



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.

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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 34.

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.

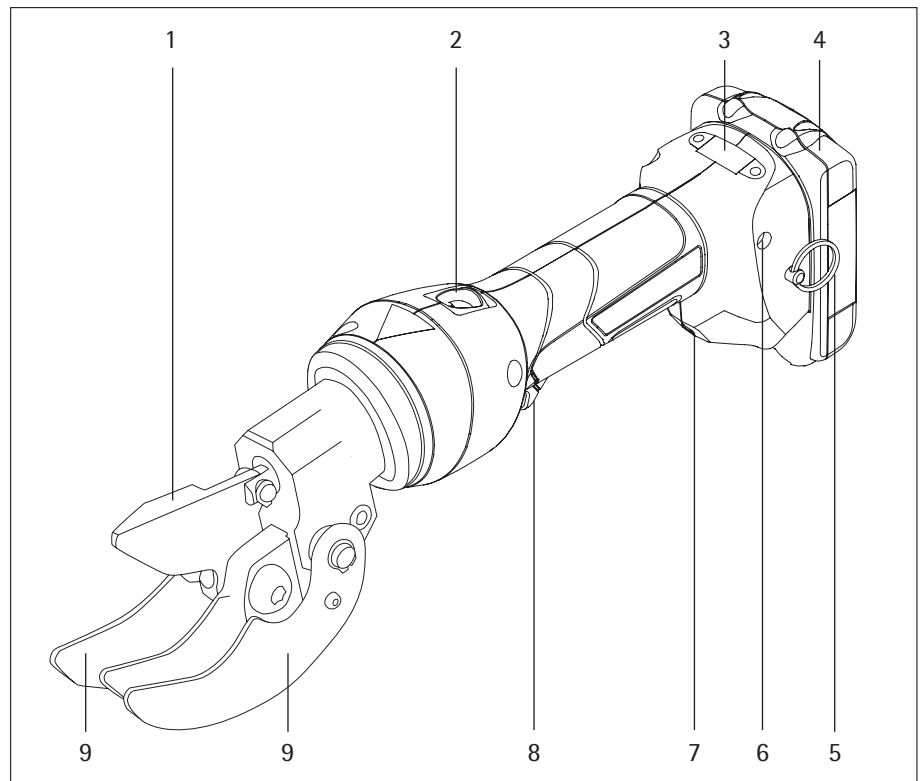


- Do not perform any service or maintenance other than as described in this manual. Injury or damage to the tool may result. Failure to observe these precautions may result in injury or property damage.



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 Operation



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.



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.



Cutting Hazard:

Keep hands away from the cutting head when cutting.

Failure to observe this warning could result in severe injury or death.



- This tool is not designed for continuous use. After 100 cutting cycles, allow the cutter to cool for 15 minutes.
 - Do not secure this tool in a vise. The cutting 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.
 - Use this tool for manufacturer's intended purpose only.
- Failure to observe these precautions may result in injury or property damage.

5.1 Charging the Battery

Read the instructions supplied with the battery charger.

IMPORTANT: Running the battery below 16 V can damage the battery.

5.2 LED Indicator (Red)

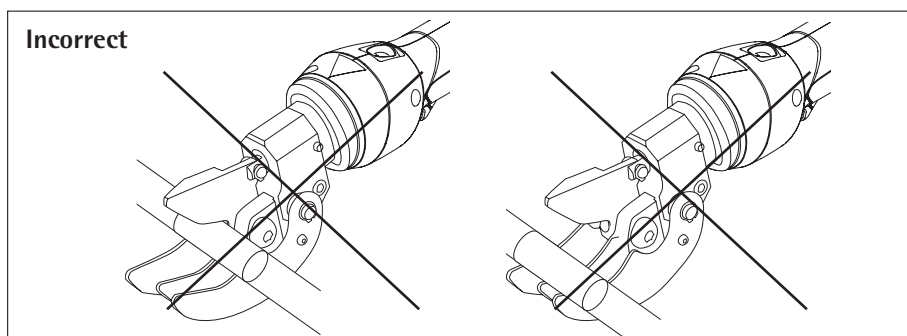
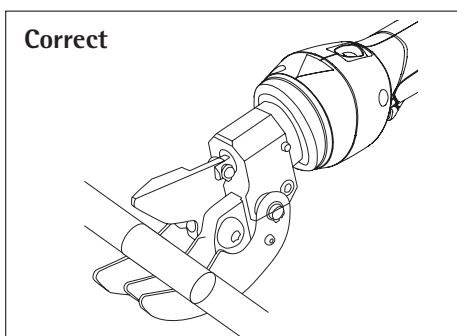
This tool is equipped with a special circuit board incorporating several important features to inform the user about the current status of the unit.

What happens	Signal	What it means
Flashing light for 2 seconds	■ ■	Battery is inserted in tool
Constant light for 20 seconds at end of cycle	■■■■	Battery charge is below 17 V at beginning of cycle
Tool will not start, and constant light for 20 seconds when trigger released	■■■■	Battery charge is below 16 V at beginning of cycle
Tool will stop, and constant light for 20 seconds after trigger is released	■■■■	Battery charge below 13 V during cycle
Tool will stop, and flashing light for 20 seconds when trigger is released	■ ■ ■ ■	- Motor current exceeds 20 A during cycle - Circuit has become too hot
Flashing light for 20 seconds at end of cycle	■ ■ ■ ■	- Send tool in for service



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.

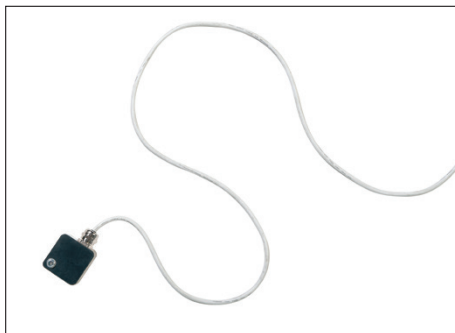
- ▶ Retract the ram putting the blades into the fully open position. Place the tool into the carrying case. Store in a cool, dry place.
- ▶ Charge the battery.

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:
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<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			
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			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					

Possible Consequences of Risk	Occurrence O	Importance I	Perception P	Risk-factor RF	Safety Measures	Info to
			0			
			0			
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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			

Possible Consequences of Risk	Occurrence O	Importance I	Perception P	Risk-factor RF	Safety Measures	Info to
			0			
			0			
			0			
			0			
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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			

Possible Consequences of Risk	Occurrence O	Importance I	Perception P	Risk-factor RF	Safety Measures	Info to
			0			
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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 "Declaration of Decontamination and Cleaning of Equipment and Components" forms.

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.



Declaration of Decontamination and Cleaning of Equipment and Components

Note: This form is to be filled out completely on a computer (not by hand) and sent to Sartorius prior to a Notification/RGA # being issued.

Instructions:

Section I

Please complete returning product name, model and serial number. Include all company and contact information in the blanks provided.

Section II

List the specific contaminant(s) the equipment is used with or came into contact with. i.e. Type of gas, bacteria, cell culture or "new part, never been used". Biowelders sent in for repair that has tubing stuck with liquid media inside is not acceptable and will be returned at customer's expense. Drain and decontaminate any tubing that is remaining in the unit. Sartorius employees are forbidden to work on systems that have ever been in a BSL3 or higher laboratory or had BSL3 or higher organisms/virus ran on it for testing. This form must be completed and reviewed before any service work is scheduled or any system is returned to Sartorius for repair/upgrade.

Section III

Describe the procedure used to clean the equipment prior to shipment. i.e. Autoclaved, wiped down with 10% bleach solution and isopropyl alcohol, "new part, never been used" or "internal circuit board/component cleaning not required".

Section IV

Complete declaration section including company name, signature, title and date.

Note: Failure to complete all sections will prevent SSNA from issuing a return authorization (Notification Number).

Please return the completed form via email or fax to bps.service.na@sartorius.com (fax 631.243.6429). Upon receipt of the completed form, the Field Service Dispatcher will contact you and issue you a Notification Number.

Note: Please do not send anything back without a Notification number. Units sent in without a notification number will not be received into our warehouse and will be immediately returned to the customer.

The notification number should be displayed on the outside of the package. Please place a copy of the decontamination form inside the box(s) with the parts to be returned.

If you have any questions please feel free to contact:

Sartorius Repair Service

Phone 631.254.4249 ext. 8926 | Fax 631.243.6429

Ship to:

Sartorius Service Group
 545-1 Johnson Ave
 Bohemia, NY 11716

Sartorius Service Group***
 PMB#177
 1636 North Cedar Crest Blvd.
 Allentown, PA 18104

Sartorius Service Group
 1173 North Service Rd. W #D4
 Oakville, ON L6M 2V9

NOTE: This location cannot receive shipments with pallets or wooden crates.

Effective Date: 01/16/2020

Company Confidential

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Declaration of Decontamination and Cleaning of Equipment and Components

"Consistent with Federal and State regulations related to the transportation of hazardous material, SSNA requires this form to be completely filled out, signed and a copy placed with the Instrument being sent in for repair. By this declaration the shipping party confirms that these goods are free of biological, chemical or radio isotopic contaminants as defined by applicable regulation."

Notification #	
----------------	--

Section I

Product Name:		
Product Model #		Product Serial Number:
Company:		
Address:		
City, State, Zip:		
Contact Name:		
Phone:		Extension:
Email Address:		

Section II

Please answer all questions by checking "Yes" or "No" where applicable. Provide specific comments below. Has the equipment been exposed internally or externally to any of the following? :

	YES	NO
Blood, body fluids, pathological specimens.....	<input type="checkbox"/>	<input type="checkbox"/>
Other biohazards.....	<input type="checkbox"/>	<input type="checkbox"/>
Biodegradable material that could become a Hazard.....	<input type="checkbox"/>	<input type="checkbox"/>
Chemicals or substances hazardous to health.....	<input type="checkbox"/>	<input type="checkbox"/>
Other hazards.....	<input type="checkbox"/>	<input type="checkbox"/>
Radioactive substances.....	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please List Specific Contaminants:
--

NOTE: Drain and decontaminate any tubing that is remaining in a Biowelder prior to sending it in for repair. Any unit containing tubing with liquid media still in it will be returned at the customer's expense.

Effective Date: 01/16/2020

Company Confidential

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Declaration of Decontamination and Cleaning of Equipment and Components

<input type="checkbox"/> New Part, never been used

Section IV

Legally binding declaration

I (we) certify that the information given in this form is correct and complete. All equipment and/or the components listed above have been adequately decontaminated and cleaned according to applicable cGMP/FDA regulations. No chemical, biological, or radio isotopic risks remain that can endanger exposed persons' safety or health.

I (we) certify that this system was not installed in a BSL3 or higher laboratory and that all organisms/viruses run on this system were BSL2 or lower.

Signature of Authorized Person: _____

Title: _____ Company: _____ Date: _____

Signatures submitted via telecopy shall have the same force and effect as original signatures and, as such, shall be valid and binding.

***In the event that a company employee submits the required decontamination documents and upon SSNA receiving the returned goods it is found that the equipment and/or component(s) were not decontaminated properly or sufficiently, the customer will be held responsible for all costs associated with the decontaminating and cleaning of the items as well as any other costs that may arise due to their negligence. Alternatively, SSNA reserves the right to refuse the shipment and return it to the client at their cost.*

10.2 CE Declaration of Conformity



Original

SARTORIUS

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

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

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

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

Modell QSCUTTERLD, QSCUTTERLD230V
 Model

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der
 folgenden Europäischen Richtlinien entspricht und die anwendbaren Anforderungen folgender
 harmonisierter Europäischer Normen einschließlich deren zum Zeitpunkt der Erklärung
 geltenden Änderungen erfüllt:

*in the form as delivered fulfils all the relevant provisions of the following European Directives
 and meets the applicable requirements of the harmonized European Standards including any
 amendments valid at the time this declaration was signed 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 Elektronik-
 geräten (RoHS) / *Restriction of the use of certain hazardous substances in electrical and
 electronic equipment (RoHS)*
 EN 50581:2012

2006/42/EG Maschinen
 2006/42/EC *Machines*
 EN ISO 12100:2010, EN 60204-1:2018

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:
The person authorised to compile the technical file:

Sartorius Stedim Biotech
 Electronics & Product Compliance 37070
 Goettingen, Germany

Sartorius Stedim North America Inc.
 Bohemia, NY 11716, 2020-08-20

Dr. Michael Zumbrum
 Director of R&D

Charles Meadows
 Senior Product Manager

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.

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