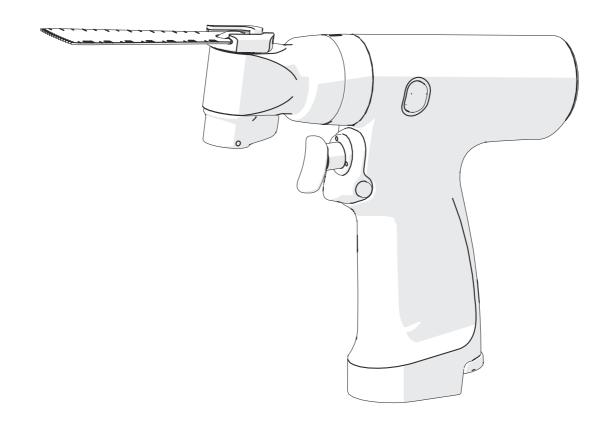


User Manual





UKPA GB1304019.1 WO 2014/135868



Contents

1	Important Information	1
	Safety Instructions	
	Disposal	
2	Symbols	3
3	Reprocessing - Sterilisable Equipment	4
	Limitations on reprocessing	
	Safety Instructions	
	Point of Use (before reprocessing)	
	Containment and Transportation	5
	Cleaning and Disinfection	
	Maintenance	
	Inspection and Function Testing	
	Packaging	7
	Sterilisation of Handpieces and Accessories	
	Sterilisation of Sterilisable Batteries	
	Storage	
	Additional Information	
4	Overview	
5	Configuring a Handpiece	
	Selecting the Mode	
6	Using Attachments	. 13
	Fitting an Attachment	. 13
	Removing Attachments	
	Using a Wire or Pin Driver	. 15
7	Using Accessories	. 16
	Fitting and Removing a Rotary Cutter	. 16
	Fitting a TPLO blade (Slocum Hub)	
	Removing a TPLO blade (Slocum Hub)	
	Fitting a TPLO blade (Synthes Hub)	
	Removing a TPLO blade (Synthes Hub)	
	Fitting a Sagittal Blade (Lever-release)	
	Removing a Sagittal Blade (Lever-release)	
	Fitting a Sagittal Blade (Knob-release)	
	Fitting a Wire or Pin (V-WQ-707)	
	Fitting a Wire or Pin Guard	
	Powering the Handpiece	
8	Technical and Ordering Information	
•	Handpiece Specifications	
	Attachments	
	Power Accessories	
	Sterilisation Accessories	

9	Troubleshooting	1
	Further Help	32
	Service and Repair Information	
	Guarantee and Liability	32
10	EMC Guidance3	3

Important Information

Save this user manual. This user manual contains important safety and operating instructions for this equipment.

Throughout this user manual, the words WARNING, CAUTION and NOTE are used to highlight important information.

WARNING: WARNING information identifies conditions or practices that could result in injury

CAUTION: CAUTION information identifies conditions or practices that could result in damage to the equipment or system

NOTE: NOTE information is provided to clarify or supplement procedural information

Safety Instructions

WARNING: do not attempt to use this equipment until this user manual and all cautionary markings have been studied and understood

WARNING: this equipment should only be used by personnel with appropriate training

WARNING: inspect all equipment before use and do not use suspect, damaged or worn equipment

WARNING: always allow the handpiece to stop before removing from the surgical site

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

WARNING: never reuse items marked for single-use (2). Risks associated with reuse include:

- cross contamination between patients
- bone necrosis due to extra heat generation
- inaccurate cutting.

WARNING: cutting accessories can get hot during use. Saline solution can be used to cool the cutting site.

WARNING: when using dedicated saws or saw attachments, follow local recommendations for the avoidance of possible hand-arm vibration damage and long-term hearing damage. (Under certain circumstances, hand-arm vibration levels exceeding 5ms⁻² can be produced and maximum sound levels can exceed 80dB(A). However, when the equipment is used for the purposes intended this poses no threat to long-term health.)

WARNING: this equipment is not intended for use in an oxygen rich environment or in the presence of flammable gases

CAUTION: this equipment must only be used in accordance with the EMC guidelines described in this user manual. Use of accessories other than those approved by De Soutter Medical may result in increased interference or emissions.

CAUTION: ensure this equipment is regularly serviced. Refer to the service and repair information section of this user manual.

CAUTION: only reprocess this equipment as directed in this user manual

CAUTION: do not immerse any part of this equipment in fluids except as required by an automatic washer-disinfector cycle

CAUTION: only use Stericut or De Soutter Medical approved accessories

CAUTION: always remove batteries when the handpiece is left unused for an extended period of time

Intended Use

The equipment described in this user manual is intended for use in veterinary surgical procedures involving drilling, reaming, wire or pin driving, and cutting bone or hard tissue.

Disposal

WARNING: do not dispose of batteries by throwing them into a fire or immersing them in water

WARNING: lithium batteries are subject to transportation restrictions

WARNING: faulty or suspect lithium batteries must not be returned by air transport. They should be

recycled or disposed of in accordance with local regulations.

All equipment should be recycled or disposed of, in accordance with local regulations.

Symbols

Symbol	Meaning	Symbol	Meaning
Ţ <u>i</u>	Refer to the user manual	$R_{\!$	Only for use by a physician
②	Single-use only		Do not immerse
X	Dispose of in accordance with local regulations		Suitable for recycling
P	Vacuum steam sterilise	★	Type BF protection
	Normal mode	€	Screwing mode
\triangleright	Drive in the direction indicated	3. 3.	Pull and/or turn in the direction shown to unlock
*	Temperature limits to which the equipment can be exposed	•••	Pressure limits to which the equipment can be exposed
<u>%</u>	Humidity limits to which the equipment can be exposed	Ť	Transport - keep away from rain
Ţ	Transport - fragile, handle with care	<u> </u>	Transport - this way up
SN 17/00500	The first two digits indicate the year of manufacture		

Reprocessing - Sterilisable Equipment

These reprocessing instructions are suitable for the sterilisable equipment described in this user manual.

- · All Handpieces
- · All Attachments
- AH-xxx Aseptic Housing
- AS-xxx Aseptic Shield

Limitations on reprocessing

Repeated processing as specified in these instructions has minimal effect on this equipment. Equipment end-of-life is normally determined by wear or damage during use.

Safety Instructions

WARNING: never reuse items marked for single-use (2). Risks associated with reuse include:

- cross contamination between patients
- bone necrosis due to extra heat generation
- inaccurate cutting.

CAUTION: following a wet cleaning process, ensure that this equipment is dried immediately

CAUTION: correct internal drying of sterilisable equipment can only be achieved by using a vacuum steam autoclave with the vacuum assisted drying period activated

CAUTION: do not immerse any part of this equipment in fluids except as required by an automatic washer-disinfector cycle

CAUTION: do not exceed temperatures of 140°C

CAUTION: do not clean any part of this equipment in an ultrasonic cleaner

CAUTION: do not wash or sterilise aseptic batteries, power supplies or battery chargers. Refer to separate reprocessing instructions.

CAUTION: ensure that aseptic battery housings are reprocessed in the open position

NOTE: ensure that attachments and handpieces with collet mechanisms are fully open when reprocessing

NOTE: cannulations, blind holes, recesses, and other surfaces which are hard to reach, require particular attention during reprocessing

NOTE: STERIS processes will affect the appearance of equipment with coloured anodizing. The discolouration caused by the processes will not affect the performance of the product.

Detergents and Rinse Aids for use on Batteries

WARNING: the choice of detergent or rinse aid, and the manner in which they are used, is critical to sustaining the reliability of the equipment. Failure to follow the instructions given in this user manual may cause premature failure of the equipment and may compromise patient safety.

CAUTION: ensure the detergent or rinse aid manufacturer's guidelines and process parameters (such as, dilution and temperature) are followed

CAUTION: ensure the detergent or rinse aid used is suitable for use on anodised aluminium and the following plastics: PEEK and PPSU

CAUTION: ensure a pH-neutral enzymatic detergent is used for cleaning batteries. Failure to do so may adversely affect the battery.

Detergents and Rinse Aids for use on all Other Equipment

WARNING: the choice of detergent or rinse aid, and the manner in which they are used, is critical to sustaining the reliability of the equipment. Failure to follow the instructions given in this user manual may cause premature failure of the equipment and may compromise patient safety.

CAUTION: ensure the detergent or rinse aid manufacturer's guidelines and process parameters (such as, dilution and temperature) are followed

CAUTION: ensure the detergent or rinse aid used is suitable for use on anodised aluminium and the following plastics: PEEK and PPSU

CAUTION: never use detergents with a pH value greater than 11.0

NOTE: the use of pH-neutral enzymatic detergents is highly recommended

Point of Use (before reprocessing)

Remove excess soil with a disposable cloth or other suitable wipe.

Containment and Transportation

It is important that this equipment is reprocessed immediately after use. In order to minimise contamination risks, the handling, collection and transportation of soiled equipment should be strictly controlled.

Cleaning and Disinfection

Manual Cleaning

- Remove all attachments and accessories and wash them separately.
- Dispose of single-use accessories in accordance with local guidelines.

Manual cleaning should only be carried out where an automatic washer-disinfector is not available, or in order to remove large contaminant deposits. Manual cleaning should be conducted in a dedicated area, by trained personnel who are wearing protective clothing, for example: gloves, a waterproof apron, and goggles or a visor.

NOTE: the use of dedicated sinks with temperature controlled water, ideally deionised or distilled, is recommended

NOTE: cannulations, blind holes, recesses, and other surfaces which are hard to reach, require particular attention during reprocessing

- 1. Wash off excess soil with running water (maximum 35°C).
 - **NOTE:** avoid fluid ingress
- 2. Prepare a solution of detergent according to the detergent manufacturer's instructions.
- 3. Remove all visible traces of contaminant, using suitable nylon brushes to scrub the equipment thoroughly.
 - Manually open and close chucks and blade clamps.
 - ii) Ensure any trapped contaminants are removed by flushing through cannulations and other surfaces which are hard to reach.
- 4. Rinse off all traces of the detergent with deionised or distilled running water (45 65°C).
- 5. Shake off any excess water and dry the surfaces with a lint-free cloth.
- 6. Visually inspect each item. Verify that all contaminants have been removed in accordance with local reprocessing guidelines.

Automatic Cleaning

- · Remove large contaminant deposits by manual cleaning.
- Remove all attachments and accessories and wash them separately.
- Dispose of single-use accessories in accordance with local guidelines.

An automatic washer-disinfector, capable of meeting the relevant national and international cleaning and disinfection standards (such as, ISO 15883 or HTM 2030), should be used.

CAUTION: the drying cycle should not be used with batteries. The drying cycle will adversely affect the performance and life of the battery.

NOTE: cannulations, blind holes, recesses, and other surfaces which are hard to reach, require particular attention during reprocessing

- Place the handpieces, attachments and accessories into an insert tray and/or a wire basket.
 - i) Set chucks and blade clamps to a middle position.
 - ii) Ensure that sterile batteries are inverted (that is, contacts facing down).
 - iii) Ensure that aseptic battery housings are empty and open, with the open side facing down.
 - iv) Fit washing spacers and end caps as required.
 - v) Ensure that all items are separated.

NOTE: the placement of items in automatic washer-disinfector baskets can be a critical factor in achieving effective cleaning. The basket type and the position of the items within the basket should be managed by suitably trained personnel and be in accordance with the washer-disinfector instructions.

2. Follow the washer-disinfector manufacturer's loading instructions and select the appropriate cycle. The cycle should include the following:

Cycle Stage	Minimum Recirculation Time (min:secs)	Temperature	Detergent
Pre-wash	5:00	< 35°C	-
Enzyme wash	5:00	55 - 65°C	Endozime AW Triple Plus ^a
Rinse 1	2:00	55 - 65°C	-
Rinse 2	2:00	55 - 65°C	-
Thermal rinse	1:00	90°C	-
Pure water rinse	0:10	66°C	-
Drying (not suitable for batteries)	20:00	110°C maximum	-

a. other brands of detergent may be used provided the suitability of the detergent is verified before use.

- 3. Remove the disinfected equipment from the washer-disinfector and place the equipment in a clean area.
- 4. Remove any washing spacers and end caps, if fitted.
- 5. Visually inspect each item. Verify that all contaminants have been removed in accordance with local reprocessing guidelines.

Disinfection

Thermal disinfection is recommended and included in the automatic cleaning process.

Where the use of an automatic washer-disinfector is not possible, the equipment should be wiped with a suitable disinfectant.

Maintenance

Lubricate collets and chucks using a suitable surgical instrument oil.

Inspection and Function Testing

WARNING: inspect all equipment before use and do not use suspect, damaged or worn equipment **WARNING:** never reuse items marked for single-use \bigcirc . Risks associated with reuse include:

- cross contamination between patients
- bone necrosis due to extra heat generation
- inaccurate cutting.
 - 1. Ensure the equipment is in good working order.
 - i) Note any unusual sounds, vibrations or operating speeds.

NOTE: if operating difficulties are experienced, refer to the troubleshooting section of this user manual

2. Inspect reusable cutting accessories (such as, drill bits and reamer shells) for damage and wear.

NOTE: dispose of worn or damaged cutting accessories appropriately

Packaging

Place the disinfected equipment into a sterilisation container.

NOTE: if wrapping is required, use a material suitable for the chosen sterilisation method

Sterilisation of Handpieces and Accessories

Steam Sterilisation

CAUTION: these sterilisation instructions are not suitable for sterilisable batteries

CAUTION: ensure that aseptic battery housings are open, with the open side facing down

Cycle	Wrapping ^a	Exposure Time and Temperature (-0°C / +3°C)	Drying Time ^b
vacuum assisted	optional	3-4 minutes at 134°C	30 minutes at maximum 110°C
vacuum assisted (flash)	unwrapped	3-4 minutes at 134°C	none
gravity	wrapped	15 minutes at 134°C	30 minutes at maximum 110°C
gravity	wrapped	50 minutes at 121°C	20 minutes at maximum 110°C

a. for reasons of non-repeatability during transport and storage, processes involving unwrapped equipment cannot be validated beyond the sterilisation procedure.

STERIS Sterilisation

Sterilisation System	Cycle
V-PRO® 1	standard
V-PRO® 1 Plus	lumen
V-PRO® maX	lumen
V-PRO® 60	lumen

NOTE: STERIS processes will affect the appearance of equipment with coloured anodizing. The discolouration caused by the processes will not affect the performance of the product.

b. the drying times specified are for a full, wrapped sterilisation case containing 3 handpieces. If different quantities are used, the necessary drying time may vary.

Sterilisation of Sterilisable Batteries

Steam Sterilisation

CAUTION: aseptic batteries (AB-xxx) are not suitable for sterilisation

CAUTION: high temperature can affect the performance and life of a battery. The specified drying times should not be exceeded.

CAUTION: ensure that sterile batteries are fitted to the holder in the sterilisation container. The contacts should be facing downwards to allow any liquid to drain away freely.

Model	Cycle	Wrapping ^a	Exposure Time and Temperature (-0°C / +3°C)	Drying Time (maximum 110°C)
SB-703 vacuum optional		3-4 minutes	12 minutes	
SB-704	assisted	οριιστίαι	maximum at 134°C	maximum

a. For reasons of non-repeatability during transport and storage, processes involving unwrapped equipment cannot be validated beyond the sterilisation procedure.

STERRAD® Sterilisation

CAUTION: insert trays are not suitable for use with the STERRAD® sterilisation process

NOTE: STERRAD® sterilisation is only suitable for SB-703 & SB-704 batteries

NOTE: prior to reprocessing any medical device in a STERRAD® System, refer to the STERRAD® System User's Guide for general reprocessing instructions, and proper cleaning, drying and packaging information

NOTE: batteries must be packaged in an approved container and wrap

Sterilisation System	Cycle
STERRAD® 100S	short or long ^a
STERRAD® NX	standard or advanced
STERRAD® 100NX	standard

a. the STERRAD® 100S long cycle is only available outside the U.S.

STERIS Sterilisation

Sterilisation System	Cycle
V-PRO® 1	standard
V-PRO® 1 Plus	lumen
V-PRO® maX	lumen
V-PRO® 60	lumen

NOTE: STERIS processes will affect the appearance of equipment with coloured anodizing. The discolouration caused by the processes will not affect the performance of the product.

Storage

To preserve sterility, wrap the sterilised equipment with a suitable material, capable of presenting a barrier to micro-organisms and particulate contamination.

Point of Use (after reprocessing)

CAUTION: do not operate this equipment while it is still warm from reprocessing

CAUTION: this equipment should not be placed in a refrigerator or similar

Following sterilisation, allow this equipment to cool to room temperature before being used.

Additional Information

Manual cleaning has been validated in accordance with AAMI TIR30.

Automated cleaning has been validated, in accordance with HTM 2030 and AAMI TIR30, using an automated washer-disinfector.

Vacuum and gravity steam sterilisation have been validated in accordance with HTM 2010, AAMI TIR12, ANSI/AAMI ST79, ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 17665-2.

Sterrad sterilisation has been validated in accordance with ANSI/AAMI/ISO 14937.

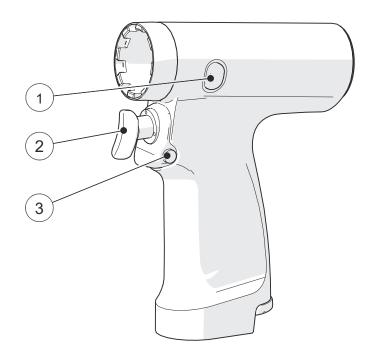
Steris sterilisation has been validated in accordance with AAMI TIR12.

The reprocessing instructions provided in this user manual are compatible with the requirements of CFPP 01-01.

The reprocessing instructions provided in this user manual have been validated by De Soutter Medical as being capable of preparing a device for reuse. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed, using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process.

Likewise, any deviation by the reprocessor from the instructions provided in this user manual, should be properly evaluated for effectiveness and potential adverse consequences.

Overview



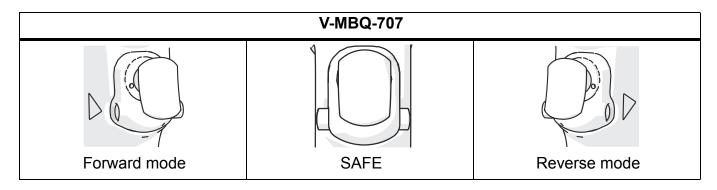
- 1) Attachment release button (x2)
- 2) Trigger
- 3) Mode selector

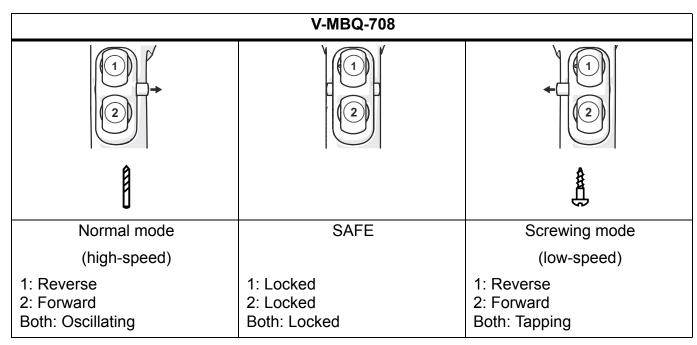
Configuring a Handpiece

Selecting the Mode

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

Slide the mode selector to choose the required mode.





WARNING: tapping mode should be used with care. To minimise the risk of damage, tapping and screwing in delicate materials should be performed with hand tools instead.

Controlling the Speed

The speed of the handpiece is controlled by progressively pressing the trigger.

Oscillating and Tapping

Oscillating and tapping modes are utilised by pressing both triggers together. The speed of the handpiece is determined by the trigger which is pressed the least.

NOTE: release both triggers to return to using independent trigger control

CAUTION: ensure the triggers are only pressed independently when using a saw attachment

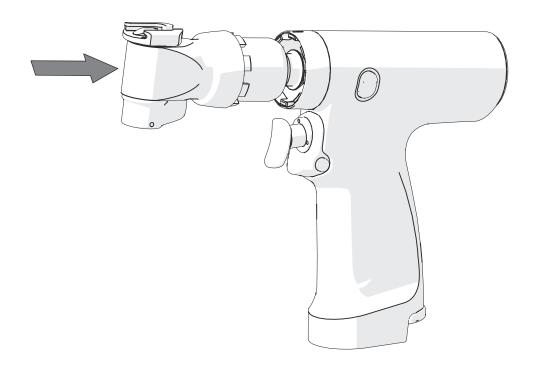
Using Attachments

Fitting an Attachment

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

Push the attachment into the end of the handpiece until it clicks into place.

NOTE: attachments can be used in any of eight angular positions

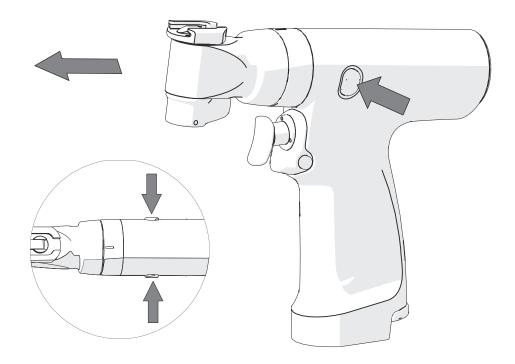


NOTE: all attachments are fitted in the same way

Removing Attachments

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

Press both attachment release buttons and remove the attachment.



NOTE: all attachments are removed in the same way

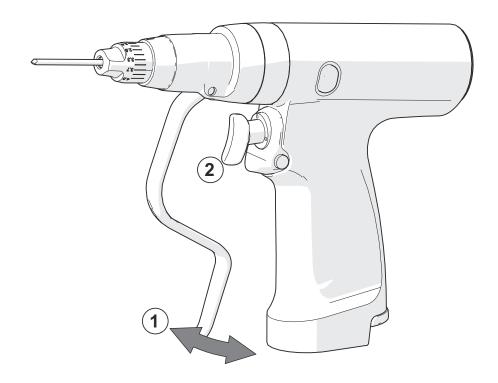
Using a Wire or Pin Driver

CAUTION: if the wire is to be removed from the surgical site, ensure the wire is wiped clean before inserting into the attachment

WARNING: if the wire or pin protrudes from the rear of the tool, a wire guard must be fitted

CAUTION: do not use bent wires

- With the wire (or pin) fitted, pull the lever to grip the wire.
 NOTE: if the wire driver features a manual adjuster, the bite point of the lever can be moved by tightening or loosening the adjuster as required
- 2. While holding the lever, use the trigger to control the rotation of the wire.



Using Accessories

Fitting and Removing a Rotary Cutter

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

To secure or release the accessory, adjust the chuck according to the chuck type.

Chuck Type	Adjustment Instructions
Keyed	Use the chuck key
Others (Quick Release)	 Pull the chuck sleeve back. When inserting an accessory, release the chuck sleeve and ensure the accessory is clamped in place.

Fitting a TPLO blade (Slocum Hub)

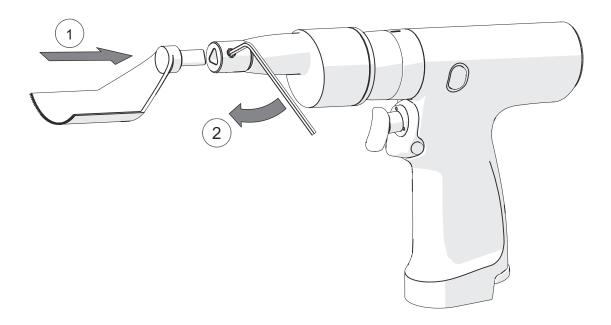
WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

1. Insert the blade in the desired orientation.

2. Using the hex tool, tighten the grub screws to secure the blade.

NOTE: all three screws must be tightened

NOTE: ensure the inserted blade is securely clamped in place

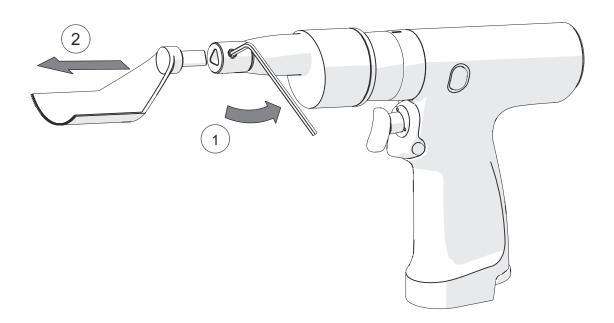


Removing a TPLO blade (Slocum Hub)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

1. Using the hex tool, loosen the grub screws. **NOTE:** all three screws must be loosened

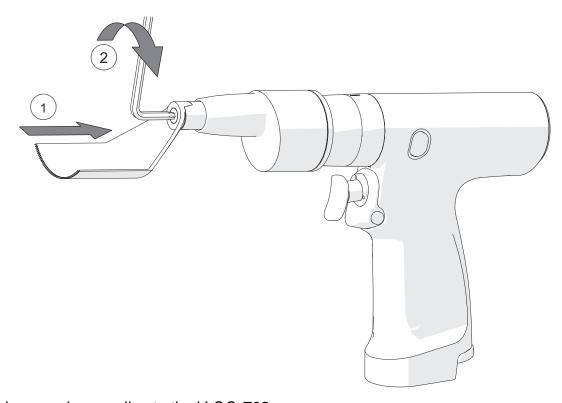
2. Remove the blade.



Fitting a TPLO blade (Synthes Hub)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

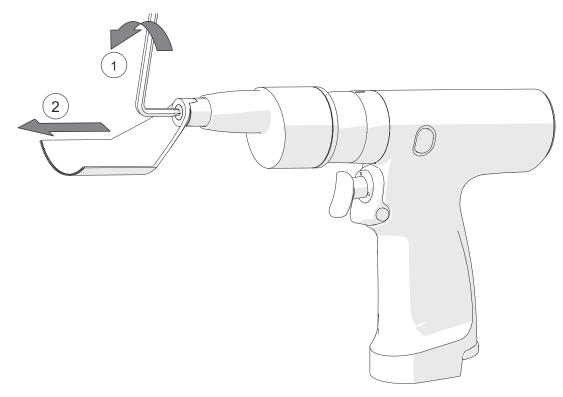
- 1. Insert the blade in the desired orientation.
- 2. Using the torx wrench, tighten the grub screw to secure the blade. **NOTE:** ensure the inserted blade is securely clamped in place



Removing a TPLO blade (Synthes Hub)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

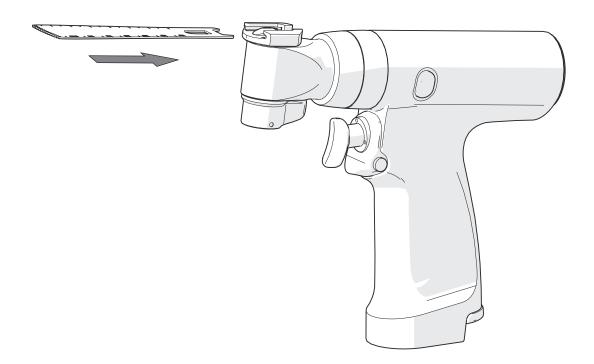
- 1. Using the torx wrench, loosen the grub screw.
- 2. Remove the blade.



Fitting a Sagittal Blade (Lever-release)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

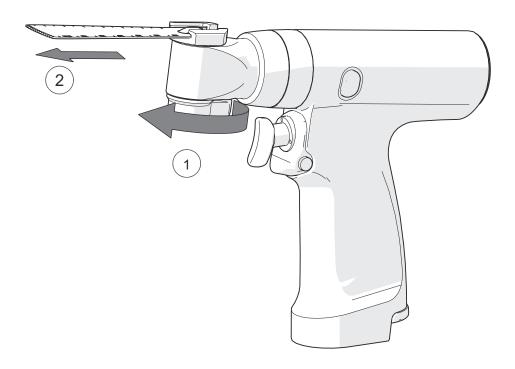
- 1. Turn the blade clamp lever anti-clockwise to open the blade clamp.
- 2. Push the blade into the blade clamp.
- 3. Turn the blade clamp lever clockwise to close the blade clamp. **NOTE:** ensure the inserted blade is securely clamped in place



Removing a Sagittal Blade (Lever-release)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

- 1. Turn the blade clamp lever anti-clockwise to release the blade.
- 2. Remove the blade.

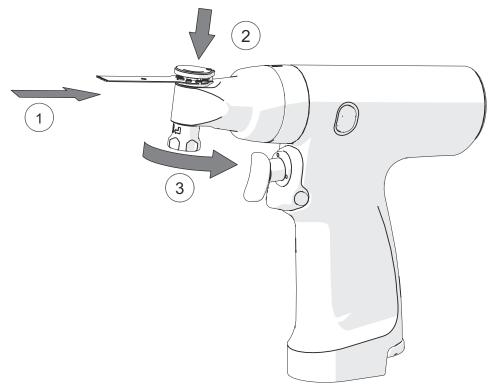


Fitting a Sagittal Blade (Knob-release)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

- 1. With the blade clamp in the open position, insert the blade.
- 2. Push the blade clamp down.
- 3. Tighten the blade clamp.

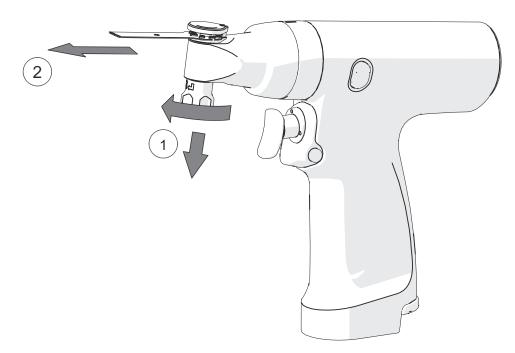
NOTE: ensure the inserted blade is securely clamped in place



Removing a Sagittal Blade (Knob-release)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

- 1. Pull the blade clamp down and unscrew, anti-clockwise.
- 2. Lift and remove the blade.



Fitting a Wire or Pin (V-WQ-707)

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

CAUTION: if the wire is to be removed from the surgical site, ensure the wire is wiped clean before inserting into the attachment

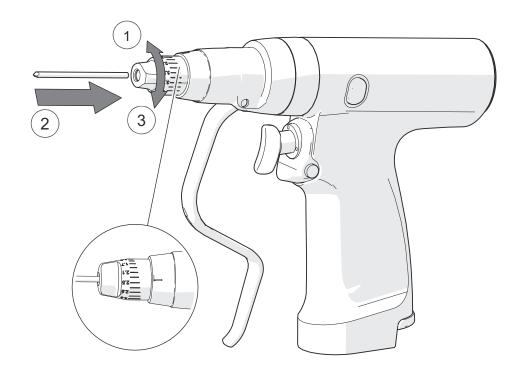
WARNING: do not grip the lever while adjusting the wire position

WARNING: if the wire or pin protrudes from the rear of the tool, a wire guard must be fitted

CAUTION: do not use bent wires

CAUTION: ensure at least 17mm (11/16 inch) of the wire remains protruding from the surgical site if the wire is to be removed

- 1. Open the adjuster fully by rotating it anti-clockwise.
- 2. Insert the wire (or pin) into the front of the wire driver until the wire is in the required position.
- 3. Tighten the adjuster according to size of the wire being used, by rotating the adjuster clockwise.

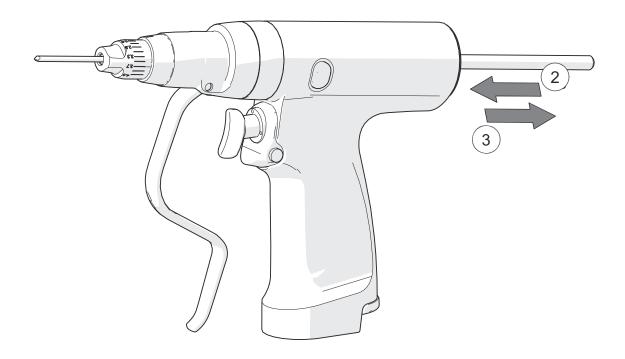


Fitting a Wire or Pin Guard

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

CAUTION: do not use bent wires

- 1. Slide the wire guard over the end of the wire at the rear of the handpiece.
- 2. Push the wire guard firmly into the handpiece until it snaps into place.
- 3. To remove, pull the wire guard away from the handpiece.



Powering the Handpiece

WARNING: ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories

- 1. Slide the battery onto the base of the handpiece until it clicks into place.
- 2. Press the release catch and slide the battery away from the handpiece.



NOTE: this procedure applies to all power options

Technical and Ordering Information

Handpiece Specifications

Model	V-MBQ-707	V-MBQ-708
Part no.	1291774	1291884
Speed	0 - 1350 rpm	0 - 1350 rpm
(using DQ-70x)	C 1000 1pm	∯ 0 - 650 rpm
Cannulation Diameter	4.4 mm	
Protection Type	Type BF protection	
Protection Class	Class 1	
Enclosure Protection	IPX0 - ordinary equipment	

Mode of Operation

The handpieces are intended for intermittent operation. The duty cycle is dependent on the attachment being used.

Attachment Type	Sagittal	Rotary
Duty Cycle	1 min on / 4 min off	
Repetitions	4	
Cooling Period	2 hours	

Environmental Conditions

Environment	Operating	Storage and Transport
Temperature (°C)	5 - 30	-20 -40
Relative humidity (%)	3075	000000000000000000000000000000000000000
Atmospheric pressure (kPa)	80 105	50

Attachments

Drill Attachments

Mo	odel	Description	Capacity	Cannulation	Part No.
V-D0	Q-708	Keyed	0.5 - 6.4 mm	4.4	18320
V-D0	Q-708	Small AO Synthes	-	2.1	18330

Rotary Chuck Accessories

Description	Part No.
Key for 0.5 - 7.4 mm keyed chuck	30062

Reaming Attachments

Model	Description	Capacity	Cannulation	Part No.
V-RQ-708	Jacobs	0.5 - 6.4 mm	4.4	18440

Other Attachments

Model	Description	Speed	Blade / Capacity	Part No.
V-KQ-707	Sagittal saw	0 - 13,500 cpm	De Soutter Medical S89	18290
V-NQ-707	Small sagittal saw	0 - 20,000 cpm	De Soutter Medical S88-1xx & S88-2xx	18300
V-OQ-708	TPLO oscillating saw	0 - 13,500 cpm	Slocum	18270
V-OQ-708	TPLO oscillating saw	0 - 13,500 cpm	Synthes	18690
V-WQ-707	Wire driver	0 - 1300 rpm	0.7 - 4.0 mm	18310

Power Accessories

Battery Systems

Small batteries are recommended for light use applications and for when a larger battery is not practical.

Medium batteries are recommended for applications where low weight or small size are important.

Large batteries are recommended for applications where long duration or high power are important.

NiMH Battery System

Model	Description	Voltage	Capacity	Part No.
AB-701	Medium aseptic battery	10.8 V	1950 mAh	15340
V-AH-701	Medium aseptic housing	-	-	18340
AS-701	Medium aseptic shield	-	-	15890

Model	Description	Voltage	Capacity	Part No.
AB-702	Large aseptic battery	14.4 V	1950 mAh	15350
V-AH-702	Large aseptic housing	-	-	18350
AS-702	Large aseptic shield	-	-	15900

Lithium Battery System

Model	Description	Voltage	Capacity	Part No.
SB-703	Small sterile lithium battery	13.2 V	1100 mAh (14.5 Wh)	17210
SB-704	Large sterile lithium battery	13.2 V	2500 mAh (33 Wh)	17220

Battery Charger

The BC-700 can be used to charger and maintain De Soutter Medical batteries.

Alternatively, a dedicated single station charger is available.

Model	Battery Type	Bays	Part No.
BC-700	All De Soutter Medical orthopaedic batteries	4	Various
BC-705	AB-701, AB-702	1	17980
BC-706	SB-703, SB-704	1	17990

For more details or for ordering information, please refer to the sales brochure or contact your De Soutter Medical representative.

Sterilisation Accessories

De Soutter Medical offer a range of sterilisation accessories to suit this equipment: including wire baskets, sterilisation cases and a variety of insert options.

For more details or for ordering information, please refer to the sales brochure or contact your De Soutter Medical representative.

Troubleshooting

Problem	Cause	Action
Handpiece does not	Battery is discharged	Charge the battery
run	Battery is expended	Replace the battery
Handpiece runs	Battery is discharged	Charge the battery
slowly or judders	Small battery is being used	Use a larger battery
	Both triggers are pressed when using a saw attachment	Ensure only one trigger is pressed
Motor runs but the	Attachment is not securely fitted	Re-fit the attachment
cutting accessory does not move	Cutting accessory is not securely fitted	Re-fit the cutting accessory
Handpiece cuts out during use	Handpiece temperature protection has activated	Release the trigger and allow the handpiece to cool Ensure the recommended duty cycle is being followed Ensure the cutting accessory is sharp
	Battery overload protection has activated	Release the trigger. The protection will reset within 2 seconds Use a larger battery Charge the battery
	Handpiece stall protection has activated	Release the trigger. The protection will reset within 2 seconds Ensure the cutting accessory is sharp
Handpiece becomes unusually hot during use	Handpiece is being loaded too heavily	Ensure the recommended duty cycle is being followed Ensure the cutting accessory is sharp
Battery becomes unusually hot during use	Handpiece is being loaded too heavily	Use a larger battery Ensure the recommended duty cycle is being followed Ensure the cutting accessory is sharp
Attachment will not fit into the handpiece	Debris on the handpiece or the attachment	Clean the handpiece or the attachment
Cutting accessory will not fit into the attachment or handpiece	Debris on the handpiece or the attachment	Clean the handpiece or the attachment

Further Help

If the problem cannot be resolved, or for any other queries, contact your De Soutter Medical representative.

Service and Repair Information

All equipment should be periodically checked and cleaned. To minimise the risks associated with loss of performance, annual servicing is recommended for normal use. Due to the specialist techniques used in the manufacture and maintenance of De Soutter Medical equipment, user servicing is not possible.

Returning Equipment for Repair

For service and repair please contact your nearest De Soutter Medical authorised service centre.

WARNING: lithium batteries are subject to transportation restrictions

WARNING: faulty or suspect lithium batteries must not be returned by air transport. They should be recycled or disposed of in accordance with local regulations.

- 1. Reprocess the equipment in accordance with this user manual.
- 2. Record the serial number of the equipment being returned and a brief statement describing the reason for returning the equipment.
- 3. Enclose the purchase order number for the equipment if warranty is being claimed. It would be helpful to include a contact name.
- 4. Pack the equipment securely.

NOTE: all equipment returned for repair must be accompanied by a declaration of contamination status

Guarantee and Liability

De Soutter Medical guarantees all equipment to be free from defects in material and workmanship for one year from the date of purchase. The following exceptions apply:

- Sterile packed consumables are guaranteed for single-use only.
- New batteries are guaranteed for a period of six months from the invoice date.
- Non-sterile consumables are guaranteed for their normal expected working life.

De Soutter Medical is not liable by warranty or otherwise in the case of any of the following:

- abuse, misuse or use in a non-surgical environment
- disassembly, alteration or unauthorised repair
- use of the product in an unreasonable manner or, a manner which is not in full compliance with these written instructions or with the equipment's intended use.

EMC Guidance

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Product is intended for use in the electromagnetic environment specified below. Users must ensure that it is used in this environment.

Emissions Test	Compliance	Electromagnetic Environment - guidance		
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, the Products RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF emissions CISPR 11	Class A	The Product is suitable for use in all establishments other than domestic, and		
Harmonic emissions IEC 61000-3-2	Class A	may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:		
Voltage fluctuations/flicker emissions IEC 61000-3-2	Complies	WARNING: this equipment or system is intended for use by healthcare professionals only. This equipment or system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Product or shielding the location.		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Product is intended for use in the electromagnetic environment specified below. Users must ensure that it is used in this environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d=1.17√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d=1.17√P 80 MHz to 800 MHz
			d=2.33√P 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
			Field strengths from fixed RF transmitters, as determined by an
			electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b
			Interference may occur in the vicinity of the equipment marked with the following symbol: (((•)))

NOTE: at 80 MHz and 800 MHz, the higher frequency range applies

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Product is used exceeds the applicable RF compliance level above, the Product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Product.
 b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Product is intended for use in the electromagnetic environment specified below. Users must ensure that it is used in this environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance		
Electrostatic discharge (ESD)	± 6 kV contact	± 6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.		
IEC 61000-4-2	± 8 kV air	± 8 kV			
Electrical fast transient/burst	± 2 kV for power supply lines	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.		
IEC 61000-4-4	± 1 kV for input/output lines	± 1 kV			
Surge	± 1 kV line(s) to line(s)	± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.		
IEC 61000-4-5	± 2 kV line(s) to earth	± 2 kV			
Voltage dips, short interruptions and voltage variations on power supply input lines	<5 % U _T (>95 % dip in U _T) for 0.5 cycle	>95 % reduction (10 ms)	Mains power quality should be that of a typical commercial or hospital environment.		
IEC 61000-4-11	40 % U _T (60 % dip in U _T) for 5 cycles	60 % reduction (200 ms)			
	70 % U _T (30 % dip in U _T) for 25 cycles	30 % reduction (500 ms)	If the user of the Product requires continued operation during power mains interruptions, it recommended that the Product be powered from an uninterruptible power supply or battery.		
	<5 % U _T (>95 % dip in U _T) for 5 sec	100 % reduction (5 sec)			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.		
NOTE: U_{T} is the a.c.main voltage prior to application of the test level					

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Product

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

	Separation Distance According to Frequency of Transmitter				
Rated Maximum Output Power of Transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz		
	d=1.17√P	d=1.17√P	d=2.33√P		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

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

NOTE: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

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

NOTE: portable and mobile RF communications equipment can interfere with medical electrical equipment. Care should taken to verify normal operation with the equipment in the configuration in which it will be used.

NOTE: product = any of the following handpieces: MBQ-7xx; MBC-7xx; DBK-7xx; DBK-7xx; DBR-7xx; MBX-6xx; MDX-6xx; KDX-6xx; CDX-6xx; SDX-6xx; RDX-6xx; MGX-6xx; MBU-4xx; DBC-4xx; DBR-4xx or TDZ-4xx. Powered by a PS-7xx and CM-7xx or CM-6xx; a PS-6xx and CM-6xx; or a battery option as appropriate.



United Kingdom

De Soutter Medical Limited Halton Brook Business Park Weston Road Aston Clinton Aylesbury

Bucks, HP22 5WF

+44 (0) 1296 634 000 **44** (0) 1296 634 033

m info@de-soutter.com

http://www.de-soutter.com

Australia

De Soutter Medical Australia Pty Ltd 2/12-14 Apollo Drive Hallam Victoria 3803

+61 (0) 3 9702 4441

月 +61 (0) 3 9702 4484

australia@de-soutter.com

België \ Belgique

De Soutter Medical Belgium In De Bruel 30 3620 Lanaken

+32 (0) 89/47 15 37

A +32 (0) 89/70 12 19

Deutschland

De Soutter Medical Germany Niederlassung Deutschland Kladenfloss

D-66625 Nohfelden

+49 (0) 68 52-99 12 46

A +49 (0) 68 52-99 12 47

Österreich

De Soutter Medical Austria Zweigniederlassung Österreich Dietrichsteingasse 10 A-3400 Klosterneuburg

+43 (0) 676 96 71 770

月 +43 (0) 2243 21 656

□ austria@de-soutter.com

France

De Soutter Medical France 949 Avenue Parc des Expositions 33260 La Teste de Buch

+33 (0) 5 56 54 89 36

且 +33 (0) 9 70 61 37 60

math france@de-soutter.com

Italia

De Soutter Medical Italy Località Fornace SNC 27022 Casorate Primo - PV

+39 (0) 2 9009 4098

月 +39 (0) 2 9009 2673

United States of America

De Soutter Medical USA Inc. 224 Rolling Hill Road, Suite 12A Mooresville, NC 28117

+1 (704) 655 9040

鱼 +1 (704) 987 2035

□ usa@de-soutter.com

Nederland

De Soutter Medical Netherlands Gelderlandhaven 2X 3433 PG Nieuwegein

+31 (0) 850491480

4 +31 (0) 850491489

m nederland@de-soutter.com