode of operation | | x | | | |
| 23 | From handling the machine (lack of stability) | | x | | | |
| 24 | Due to the source and to the transmission of power | | x | | | |
| 24,1 | Hazards from the engine and the batteries | | x | | | |
| 24,2 | Hazards from transmission of power between machines | | x | | | |
| 24,3 | Hazards from coupling and towing | | x | | | |
| 25 | From to third person | | x | | | |
| 25,1 | Unauthorized start-up use | | x | | | |
| 25,2 | Drift of a part away from its stopping position | | x | | | |
| 25,3 | Lack of inadequacy visual or acoustic warning means | | x | | | |
| 26 | Insufficient instructions for the operator | | x | | | |

| Position | Possible Risk according to EN 14121-1 | Risk | | Operational Step or Procedure | Body Part Place Persons and Property | Possible Cause according to EN 12100, Annex A |
|-----------|--|------|---|-------------------------------|--|---|
| | | Y | N | | | |
| 27 | Mechanical hazards and hazardous events | | x | | | |
| 27,1 | from load falls, collisions, machine tipping caused by: | | x | | | |
| 27.1.1 | lack of stability | | x | | | |
| 27.1.2 | uncontrolled loading-overloading-overturning moment exceeded | | x | | | |
| 27.1.3 | uncontrolled amplitude of movements | | x | | | |
| 27.1.4 | unexpected unintended movements of load | | x | | | |
| 27.1.5 | inadequate holding devices accessories | | x | | | |
| 27.1.6 | collision of more than one machine | | x | | | |
| 27,2 | from access of persons to load support | | x | | | |
| 27,3 | from derailment | | x | | | |
| 27,4 | from insufficient mechanical strength of parts | | x | | | |
| 27,5 | from inadequate design of pulleys, drums | | x | | | |
| 27,6 | from inadequate selection of chains, ropes lifting and accessories and their inadequate integration into the machine | | x | | | |
| 27,7 | from lowering of the load under the control of friction brake | | x | | | |
| 27,8 | from abnormal conditions of assembly testing use maintenance | | x | | | |
| 27,9 | from the effect of load on person | | x | | | |
| 28 | Electrical hazard | | x | | | |
| 28,1 | from lighting | | x | | | |
| 29 | Hazard generated by neglecting ergonomic principles | | x | | | |
| 29,1 | insufficient visibility from the driving position | | x | | | |
| 30 | Mechanical hazards and hazardous events due to: | | x | | | |
| 30,1 | Lack of stability of powered roof supports | | x | | | |
| 30,2 | Failing accelerator or brake control of machinery running on rails | | x | | | |
| 30,3 | Failing or lack of deadman's control of machinery running on rails | | x | | | |
| 31 | Restricted movement of person | | x | | | |
| 32 | Fire and Explosion | | x | | | |
| 33 | Emission of dust, gases etc. | | x | | | |

10 Appendix

10.1 Service

Repairs and service must be performed by authorized personnel.

Returning Devices

Devices requiring service should be sent to Sartorius.

Please complete the Service Maintenance and Request Form. E-mail the completed form to QualityNOX.NA@sartorius.com

Your request will be reviewed and a repair number will be assigned to the tool and shipping instructions will be emailed.

DO NOT send tools until you receive your repair number.

Tools sent in without a repair number may be refused.

No repairs will be performed without consent.



Returned devices must be clean and in hygienically flawless condition and packed carefully.

Transport damage as well as measures for subsequent cleaning and disinfection of the parts by Sartorius shall be charged to the sender.

10.2 Decontamination Declaration

When returning equipment, copy the following form as required, carefully complete it and enclose it with the delivery documents.



The recipient must be able to inspect the completed declaration before removing the device from the packaging

10.3 CE Declaration of Conformity



EG-/EU-Konformitätserklärung EC / EU Declaration of Conformity

Hersteller
Manufacturer

Sartorius Stedim North America Inc.
5 Orville Drive, Bohemia, NY 11716, USA

erklärt in alleiniger Verantwortung, dass das
declares under sole responsibility that the

Geräteart
Device type

handgeführte motorbetriebene Elektroschneidewerkzeug für pharmazeutische Anwendungen
/ Schläuche
hand held, motor operated electric cutting tool for pharmaceutical applications / hoses

Modell
Model

QSCUTTERLD, QSCUTTERLD230V

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien – einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen – entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen erfüllt:
in the form as delivered fulfils all the relevant provisions of the following European Directives – including any amendments valid at the time this declaration was signed – and meets the applicable requirements of the harmonized European Standards listed below:

2014/30/EU

Elektromagnetische Verträglichkeit | *Electromagnetic compatibility*
EN 61000-6-2:2005, EN 61000-6-3:2007 + A1:2011

2011/65/EU

Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS)
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
EN 50581:2012

2006/42/EG
2006/42/EC

Maschinen
Machines
EN ISO 12100:2010, EN ISO 13857:2008, EN 349:1993+A1:2008, EN 60204-1:2006

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:

The person authorised to compile the technical file:

Sartorius Lab Instruments GmbH & Co. KG
International Certification Management
37070 Goettingen, Germany

Jahreszahl der CE-Kennzeichenvergabe | *Year of the CE mark assignment:* **17**

Sartorius Stedim North America Inc.
Bohemia, NY 11716, 2017-08-08

Dr. Michael Zumbum
Director of R&D

Charles Meadows
Senior Product Manager

Diese Erklärung bescheinigt die Übereinstimmung mit der genannten EU-Richtlinie, ist jedoch keine Zusicherung von Eigenschaften. Bei einer mit uns nicht abgestimmten Änderung des Produktes verliert diese Erklärung ihre Gültigkeit. Die Sicherheitshinweise der zugehörigen Produktdokumentation sind zu beachten.

This declaration certifies conformity with the above mentioned EU Directive, but does not guarantee product attributes. Unauthorised product modifications make this declaration invalid. The safety information in the associated product documentation must be observed.

Doc: 2296178-00 SSNA17CE001-00.de,en 1 / 1 PMF: 2296176 OP-113_fo1_2015.10.12

10.4 Service and Maintenance Request Form



QUICKSEAL® Large Diameter Cutting Tool Service and Maintenance Request Form

Company Name: _____

Shipping Address: _____

Contact Name: _____

email address: _____

Phone Number: _____

Part Number for Service: _____

Serial Number: _____

Other General Comments on Condition of Tool: _____

Purchase Order Number for Repair and Service: _____

Declaration Concerning the Decontamination and Cleaning of Equipment and Components

To protect our personnel, we require that all equipment or components which come into contact with our personnel be free of biological, chemical or radioactive contaminants.

Therefore, we can only perform maintenance if:

- the device has been adequately CLEANED and DECONTAMINATED.
- this declaration has been filled out, signed and returned to Sartorius

We ask for your understanding of our measures to ensure a safe and non-hazardous work environment for our employees.

Contamination | Cleaning

| Attention: Please specify exactly the biological, chemical or radioactive contaminant | Attention: Please describe the cleaning and decontamination procedure method |
|---|--|
| The equipment was contaminated with: | It has been cleaned and decontaminated by: |
| | |
| | |
| | |

Legally Binding Declaration

I | we hereby certify that the information provided on this form is true and complete. The equipment and components have been adequately decontaminated and cleaned according to the legal requirements. No chemical or biological or radioactive risks remain that could endanger exposed persons' safety or health.

Contact Name: _____

Title: _____

Phone Number: _____ Email Address: _____

Signature & Date: _____



QUICKSEAL® Large Diameter Cutting Tool Service and Maintenance Request Form

E-mail the completed form to QualityNOX.NA@sartorius.com

Your request will be reviewed and a repair number will be assigned to the tool and shipping instructions will be emailed.

DO NOT send tools until you receive your repair number.
Tools sent in without a repair number may be refused.

No repairs will be performed without consent.

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

Phone: +49.551.308.0
www.sartorius.com

The information and figures contained in these instructions correspond to the version date specified below.

Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.

Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

Copyright notice:

This instruction manual, including all of its components, is protected by copyright. Any use beyond the limits of the copyright law is not permitted without our approval. This applies in particular to reprinting, translation and editing irrespective of the type of media used.

© Sartorius Germany

Last updated:
09 | 2018