

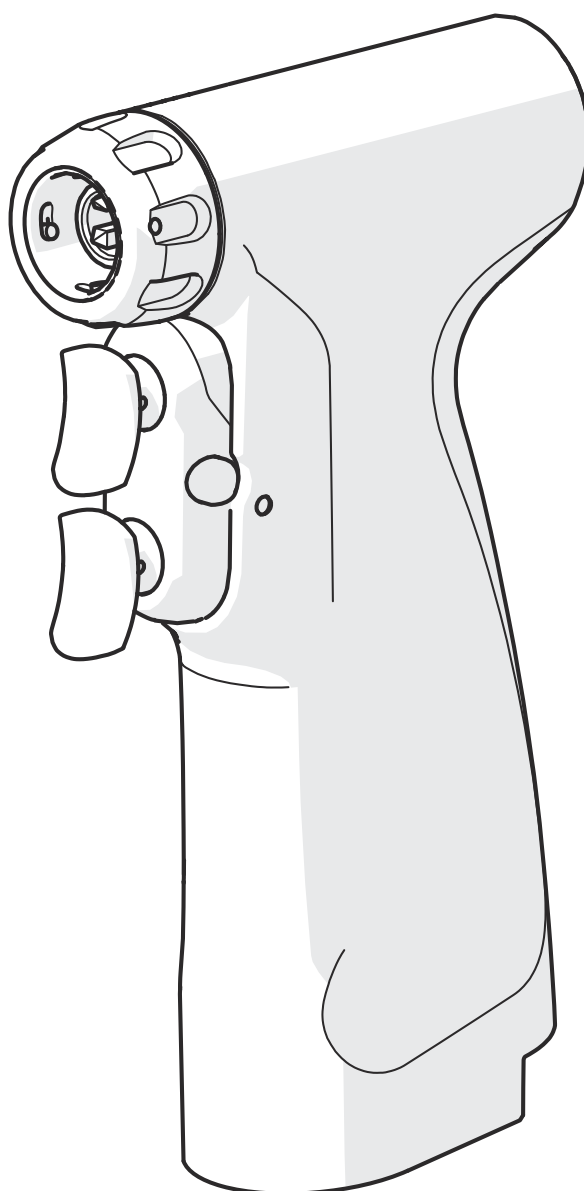
VdriveTM

V-MBU-470

International

English

User Manual



deSouther
MEDICAL



**MEDICAL - GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL
HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI
ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012, IEC
60601-1-6:2010 + A1:2013, CAN/CSA-C22.2 No. 60601-
1:2014, CAN/CSA-C22.2 No. 60601-1-6:2011 + A1:2015**



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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 . 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 and Benefits

The equipment described in this user manual is intended for use by a professional surgeon, in a surgical procedure. The equipment is intended to efficiently drill, ream, bur or cut bone and hard tissue. The equipment is also intended to drive wires and pins into bone.

There are no known contraindications.

Disposal

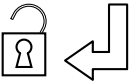
WARNING: *do not dispose of batteries by throwing them into a fire or immersing them in water*

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
	Refer to the user manual		Only for use by a physician
	Single-use only		Do not immerse
	Refer to the user manual for the duty cycle		Dispose of in accordance with local regulations
	Suitable for recycling		Drive in the direction indicated
	Normal mode		Screwing mode
	Attachment locked		Attachment unlocked
	Pull and/or turn in the direction shown to unlock		Type BF protection
	Temperature limits to which the equipment can be exposed		Pressure limits to which the equipment can be exposed
	Humidity limits to which the equipment can be exposed		Transport - keep away from rain
	Transport - fragile, handle with care		Transport - this way up
SN YY/000000	The first two digits (YY) indicate the year of manufacture		Manufacturer
	Do not use if packaging is damaged or opened		Medical Device
	EC authorised representative		

Reprocessing - Sterilisable Equipment

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

- All Handpieces
- All Attachments
- SB-xxx - Sterile Battery
- AS-xxx - Aseptic Shield
- V-AH-xxx - Aseptic Housing

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 ☒. Risks associated with reuse include:*

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

WARNING: *do not clean any part of this equipment with pressurised air*

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 use saline water to rinse the equipment*

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, PPSU and PAEK

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, PPSU and PAEK

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)

WARNING: do not allow the soil to dry on the equipment

WARNING: ensure the equipment is reprocessed as soon as practically possible after use

CAUTION: do not use saline water to rinse the equipment

CAUTION: only use pH neutral substances prior to reprocessing

Excess soil may be removed with a suitable wipe, or rinsed away with deionised or distilled running water after use (maximum 35°C).

CAUTION: do not immerse any part of the equipment

Containment and Transportation

It is important that this equipment is reprocessed as soon as practically possible 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.

CAUTION: *do not use saline water to rinse the equipment*

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).

CAUTION: *do not immerse any part of the equipment*

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.

CAUTION: *when using brushes, extra care must be taken to avoid damaging the equipment*

- i) 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*

1. 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) Fit washing spacers and end caps as required.
 - iii) 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	Neutral Enzymatic Triple Enzyme Detergent
Rinse 1	2:00	55 - 65°C	-
Rinse 2	2:00	55 - 65°C	-
Thermal rinse	5:00	90°C	-
Pure water rinse	1:00	60°C	-
Drying (<i>not suitable for batteries</i>)	20:00	110°C maximum	-

3. Remove the disinfected equipment from the washer-disinfector and place the equipment in a clean area.

CAUTION: *ensure the equipment has been sufficiently dried. Check cannulations, blind holes and recesses for moisture.*

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.

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 ☒. 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 for damage and wear.

NOTE: *dispose of worn or damaged and single-use 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

CAUTION: these sterilisation instructions are not suitable for sterilisable batteries

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

Steam Sterilisation Using a Wire Sterilisation Case

Cycle	Wrapping ^a	Exposure Time and Temperature (-0°C / +3°C)	Minimum Drying Time ^b
vacuum assisted	wrapped	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
	wrapped	50 minutes at 121°C	60 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.

b. the drying times specified for the wrapped cycles are based on using 2 layers of 56gsm Crepe paper wrap. If different wrapping is used, the necessary drying time may vary.

Steam Sterilisation Using a Filtered Sterilisation Case

CAUTION: filtered sterilisation cases are not suitable for gravity steam sterilisation

Cycle	Exposure Time and Temperature (-0°C / +3°C)	Minimum Drying Time
vacuum assisted	3-4 minutes at 134°C	30 minutes at maximum 110°C
vacuum assisted (flash)	3-4 minutes at 134°C	none

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.

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) ^b
SB-703	vacuum assisted	wrapped	3-4 minutes maximum at 134°C	12 minutes maximum
SB-704				
SB-xxx	vacuum assisted (flash)	unwrapped	3-4 minutes maximum at 134°C	none

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

b. the drying times specified for the wrapped cycles are based on using 2 layers of 56gsm Crepe paper wrap. If different wrapping is used, the necessary drying time may vary.

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.

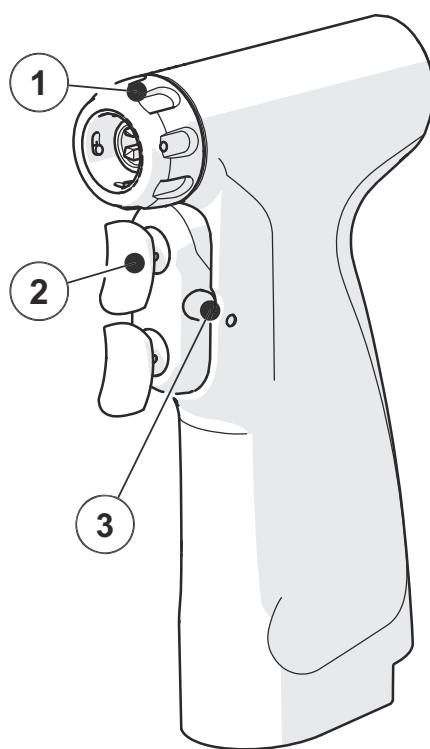
Steris sterilisation has been validated in accordance with AAMI TIR12.

The reprocessing instructions provided in this user manual are compatible with the requirements of HTM 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



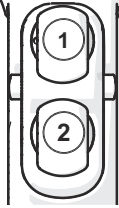
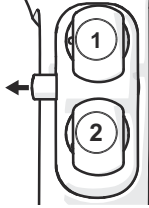
- 1) Release ring
- 2) Trigger
- 3) Mode selector

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.

V-MBU-470		
		
Normal mode (high-speed) 1: Reverse 2: Forward Both: Oscillating	SAFE 1: Locked 2: Locked Both: Locked	Screwing mode (low-speed) 1: Reverse 2: Forward Both: Tapping

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.

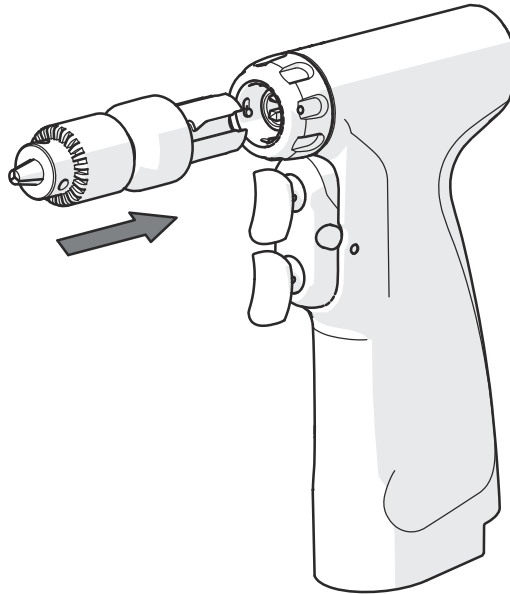
NOTE: release both triggers to return to using independent trigger control

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

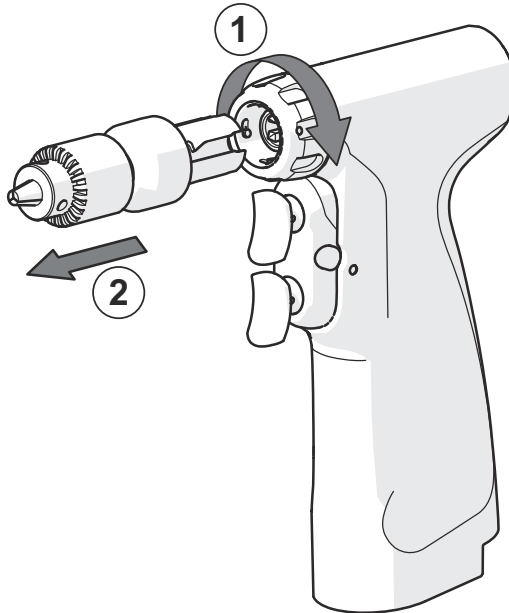


NOTE: all attachments are fitted in the same way

Removing 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

1. Holding both the attachment and the handpiece, rotate the release ring clockwise.
2. Remove the attachment.

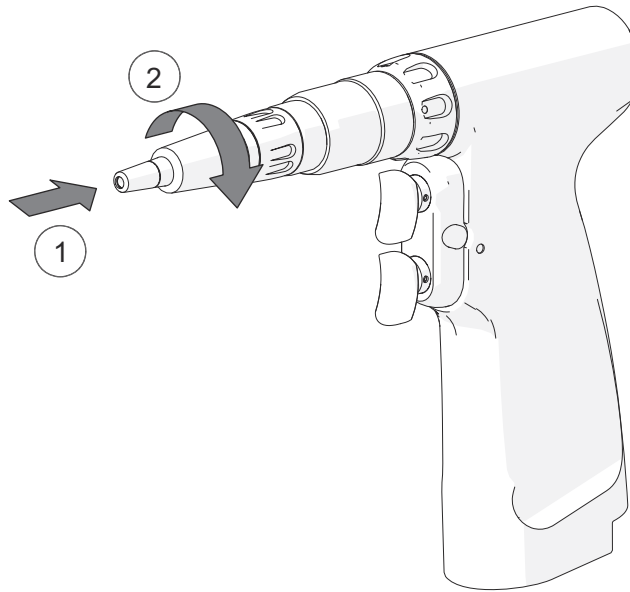


NOTE: all attachments are removed in the same way

Fitting a Bur 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

1. Place the bur guard onto the attachment.
2. Rotate the bur guard clockwise to lock it in place.

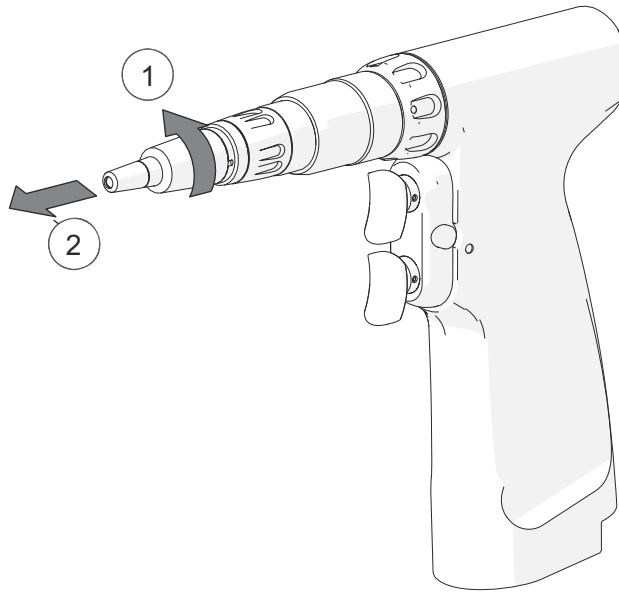


NOTE: this procedure applies to the V-BU-472

Removing a Bur 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

1. Rotate the bur guard anti-clockwise to unlock.
2. Pull the bur guard away from the handpiece



NOTE: this procedure applies to the V-BU-472

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

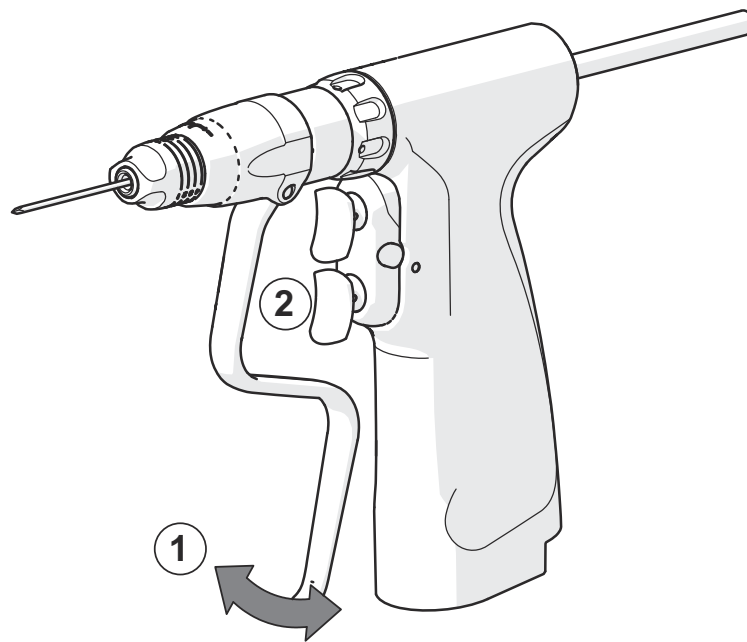
WARNING: if the wire or pin protrudes from the rear of the tool, a wire guard must be fitted

CAUTION: do not use bent wires

1. 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
Keyless	Rotate the chuck ring
Quick Release	• Pull the chuck sleeve back. • When inserting an accessory, release the chuck sleeve and ensure the accessory is clamped in place.

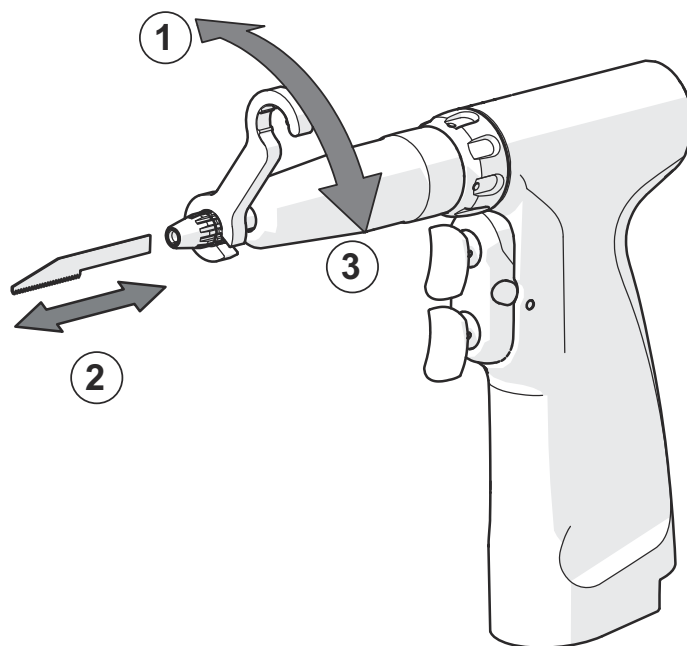
NOTE: to prevent loosening of the chuck, only use keyless chucks in a clockwise direction with a smooth and moderate feed rate

Fitting and Removing a Small Reciprocating Blade

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. Rotate the blade clamp anti-clockwise using the wrench.
2. Insert or remove the blade.
3. Tighten the blade clamp by rotating the wrench clockwise.

NOTE: ensure the inserted blade is securely clamped in place



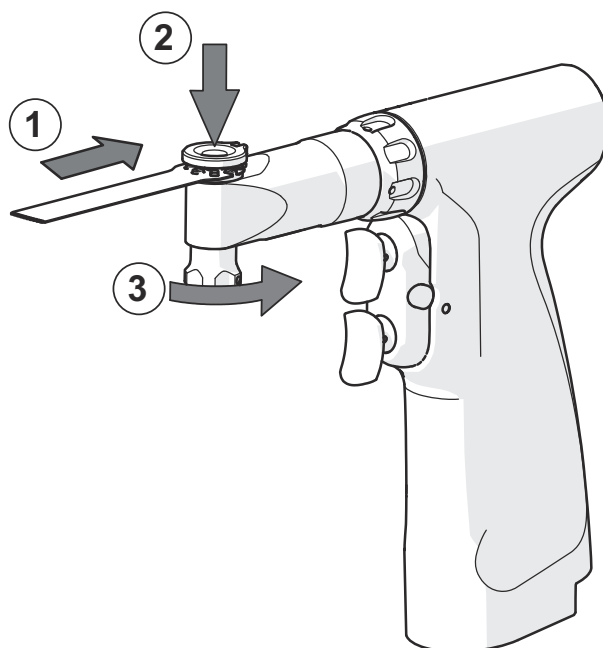
NOTE: this procedure applies to the V-CU-470

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

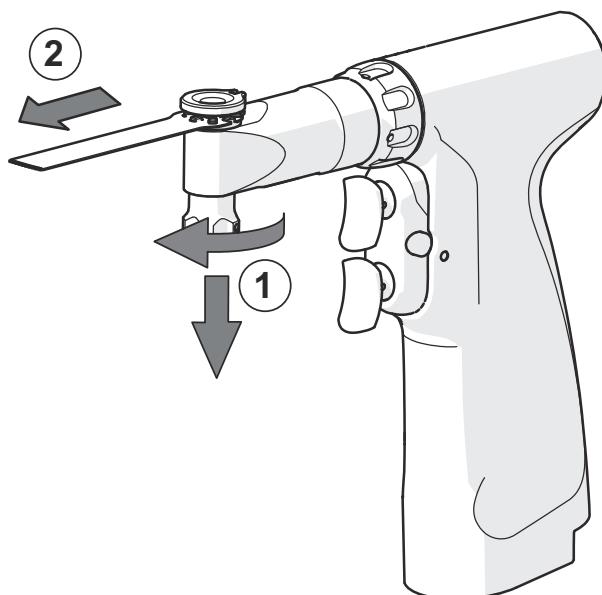


NOTE: this procedure applies to the V-NU-470

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.



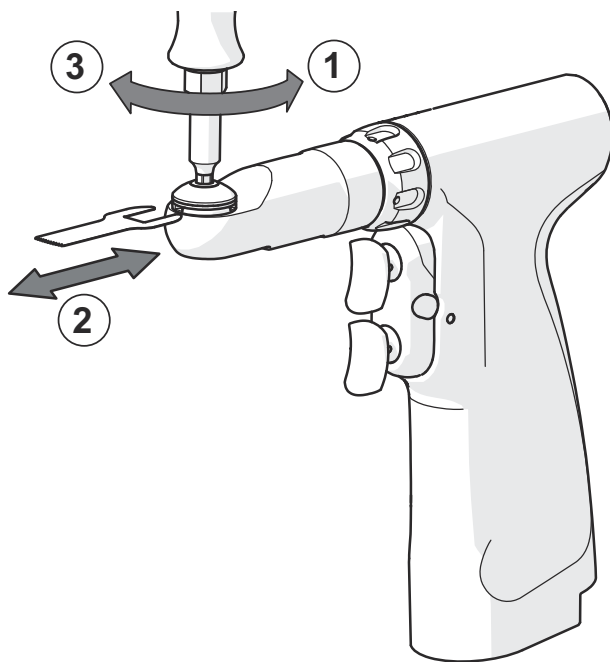
NOTE: this procedure applies to the V-NU-470

Fitting and Removing a Sagittal Blade (Manual-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. Using the blade clamp tool, rotate the blade clamp anti-clockwise.
2. Insert or remove the blade.
3. Using the blade clamp tool, rotate the blade clamp clockwise to secure the blade.

NOTE: ensure the inserted blade is securely clamped in place



NOTE: this procedure applies to the V-SU-470

Fitting and Removing a Bur

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: never run the handpiece with the locking sleeve in the unlocked position.

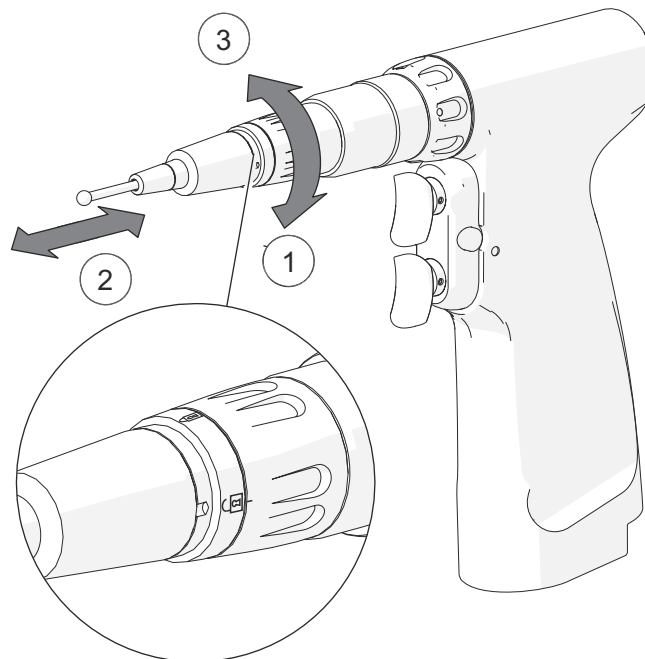
CAUTION: when using a bur attachment, always use a bur guard

1. Rotate the locking sleeve clockwise to the unlocked position.
2. Fit or remove the bur.

NOTE: ensure that the bur does not protrude more than 25mm from the end of the bur guard

3. Rotate the locking sleeve anti-clockwise to the locked position.

NOTE: when removing a bur, leave the locking sleeve in the unlocked position



NOTE: this procedure applies to the V-BU-472

Fitting a Wire or Pin (V-WU-470 & V-PU-470)

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

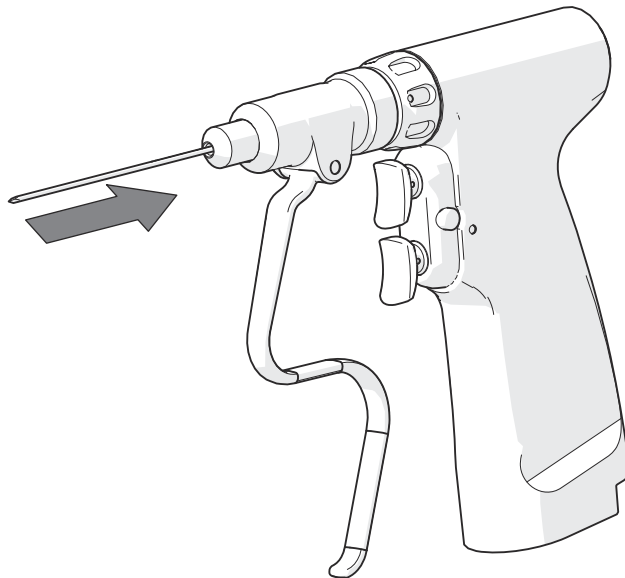
WARNING: if the wire or pin protrudes from the rear of the tool, a wire guard must be fitted

CAUTION: do not use bent wires

CAUTION: ensure at least 8mm (5/16 inch) of the wire remains protruding from the surgical site if the wire is to be removed

Insert the wire (or pin) into the front of the wire driver until the wire is in the required position.

NOTE: the wire/pin driver will automatically adjust to accommodate the wire being used



Fitting a Wire or Pin (V-WU-471)

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

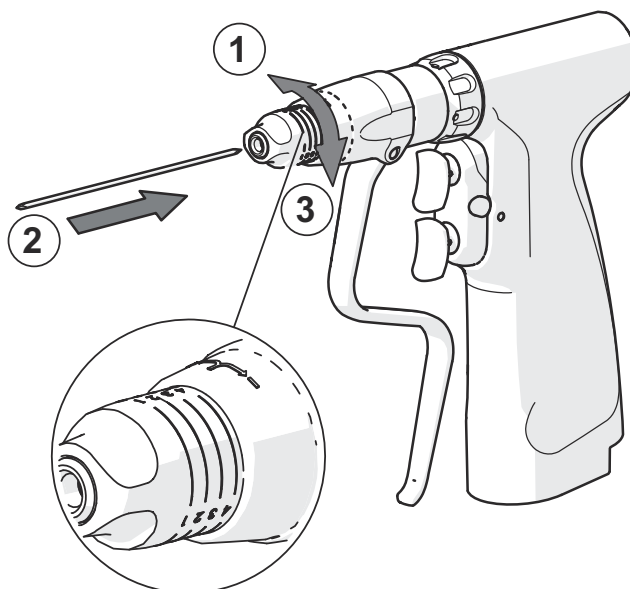
CAUTION: if the wire is to be removed from the surgical site, ensure the wire is wiped clean before inserting into the attachment

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

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.

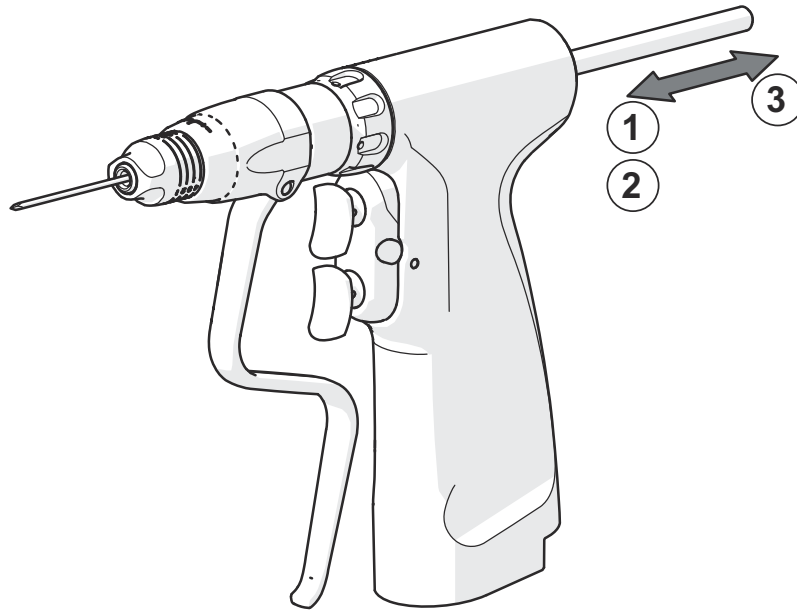


Fitting a Wire or Pin Guard

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

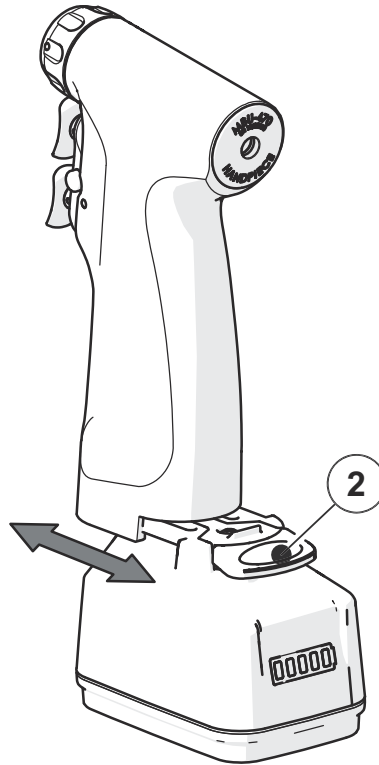
1. Slide the wire guard over the end of the wire at the rear of the handpiece.
2. Push the wire guard firmly into the handpiece until it snaps into place.
3. To remove, pull the wire guard away from the handpiece.



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-MBU-470
Part no.	1292444
Speed	 0 - 1350 rpm
	 0 - 270 rpm
Cannulation Diameter	4.2 mm
Protection Type	 Type BF protection
Enclosure Protection	IP69
Mode of Operation	Intermittent - 2 minutes on / 8 minutes off, 4 times with a 2 hour cooling period

Environmental Conditions

Environment	Operating	Storage and Transport
Temperature (°C)	 30 5	 40 -20
Relative humidity (%)	 75 30	 90 0
Atmospheric pressure (kPa)	 105 80	 150 50

Attachments

Drill Attachments

Model	Description	Capacity	Cannulation (mm)	Part No.
V-DU-470	Keyed	0.5 - 4.0 mm (5/32 inch)	4.1	18780
V-DU-470		0.5 - 7.4 mm (1/4 inch)	4.2	18770
V-DU-470	AO Synthes	-	2.5	18800
V-DU-470	Hudson/Zimmer	-	4.2	18790

Rotary Chuck Accessories

Description	Part No.
Key for 0.5 - 4.0 mm keyed chuck	8780
Key for 0.5 - 7.4 mm keyed chuck	30062

De Soutter Medical offer a range of chuck adaptors to suit this equipment. For more details or for ordering information, please refer to the sales brochure or contact your De Soutter Medical representative.

Reamer Attachments

All reamer attachments have a speed range of 0 - 350 rpm.

Model	Description	Capacity	Cannulation (mm)	Part No.
V-RU-470	Keyed	0.5 - 7.4 mm	4.2	18820
V-RU-470	AO Synthes	-	4.2	18830
V-RU-470	Hudson/Zimmer	-	4.2	18840

Other Attachments

Model	Description	Speed	Blade / Capacity	Part No.
V-BU-472	High-speed bur	0 - 27,000 rpm	De Soutter Medical R-Series	19480
V-SU-470	Manual-release sagittal saw	0 - 22,000 cpm	De Soutter Medical S85	18870
V-NU-470	Quick-release sagittal saw	0 - 20,500 cpm	De Soutter Medical S88-1xx	18880
V-CU-470	Small reciprocating saw	0 - 8000 cpm	De Soutter Medical S92	18890
V-WU-470	Wire/Pin driver	0 - 1350 rpm	0.6 - 1.8 mm	18900
V-WU-471	Wire/Pin driver	0 - 1350 rpm	0.7 - 4.0 mm	18910
V-PU-470	Pin driver	0 - 1350 rpm	1.8 - 3.2 mm	18920

Attachment Accessories

Description	Part No.
Hex tool for V-SU-470	9590
Wrench for V-CU-470	9940
Bur guard - standard	19490
Bur guard - long	19500
Bur guard - extra long	19510
Wire/pin guard	9570
Cleaning brush for wire/pin drivers	8120

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.
AB-703	Small aseptic lithium battery	10.95 V	2000 mAh (21.9 Wh)	17910
V-AH-703	Small aseptic lithium battery housing	-	-	18850
AS-703	Small aseptic lithium battery shield	-	-	18100

Model	Description	Voltage	Capacity	Part No.
AB-704	Large aseptic lithium battery	14.6 V	2000 mAh (29.2 Wh)	17920
V-AH-704	Large sterile lithium battery housing	-	-	18860
AS-704	Large sterile lithium battery shield	-	-	18110

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, with various interchangeable charging adaptors, to charge a range of De Soutter Medical batteries.

Alternatively, a dedicated single station charger is available for use with the 700 Series batteries.

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
BC-707	AB-703	1	18000
BC-708	AB-704	1	18010

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 run	Battery is discharged	Charge the battery
	Battery is expended	Replace the battery
	Power supply fuses have tripped	Replace the fuses
Handpiece runs slowly or judders	Battery is discharged	Charge the battery
	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 cutting accessory does not move	Attachment is not securely fitted	Refit the attachment
	Cutting accessory is not securely fitted	Refit 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.

In the unlikely event that a serious, adverse event occurs in relation to using this equipment, details of the event should be reported to De Soutter Medical. The competent authority of the EU Member State should also be notified, as appropriate.

EMC Information

General Information

The equipment described in this user manual is intended for use in hospitals, except near areas where the potential for EM disturbances is high (such as, near HF Surgical equipment or near the shielded room of an MRI system).

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

CAUTION: the use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

CAUTION: portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of this equipment, including cables specified by the manufacturer. Otherwise, the performance of this equipment could degrade.

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

EM Compliance (emissions)

This equipment complies with the tests and levels described.

Test	Standard	Compliance Level
RF Emissions	CISPR 11	Group 1, Class A
Harmonic Emissions	IEC 61000-3-2	Class A
Voltage fluctuations & flicker emissions	IEC 61000-3-3	Complies

EM Compliance (immunity)

This equipment complies with the tests and levels described.

Test	Test Standard	Compliance Level
Conducted RF Immunity	IEC 61000-4-6	3 Vrms, from 150 kHz to 80 MHz
		6 Vrms, in ISM bands between 150 kHz and 80 MHz
Radiated RF Immunity	IEC 61000-4-3	3 V/m, from 80 MHz to 2.7 GHz
Electrostatic Discharge (ESD)	IEC 61000-4-2	± 8 kV contact
		± 15 kV air
Electrical fast transient/burst	IEC 61000-4-4	± 2 kV for power supply lines
		± 1 kV for input/output lines
Surge	IEC 61000-4-5	± 2 kV line(s) to earth
		± 1 kV line(s) to line(s)
Voltage dips ^a	IEC 61000-4-11	0 % U _T for 0.5 cycle
		0 % U _T for 1 cycle
		70% U _T for 25/30 cycle
Interruptions	IEC 61000-4-11	0 % U _T for 250/300 cycle
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m, 50 or 60 Hz
Proximity fields from RF wireless communications equipment	IEC 60601-1-2	Complies with the requirements of IEC 60601-1-2

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



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