

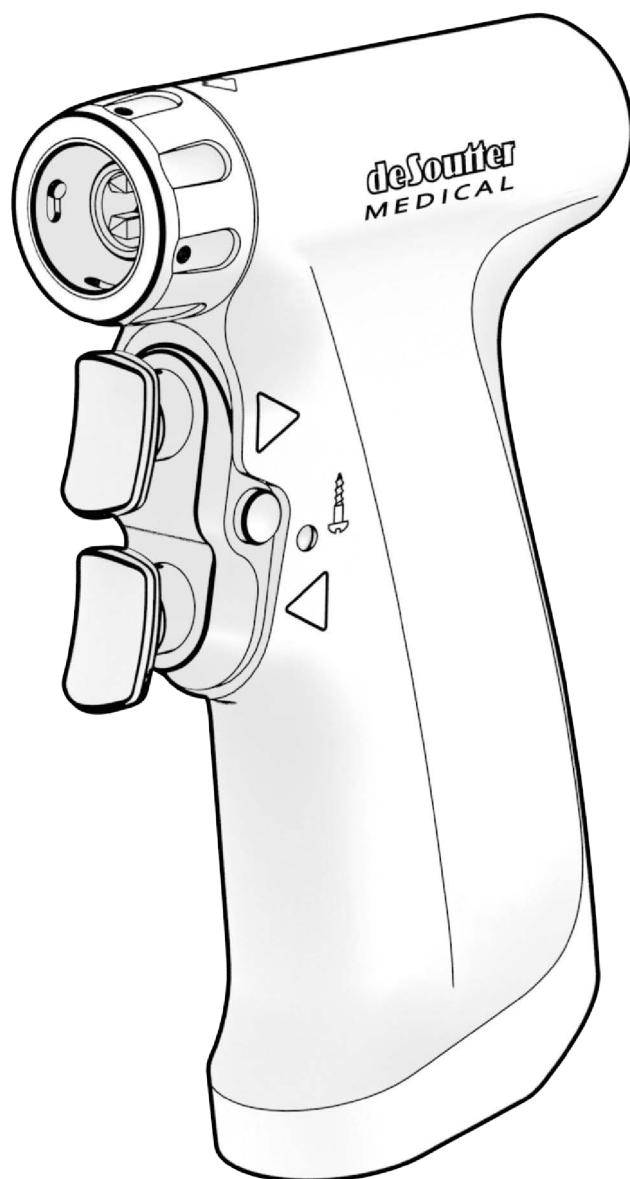
osteodrive® //

International

English

User Manual

MCU-480



deSoutter
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**



Contents

1	Important Information	1
	Safety Instructions	1
	Intended Use and Benefits	2
	Disposal	2
2	Symbols	3
3	Reprocessing - Sterilisable Equipment	4
	Limitations on reprocessing	4
	Safety Instructions	4
	Point of Use (before reprocessing)	5
	Containment and Transportation	5
	Cleaning and Disinfection	5
	Maintenance	7
	Inspection and Function Testing	7
	Packaging	7
	Sterilisation of Handpieces and Accessories	7
	Storage	8
	Point of Use (after reprocessing)	8
	Additional Information	8
4	Overview	9
5	Configuring a Handpiece	10
	Selecting the Mode	10
	Controlling the Speed	10
	Powering the Handpiece	11
	Disconnecting the Handpiece	12
6	Using Attachments	13
	Fitting an Attachment	13
	Removing an Attachment	14
	Rotating a Sagittal Head (SU-481)	15
	Fitting a Bur Guard	16
	Removing a Bur Guard	17
	Using a Wire or Pin Driver	18
7	Using Accessories	19
	Fitting and Removing a Rotary Cutter	19
	Fitting a Small Reciprocating Blade (CU-480)	20
	Removing a Small Reciprocating Blade (CU-480)	21
	Fitting a Sagittal Blade (Lever-release)	22
	Removing a Sagittal Blade (Lever-release)	23
	Fitting and Removing a Sagittal Blade (Button-release)	24
	Fitting a Sagittal Blade (Knob-release)	25
	Removing a Sagittal Blade (Knob-release)	26
	Fitting and Removing an Oscillating Blade (OU-480)	27
	Fitting an Irrigation Kit (OU-480)	28
	Fitting and Removing a Bur (BU-480)	29
	Fitting a Wire or Pin (WU-480 & PU-480)	30
	Fitting a Wire or Pin (WU-481)	31
	Fitting a Wire or Pin Guard	32

8	Technical and Ordering Information	33
	Handpiece Specifications	33
	Attachments	34
	Sterilisation Accessories	36
9	Troubleshooting	37
	Further Help	37
	Service and Repair Information	38
	Guarantee and Liability	38
10	EMC Information	39
	General Information	39
	EM Compliance (emissions)	39
	EM Compliance (immunity)	39

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*

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 for use in combination with the PC-47x Power Console to efficiently drill, ream, bur or cut bone, metal and hard tissue. The equipment is also intended to drive wires and pins into bone.

There are no known contraindications.

Disposal

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
	Dispose of in accordance with local regulations		Suitable for recycling
	Refer to the user manual for the duty cycle		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
	EC authorised representative		Do not use if packaging is damaged or opened
	Medical Device		

Reprocessing - Sterilisable Equipment

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

- All Handpieces
- All Attachments
- 4m handpiece cable

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: clean, disinfect and sterilise the equipment before use

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

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.

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.

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

Detergents and Rinse Aids

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)

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.

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	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

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

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.

WARNING: *manual cleaning of the DBZ-70x must be followed by a validated automatic washer-disinfector cycle to ensure the device is adequately cleaned*

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

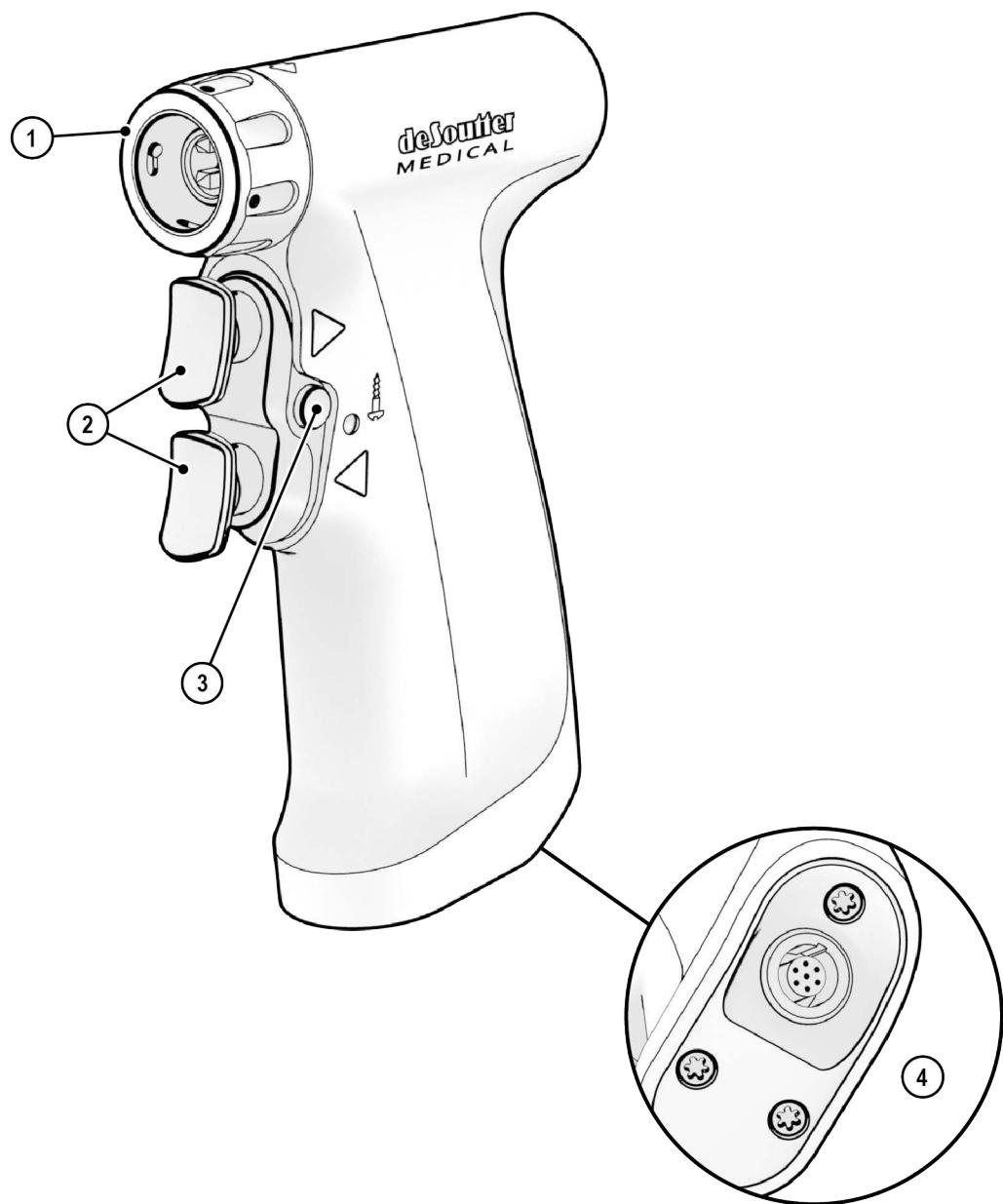
Vacuum and gravity steam sterilisation have been validated in accordance with HTM 2010, AAMI TIR12, ANSI/AAMI ST79, ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 17665-2.

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



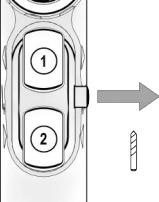
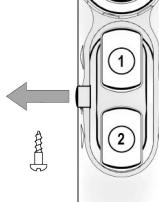
- 1) Release ring
- 2) Trigger
- 3) Mode selector
- 4) Power connection

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.

MCU-480		
		
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

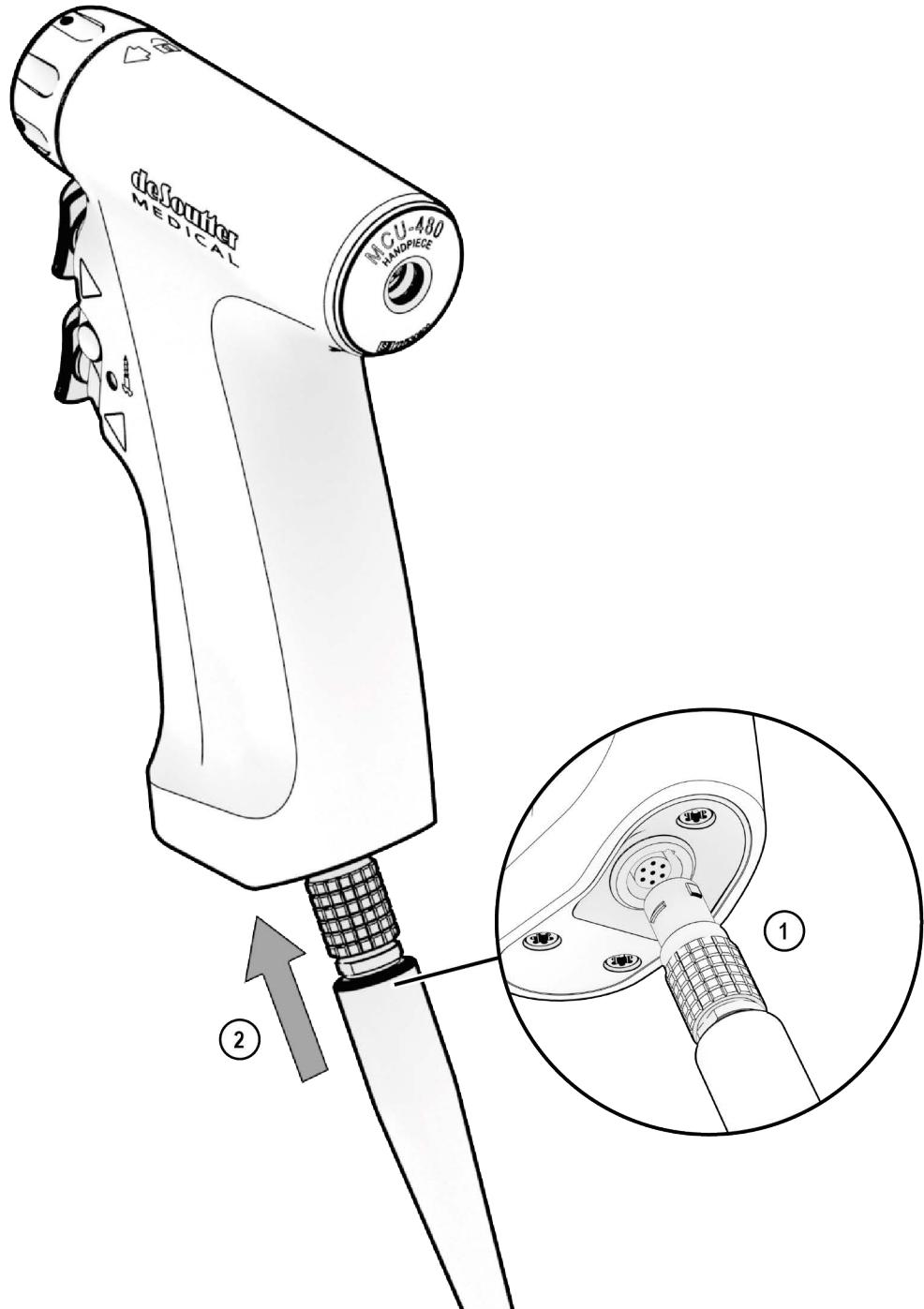
CAUTION: ensure the triggers are only pressed independently when using a saw attachment

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. Align the red marker on the plug with the corresponding marker on the handpiece.
2. Push the plug firmly into the handpiece.

NOTE: ensure the plug is securely fitted

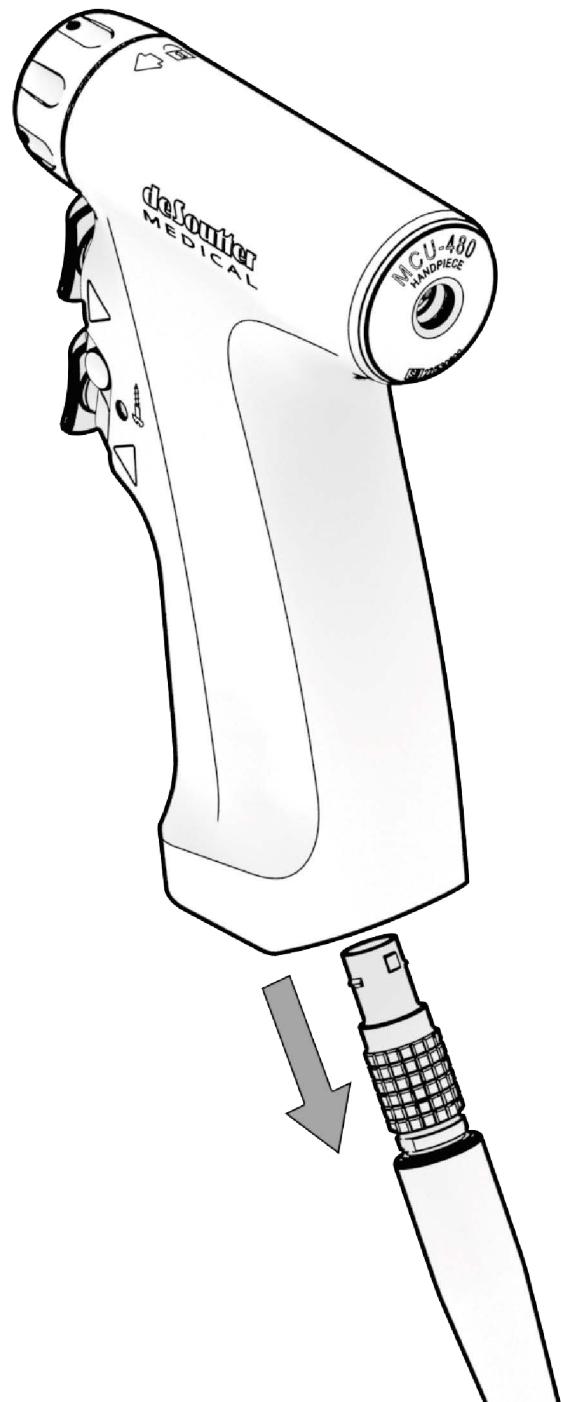


Disconnecting the Handpiece

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

Hold the plug by the textured section and pull away from the handpiece.

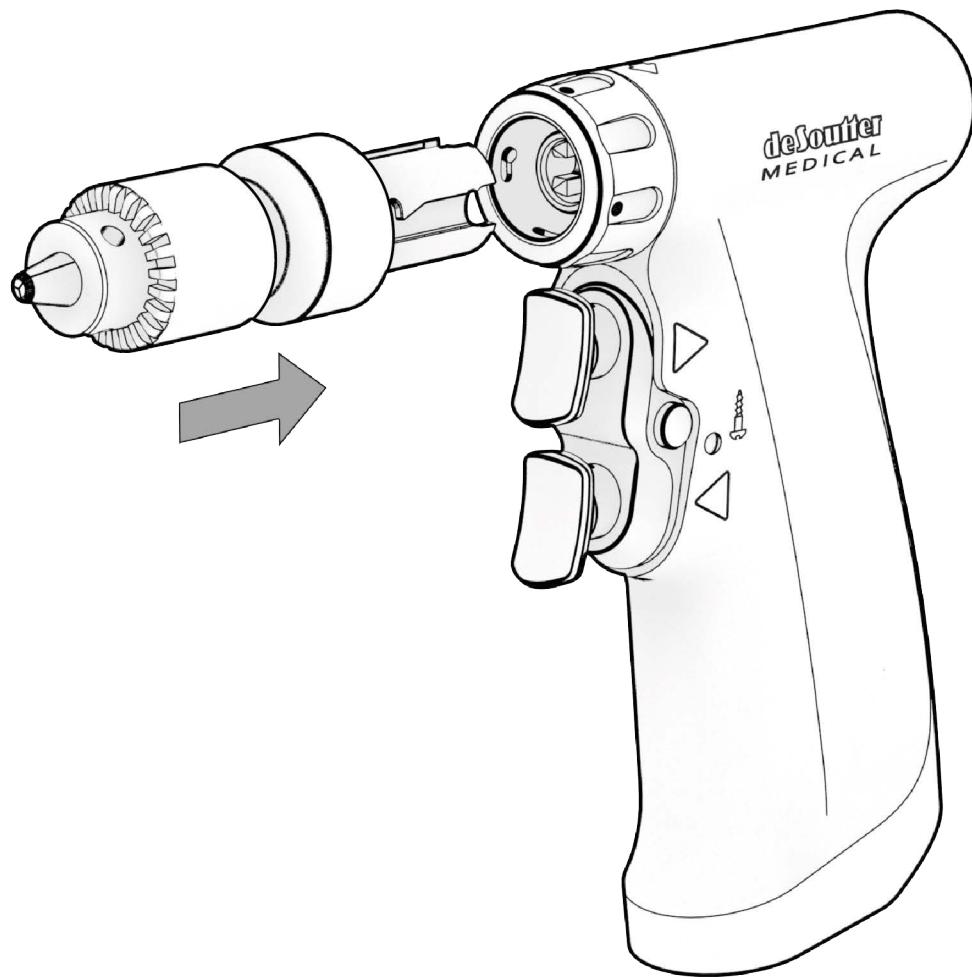
NOTE: do not attempt to remove the power cord by pulling the cable



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

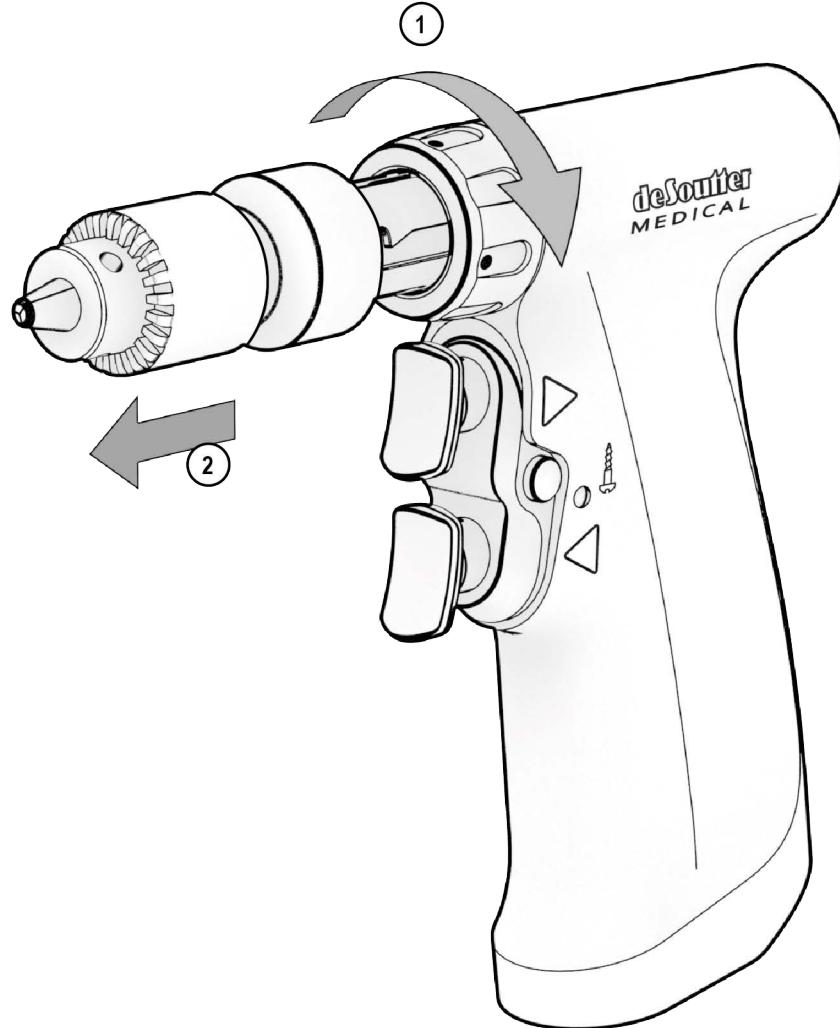


NOTE: all attachments are fitted in the same way

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.



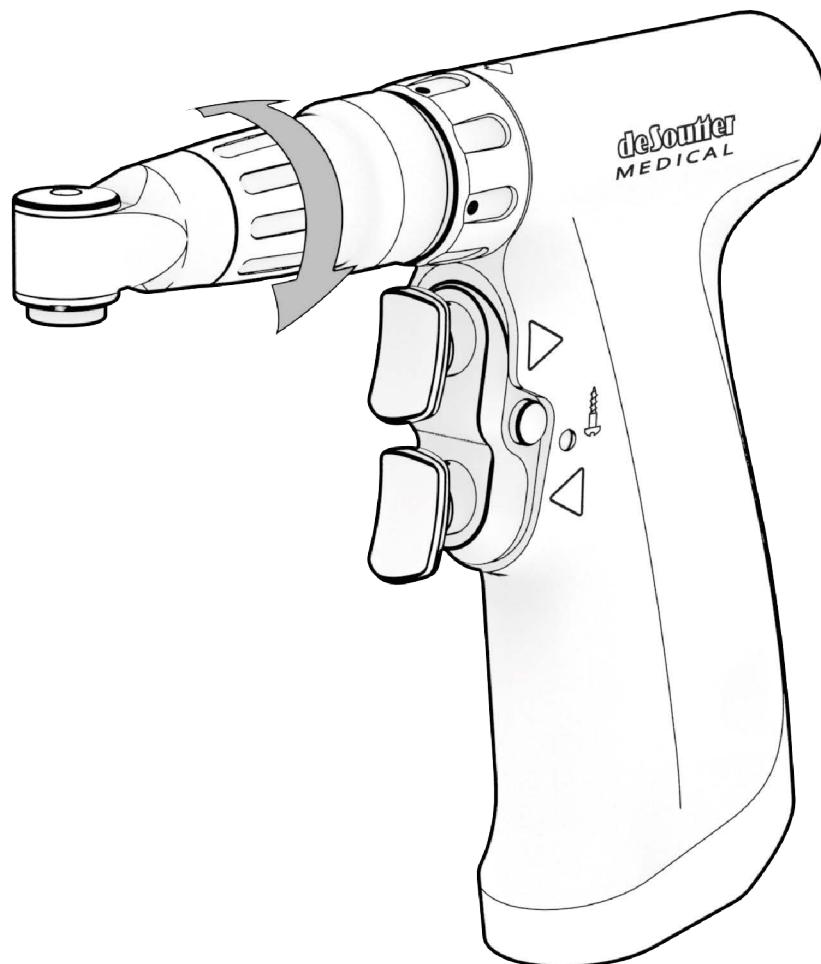
NOTE: all attachments are removed in the same way

Rotating a Sagittal Head (SU-481)

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

Rotate the head to the desired position until a click is heard.

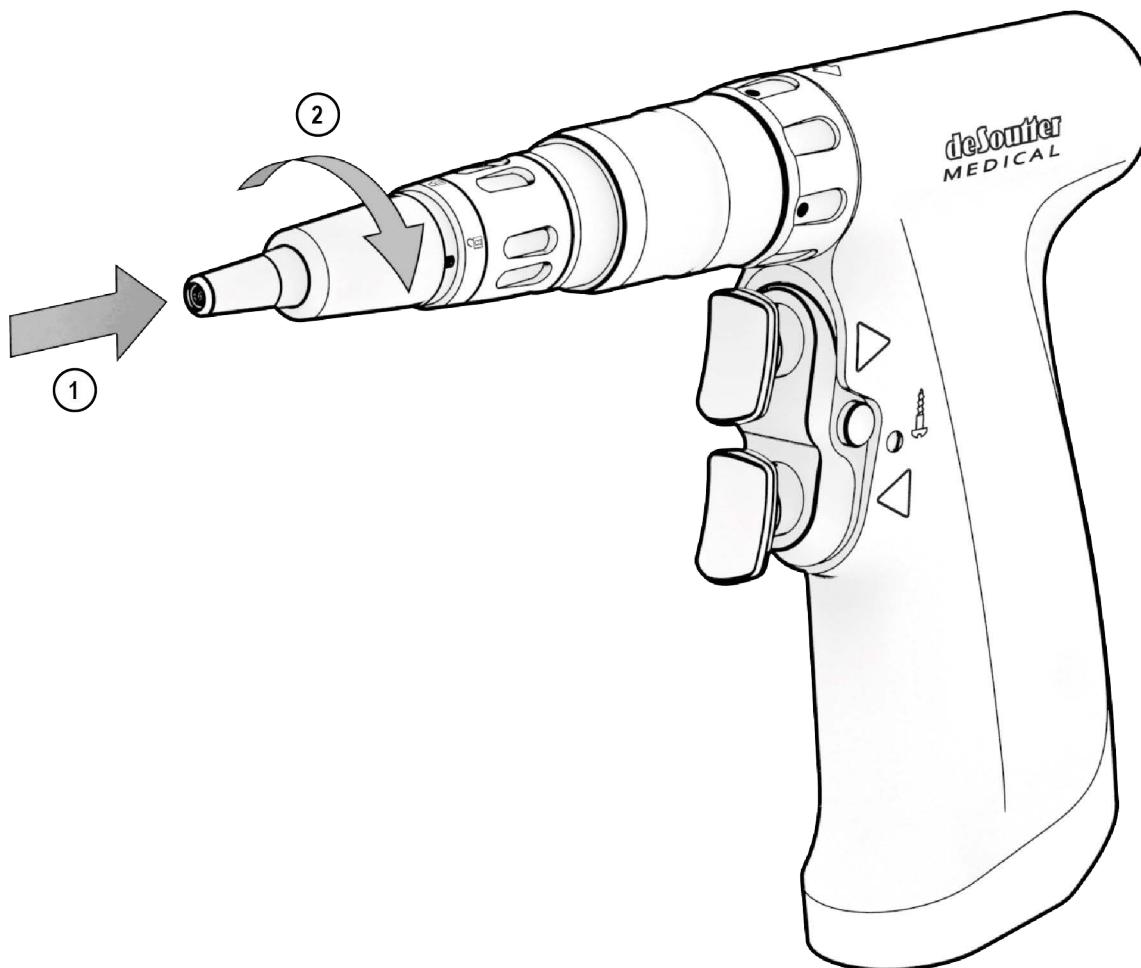
NOTE: the head can be positioned in increments of 45°



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

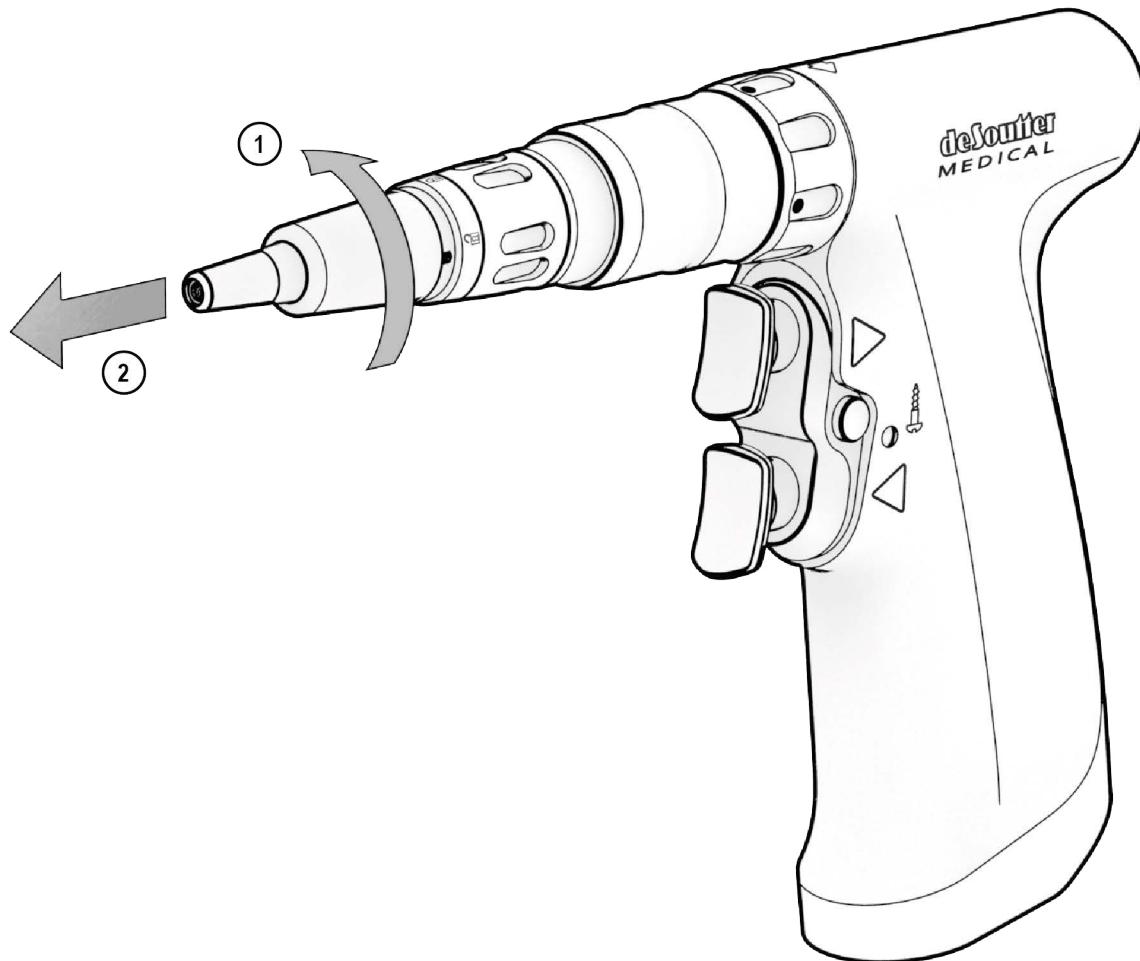


NOTE: this procedure applies to the BU-480

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 BU-480

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

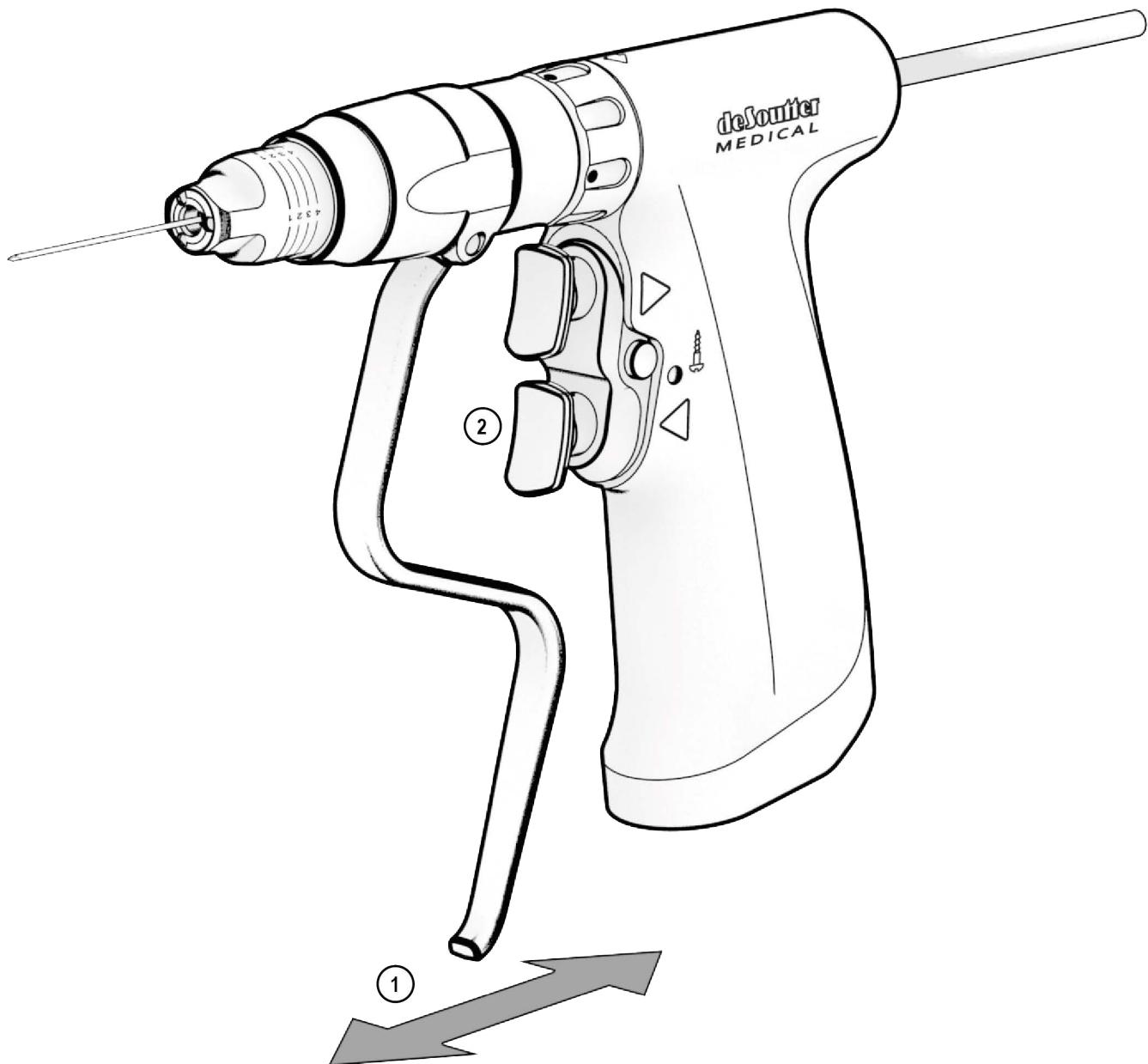
WARNING: if the wire or pin protrudes from the rear of the tool, a wire guard must be fitted

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	<ul style="list-style-type: none">• Pull the chuck sleeve back.• When inserting an accessory, release the chuck sleeve and ensure the accessory is clamped in place.

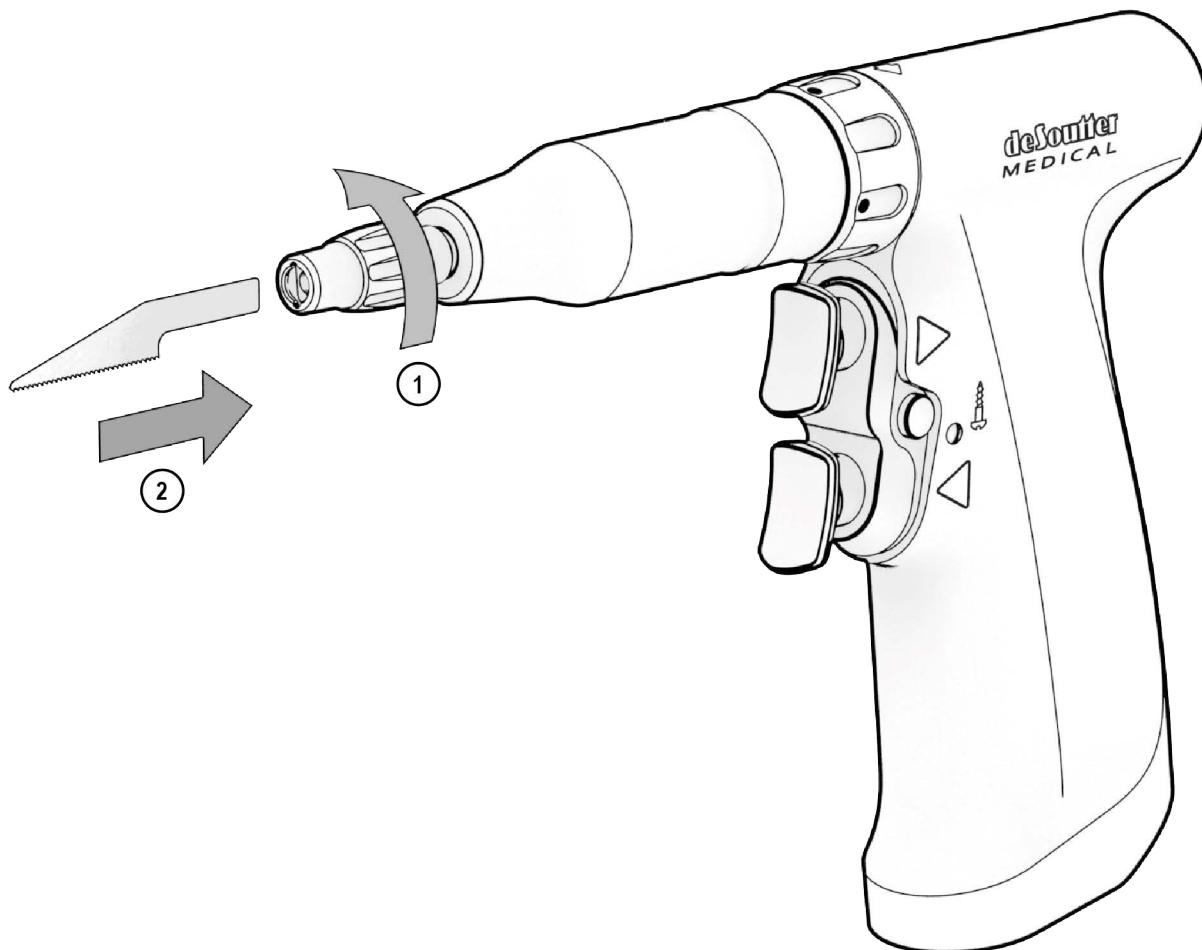
NOTE: to prevent loosening of the chuck, only use keyless chucks in a clockwise direction with a smooth and moderate feed rate

Fitting a Small Reciprocating Blade (CU-480)

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 locking sleeve anti-clockwise to unlock the blade clamp.
2. Insert the blade into the attachment and push the blade firmly until the blade clamp locks.

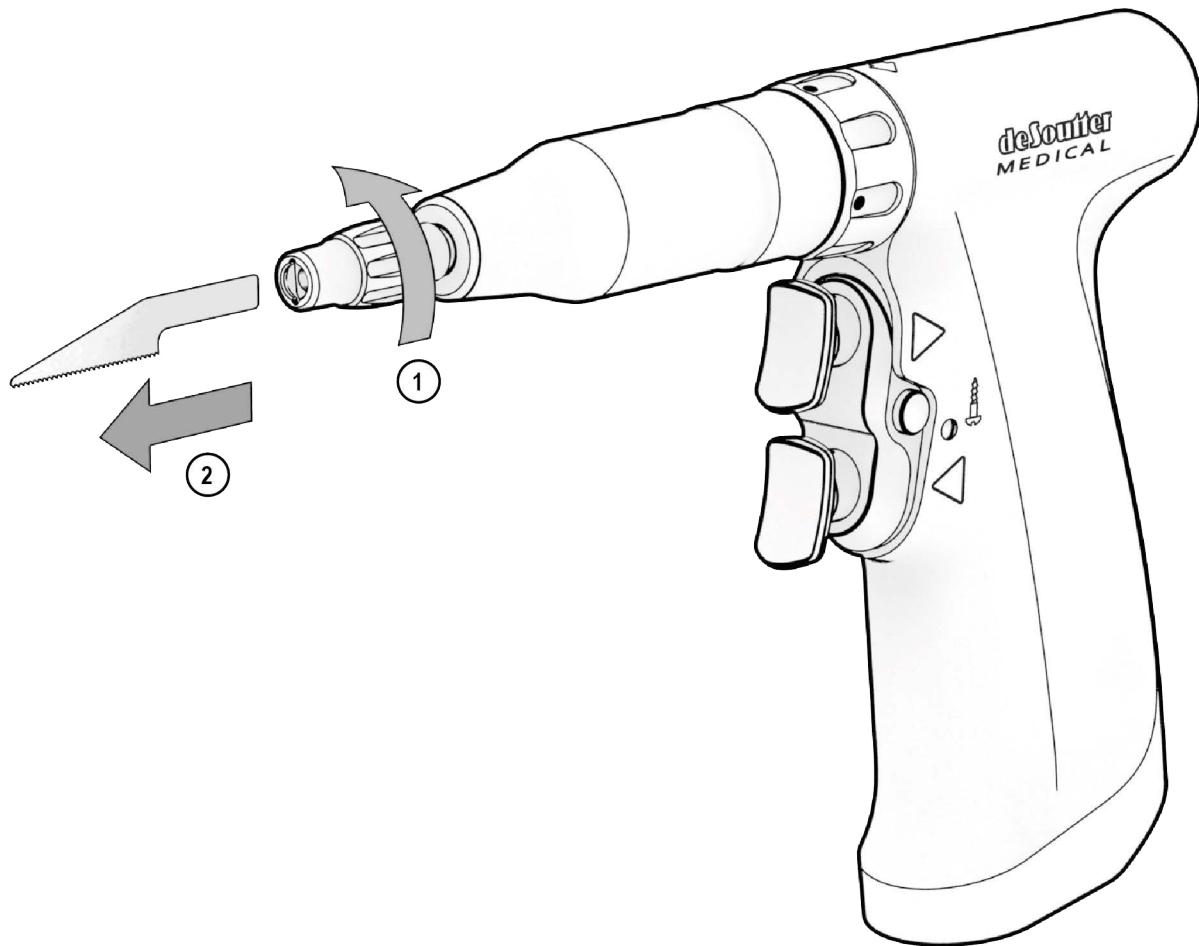
NOTE: ensure the blade is secured in place



Removing a Small Reciprocating Blade (CU-480)

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 locking sleeve anti-clockwise.
2. Remove the blade.

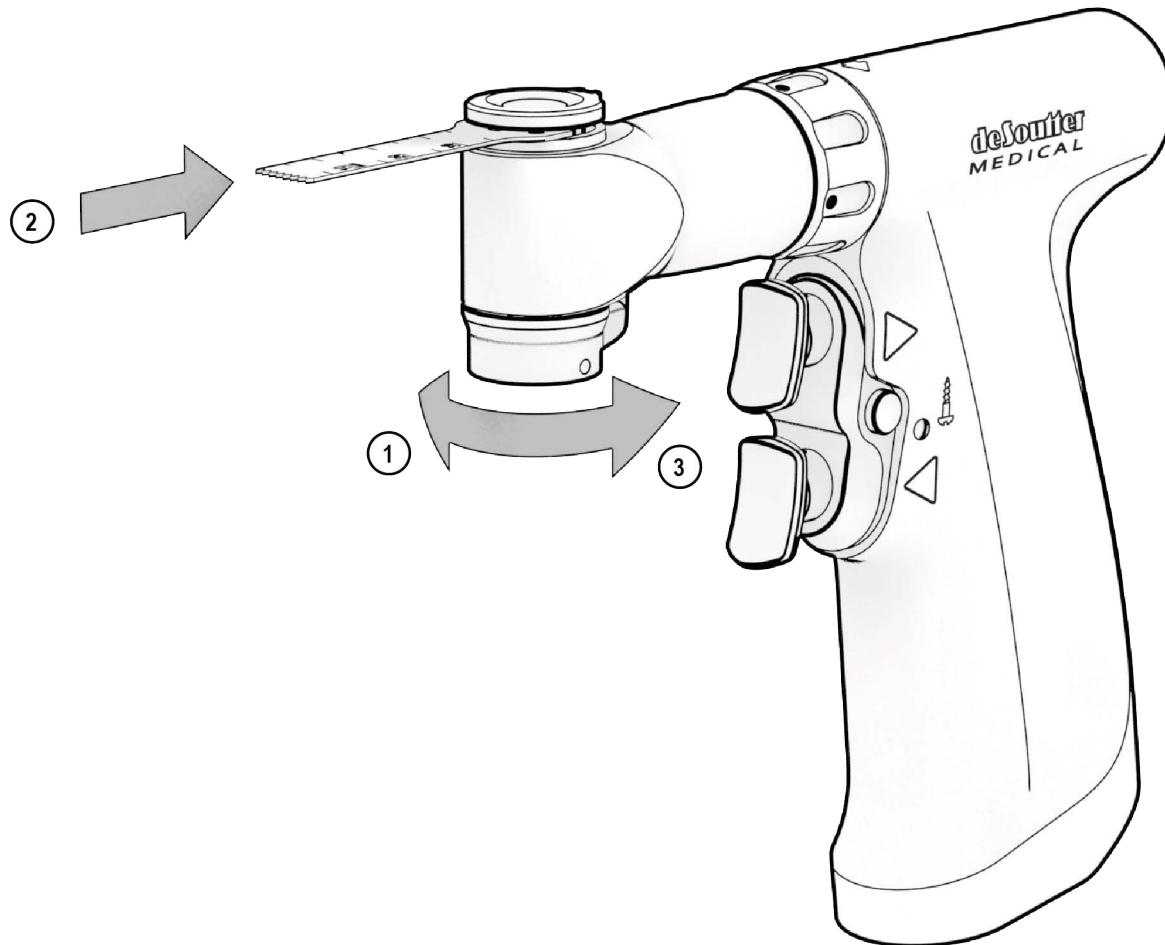


Fitting a Sagittal Blade (Lever-release)

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

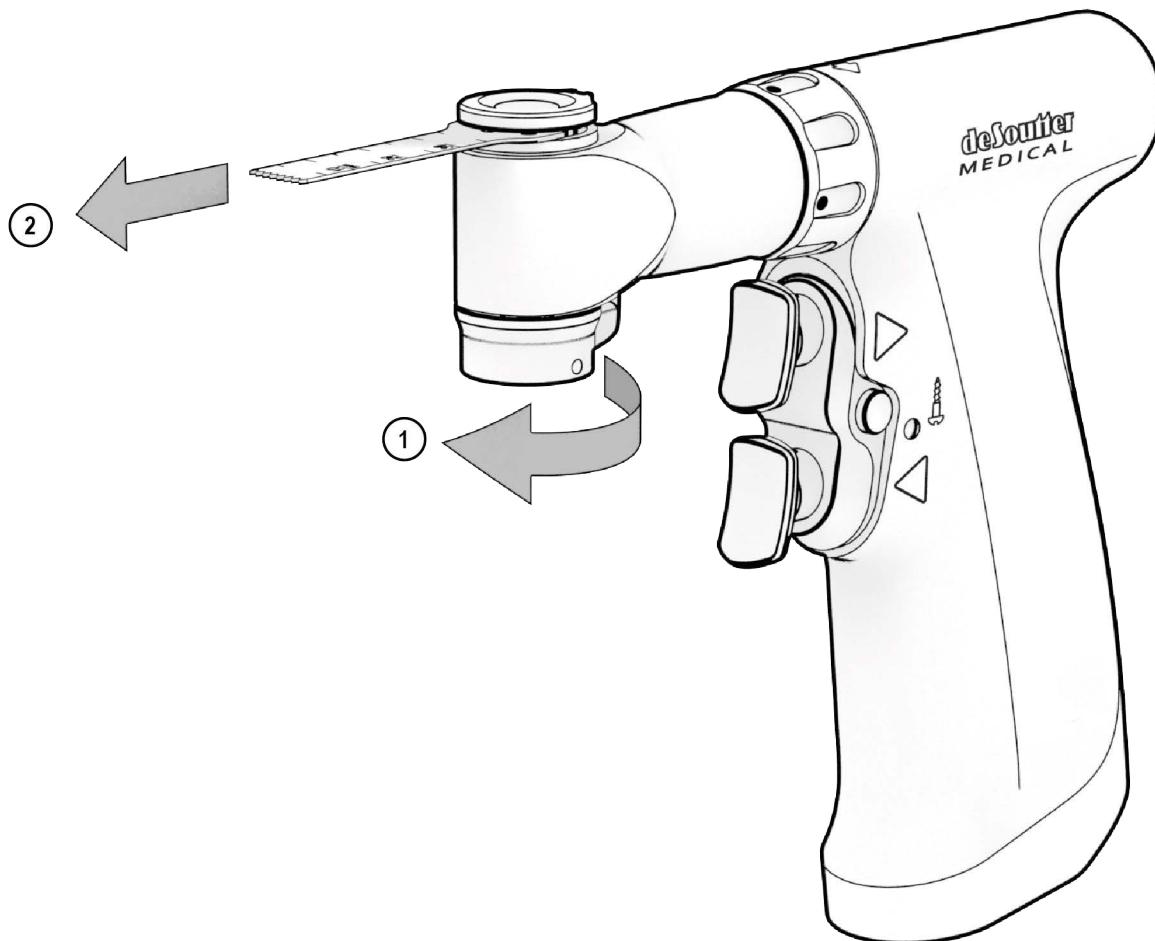


NOTE: this procedure applies to the NU-481

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.



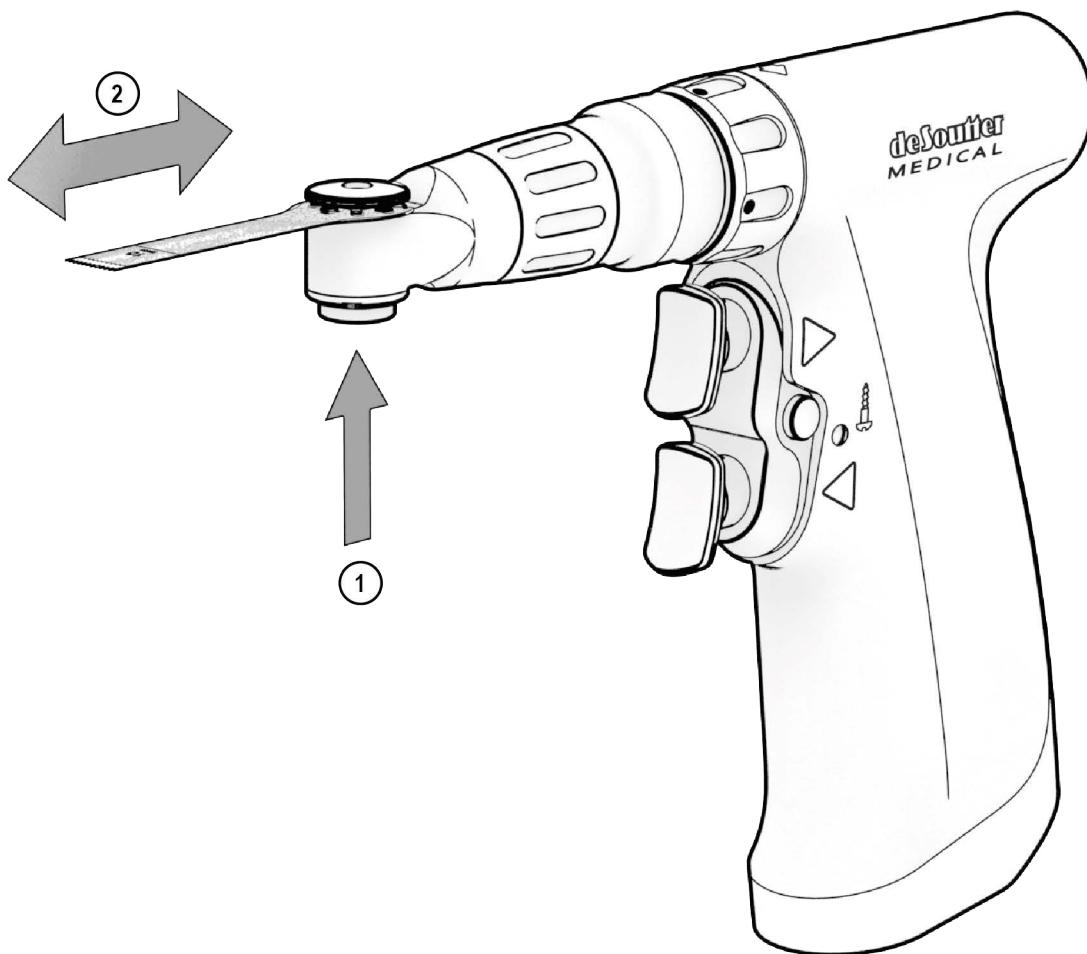
NOTE: this procedure applies to the NU-481

Fitting and Removing a Sagittal Blade (Button-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. Push the bottom of blade clamp upwards.
2. Insert or remove the blade.

NOTE: ensure the inserted blade is securely clamped in place



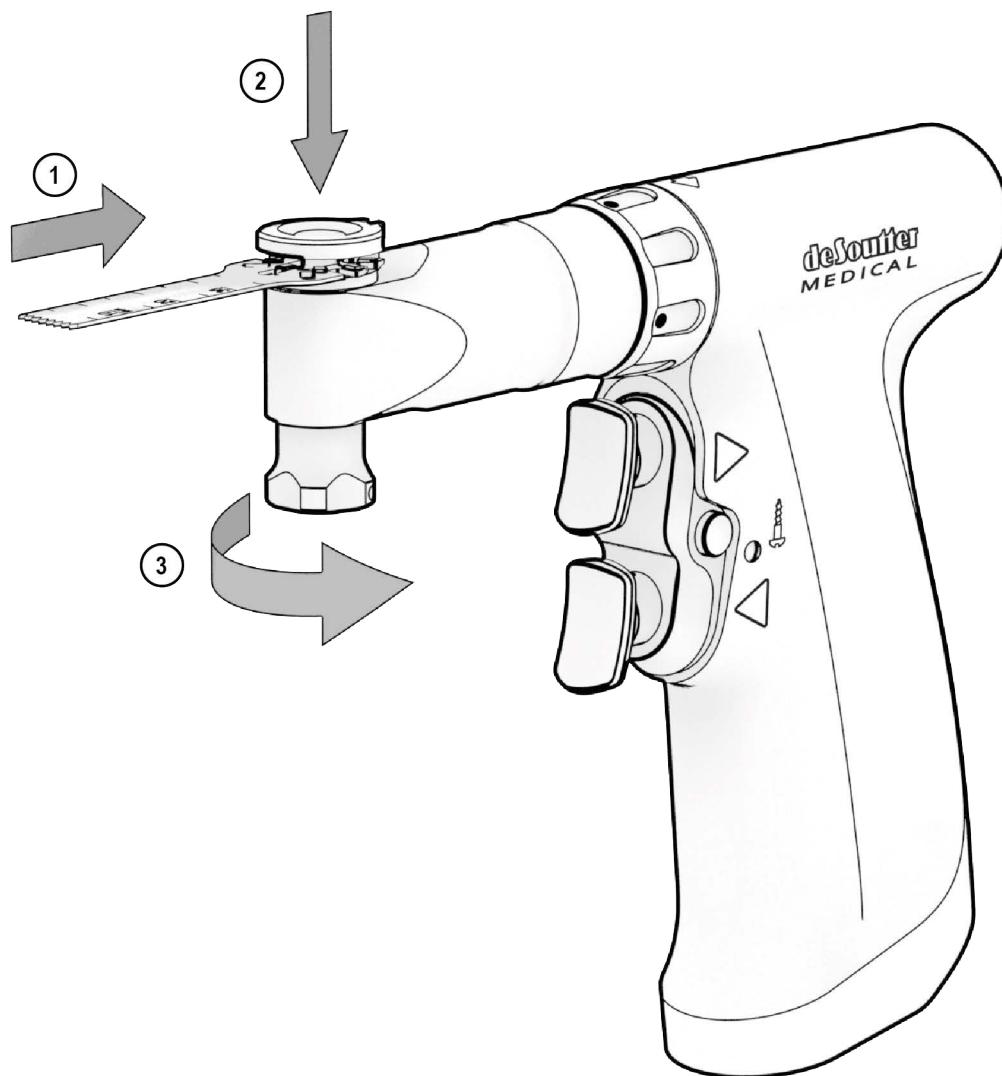
NOTE: this procedure applies to the SU-480 and SU-481

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

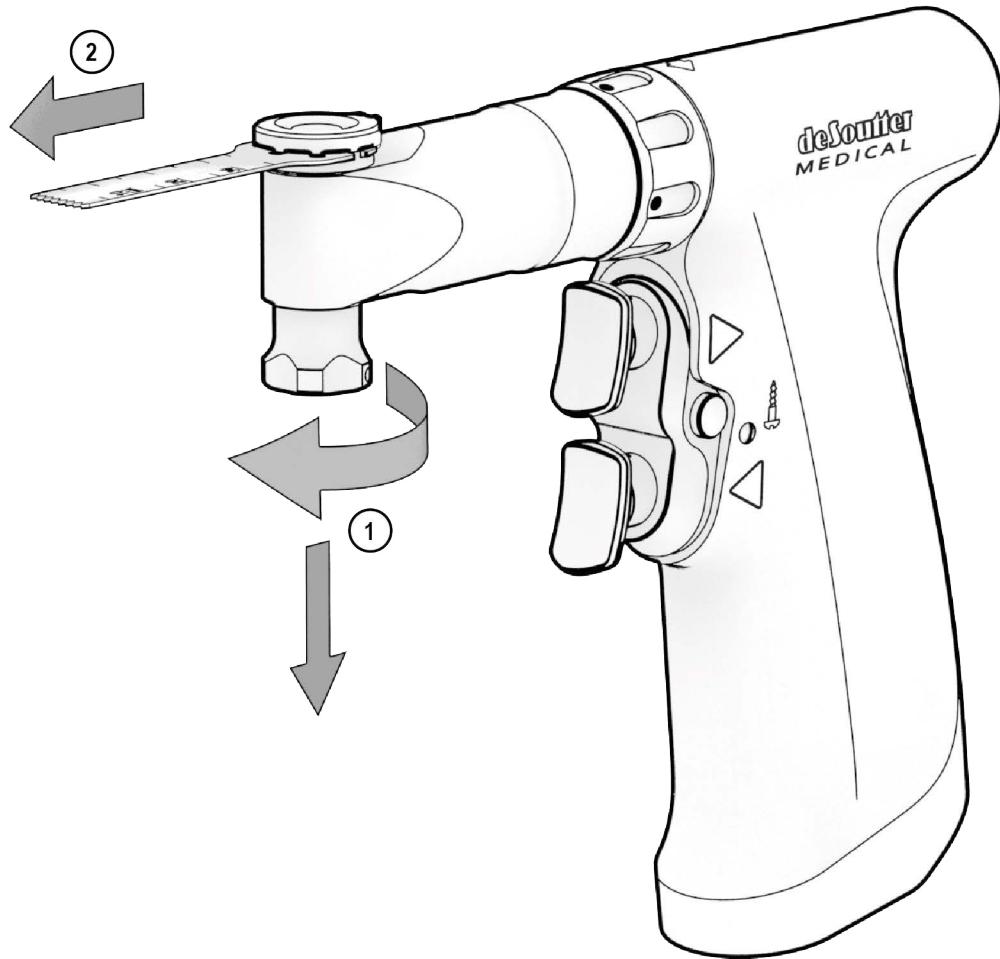


NOTE: this procedure applies to the NU-480 and the NU-482

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 NU-480 and NU-482

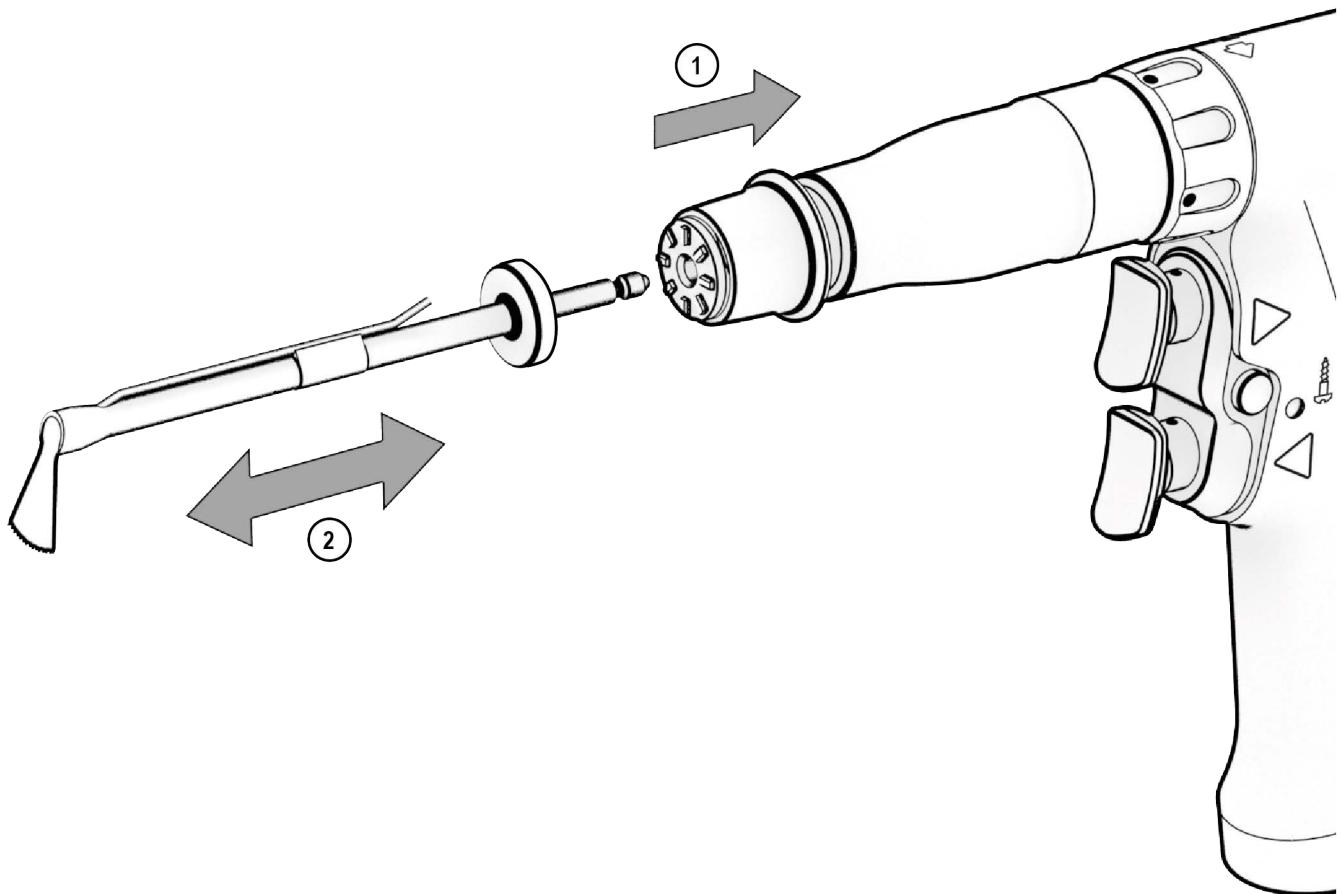
Fitting and Removing an Oscillating Blade (OU-480)

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 chuck sleeve back.
2. Fit or remove the blade.

WARNING: once the blade is inserted, release the chuck sleeve and ensure the blade is secured in place

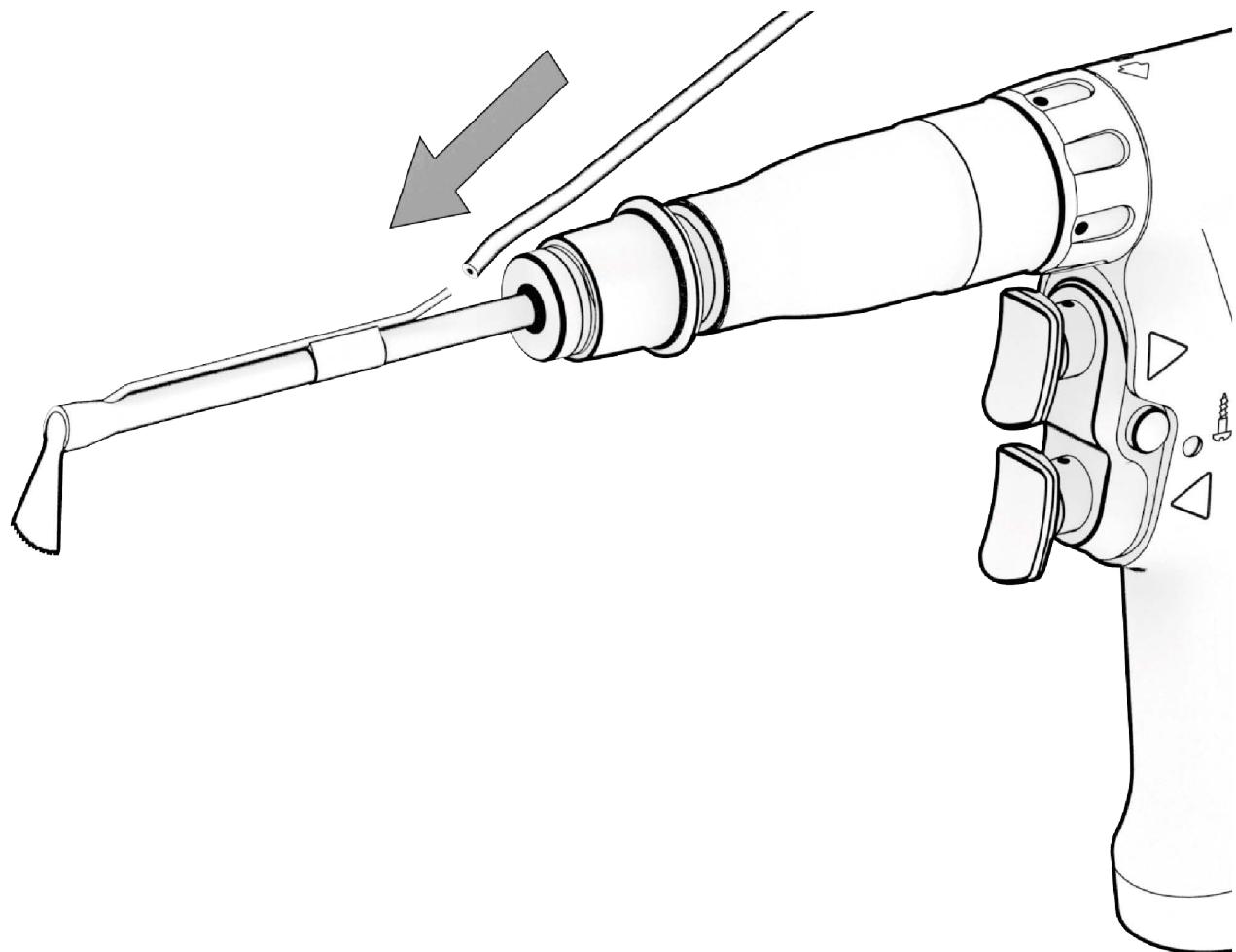
NOTE: blades can be used in any of eight angular positions



Fitting an Irrigation Kit (OU-480)

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

Fit the irrigation tube onto the nozzle.



NOTE: this procedure applies to the OU-480 and T20 irrigation kit

Fitting and Removing a Bur (BU-480)

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

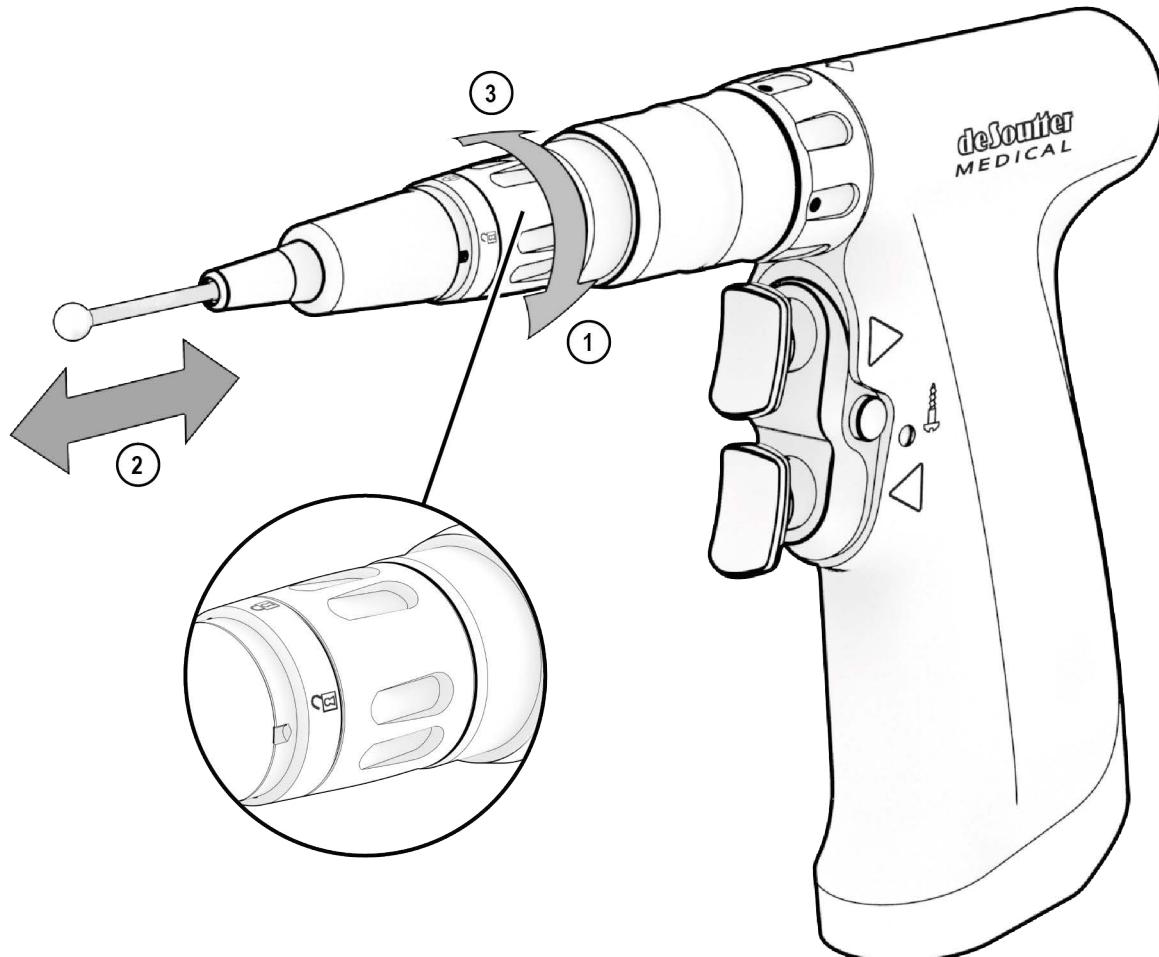
1. Rotate the locking sleeve clockwise to the unlocked position.

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 BU-480

Fitting a Wire or Pin (WU-480 & PU-480)

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

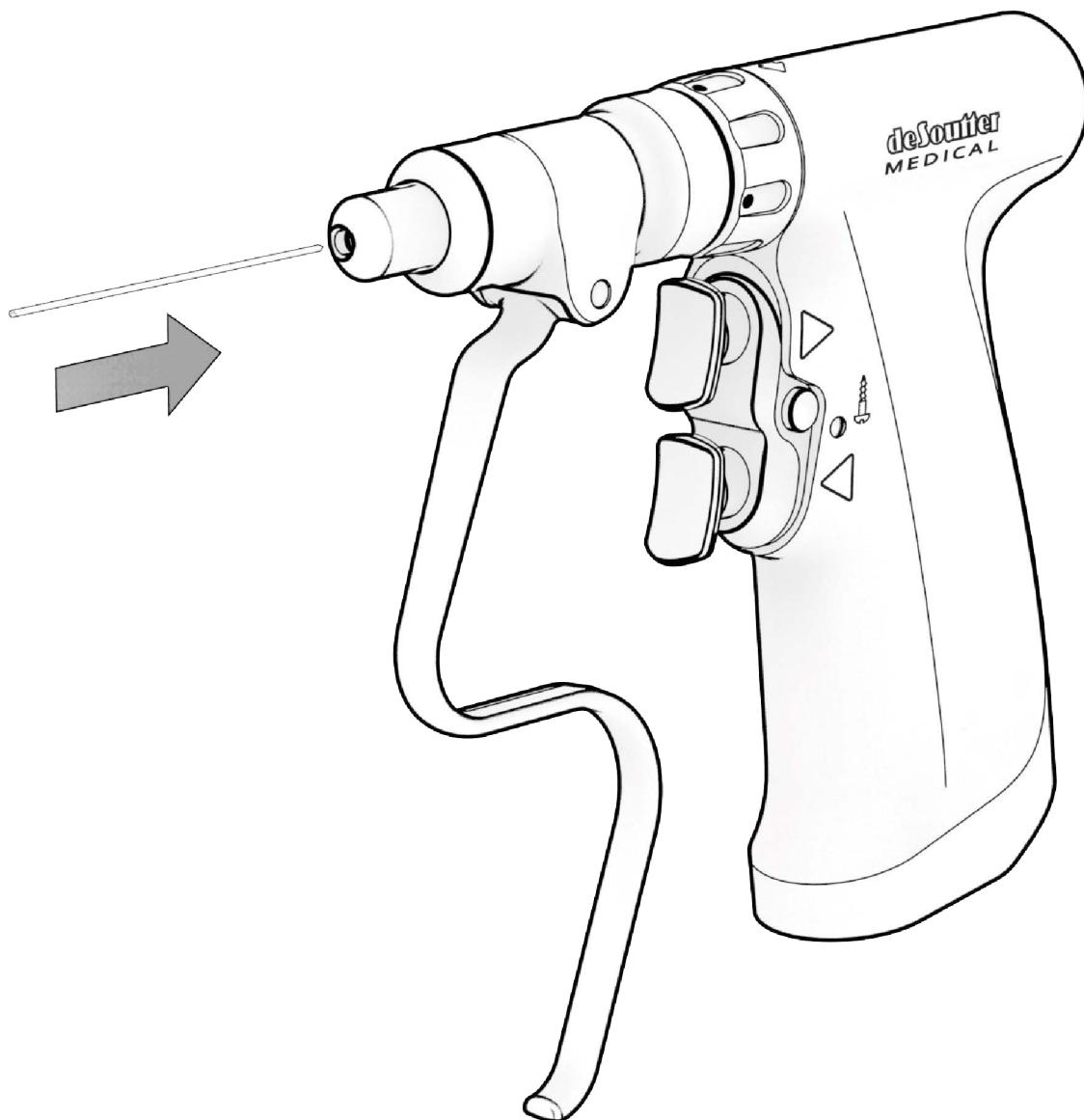
WARNING: if the wire or pin protrudes from the rear of the tool, a wire guard must be fitted

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 (WU-481)

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

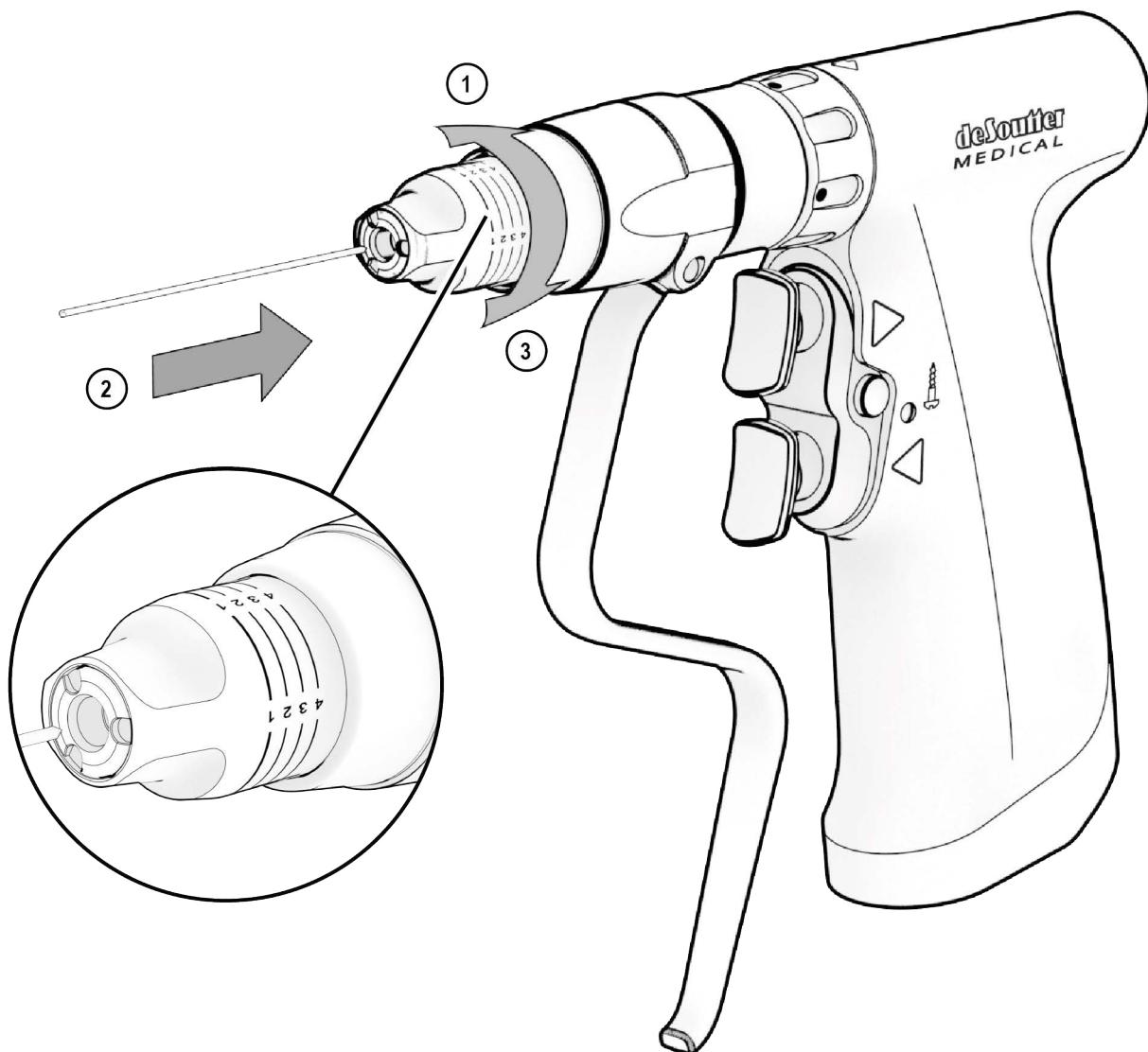
CAUTION: if the wire is to be removed from the surgical site, ensure the wire is wiped clean before inserting into the attachment

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.

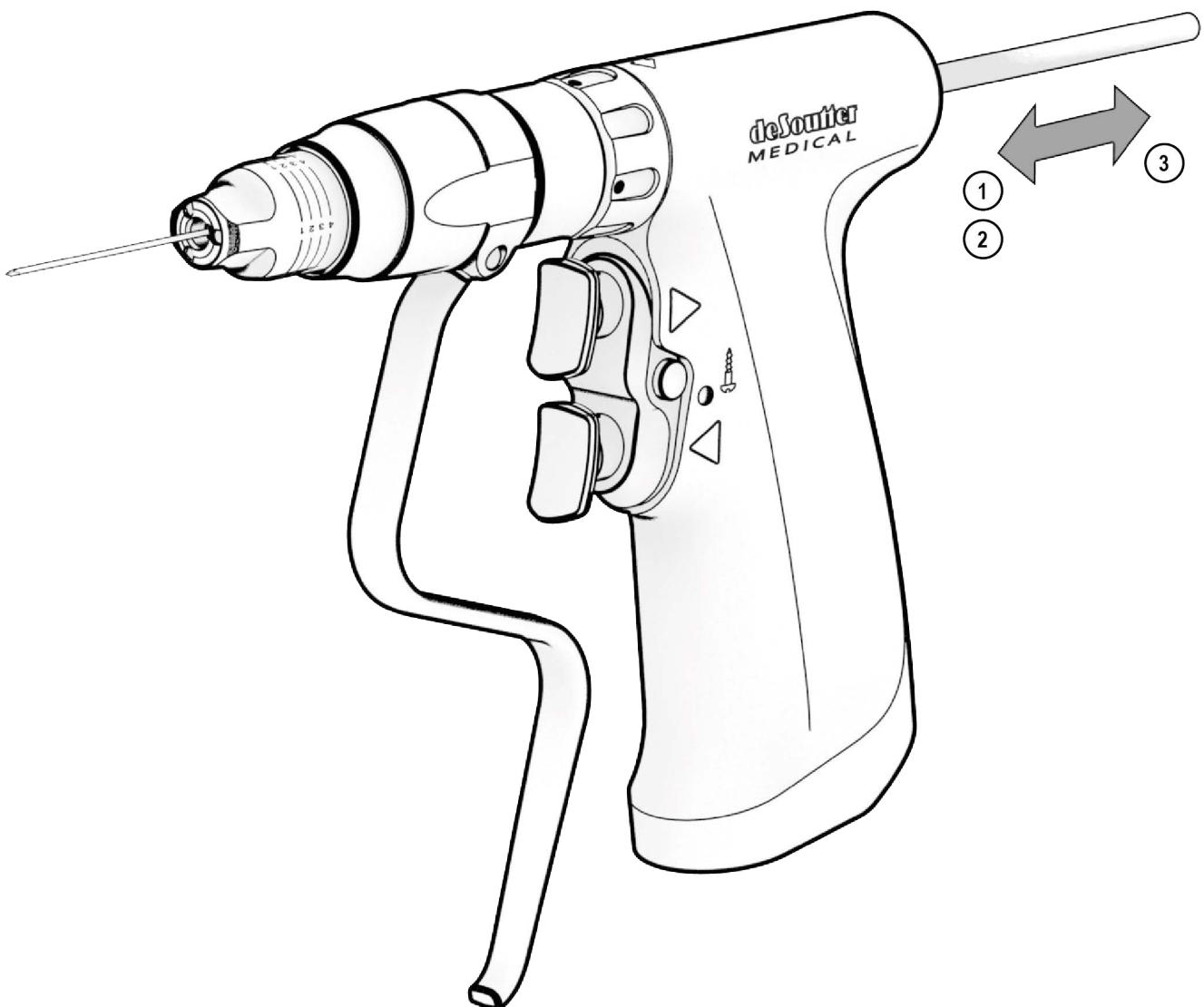


Fitting a Wire or Pin Guard

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.



NOTE: this procedure applies to all wire and pin driver options

Technical and Ordering Information

Handpiece Specifications

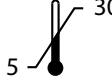
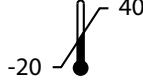
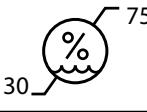
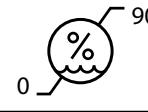
Model	MCU-480
Part no.	1295004
Speed	0 - 1350 rpm
	0 - 270 rpm
Cannulation Diameter	4.2 mm
Protection Type	 Type BF protection
Enclosure Protection	IPX0 - ordinary equipment

Mode of Operation

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

Attachment Type	Reciprocating	Sagittal	Rotary
Duty Cycle	30 sec on / 2 min off	1 min on / 4 min off	
Repetitions	3	4	
Cooling Period	2 hours		

Environmental Conditions

Environment	Operating	Storage and Transport
Temperature (°C)		
Relative humidity (%)		
Atmospheric pressure (kPa)		

Attachments

Drill Attachments

Model	Description	Speed	Capacity	Cannulation (mm)	Part No.
DU-480	Keyed	0 - 1350 rpm	0.5 - 4.0 mm (5/32 inch)	4.1	20820
DU-480		0 - 1350 rpm	0.5 - 7.4 mm (1/4 inch)	4.2	20830
DU-480	Keyless	0 - 1350 rpm	0.3 - 3.0 mm (1/8 inch)	3.0	20840
DU-480		0 - 1350 rpm	0.3 - 7.4 mm (1/4 inch)	4.2	20850
DU-480	Square	0 - 1350 rpm	1/4 inch	4.2	21220
DU-480	AO Synthes	0 - 1350 rpm	-	2.5	20860
DU-480	Hudson/ Zimmer	0 - 1350 rpm	-	4.2	20870
DU-480	DHS/DCS	0 - 1350 rpm	-	4.2	20880
DU-480	Aesculap Targon TX	0 - 1350 rpm	-	-	20890

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.
RU-480	Keyed	0.5 - 7.4 mm	4.2	20910
RU-480	AO Synthes	-	4.2	20920
RU-480	Hudson/Zimmer	-	4.2	20930
RU-480	Hudson	-	4.2	20940
RU-480	Zimmer	-	4.2	20950
RU-480	DHS/DCS	-	4.2	20960
RU-480	Square	1/4 inch	4.2	21210
RU-481	AO Synthes	-	4.2	20970
HU-480 ^a	DHS/DCS	-	4.2	20610

a. speed range of 0 - 285rpm

NOTE: RU-481 reamer attachments will only run in forward mode

Other Attachments

Model	Description	Speed	Blade / Capacity	Part No.
QU-480	Quick-release Medium Speed Drill	0 - 4500 rpm	ISO 1797 Type 1	20900
BU-480	High-speed bur	0 - 27,000 rpm	De Soutter Medical R-Series	20980
SU-480	Button-release sagittal saw (non-rotating)	0 - 22,000 cpm	De Soutter Medical S86	20570
SU-481	Button-release sagittal saw (rotating)	0 - 22,000 cpm	De Soutter Medical S86	20620
NU-480	Quick-release sagittal saw	0 - 20,500 cpm	De Soutter Medical S88-1xx	20990
NU-481	Quick-release sagittal saw	0 - 15,000 cpm	De Soutter Medical S88-1xx & S88-4xx	21000
NU-482	Quick-release sagittal saw	0 - 24,300 cpm	De Soutter Medical S88-1xx	21010
CU-480	Small reciprocating saw	0 - 13,950 cpm	De Soutter Medical S83	20580
OU-480	Oscillating Saw	0 - 20,000 cpm	De Soutter Medical S86-9xxx	20300
LU-480	Pulse lavage adaptor	0 - 1350 rpm	P30-7xx pump kits	21030
P30-7xx	Pump kit ^a	0 - 1350 rpm	-	see brochure
TU-480	Radiolucent adaptor	0 - 1350 rpm	-	21040
WU-480	Wire/Pin driver	0 - 1350 rpm	0.6 - 1.8 mm	21050
WU-481	Wire/Pin driver	0 - 1350 rpm	0.7 - 4.0 mm	21060
PU-480	Pin driver	0 - 1350 rpm	1.8 - 3.2 mm	21070

a. requires LU-480

Attachment Accessories

Description	Part No.
Bur guard - standard	21120
Bur guard - long	21130
Bur guard - extra long	21140
Wire/pin guard	9570
Cleaning brush for wire/pin drivers	8120

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	Handpiece is in SAFE mode	Select the required mode
	Power console fuses have tripped	Replace the fuses
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
	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
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.

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



United Kingdom

De Soutter Medical Limited
Halton Brook Business Park
Weston Road
Aston Clinton
Aylesbury
Bucks, HP22 5WF
📞 +44 (0) 1296 634 000
✉️ 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
✉️ australia@de-soutter.com

België \ Belgique

De Soutter Medical Belgium
Bessemerstraat 14
3620 Lanaken
📞 +32 (0) 89/47 15 37
✉️ belgium@de-soutter.com

Deutschland

De Soutter Medical Germany
Bahnhofstraße 4
66625 Nohfelden
📞 +49 (0) 68 52-99 12 46
✉️ deutschland@de-soutter.com

Österreich

De Soutter Medical Austria
Zweigniederlassung Österreich
Dietrichsteingasse 10
A-3400 Klosterneuburg
📞 +43 (0) 676 96 71 770
✉️ austria@de-soutter.com

France

De Soutter Medical France
1252 Avenue Parc des Expositions
33260 La Teste de Buch
📞 +33 (0) 5 56 54 89 36
✉️ france@de-soutter.com

Italia

De Soutter Medical Italy
Località Fornace SNC
27022 Casorate Primo - PV
📞 +39 (0) 2 9009 4098
✉️ italy@de-soutter.com

United States of America

De Soutter Medical USA Inc
224 Rolling Hill Road, Suite 12A
Mooresville, NC 28117
📞 +1 (704) 655 9040
✉️ usa@de-soutter.com

EC REP Nederland

De Soutter Medical Netherlands
Gelderlandhaven 2X
3433 PG Nieuwegein
📞 +31 (0) 85 0491480
✉️ nederland@de-soutter.com