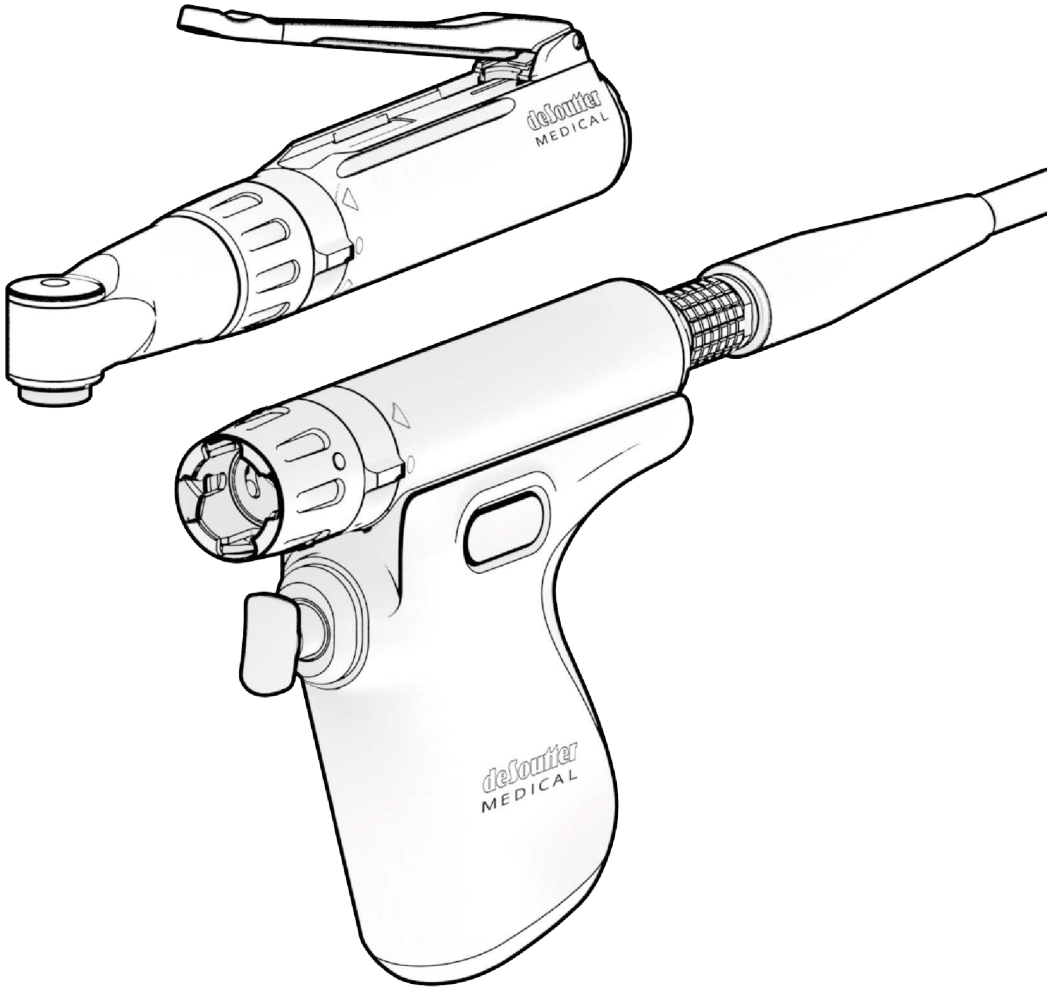
osteodrive®II

International
English

User Manual

MCI-280/281

DCS-280



deSoutter
MEDICAL

E350308

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

CE 1639

UK CA 0120

Contents

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. (Under certain circumstances, hand-arm vibration levels exceeding* $5ms^{-2}$ *can be produced. 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		Refer to the user manual for the duty cycle
0	Safe mode		Drive in the direction indicated
	Attachment unlocked		Attachment locked
	Pull and/or turn in the direction shown to unlock		Type BF protection
SN YY/000000	The first two digits (YY) indicate the year of manufacture		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		Manufacturer
EC REP	EC authorised representative		Do not use if packaging is damaged or opened
MD	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: *remove the lever before washing and sterilising the handpiece*

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.

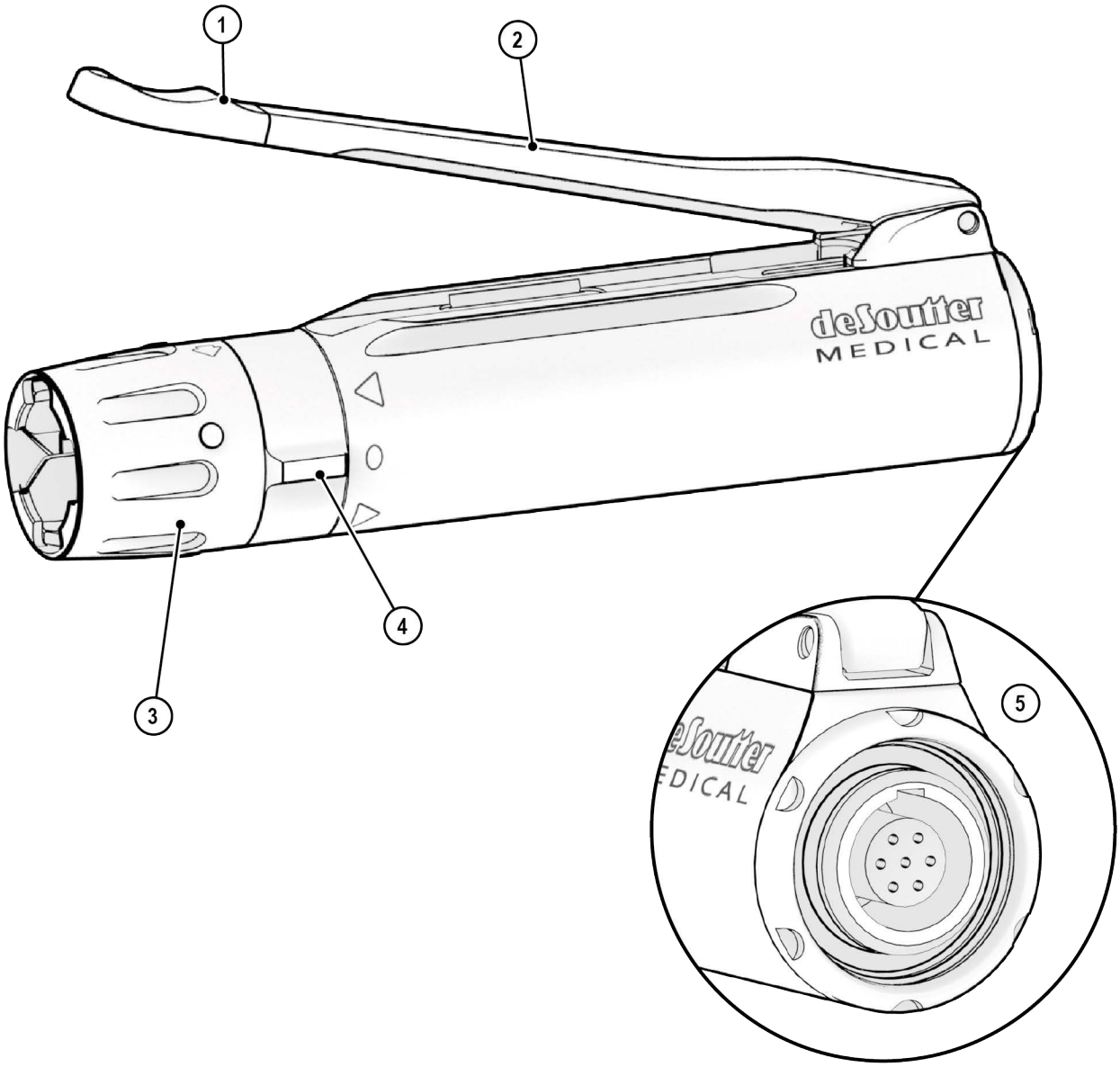
Vacuum and gravity steam sterilisation have been validated in accordance with HTM 2010, AAMI TIR12, ANSI/AAMI ST79, ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 17665-2.

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



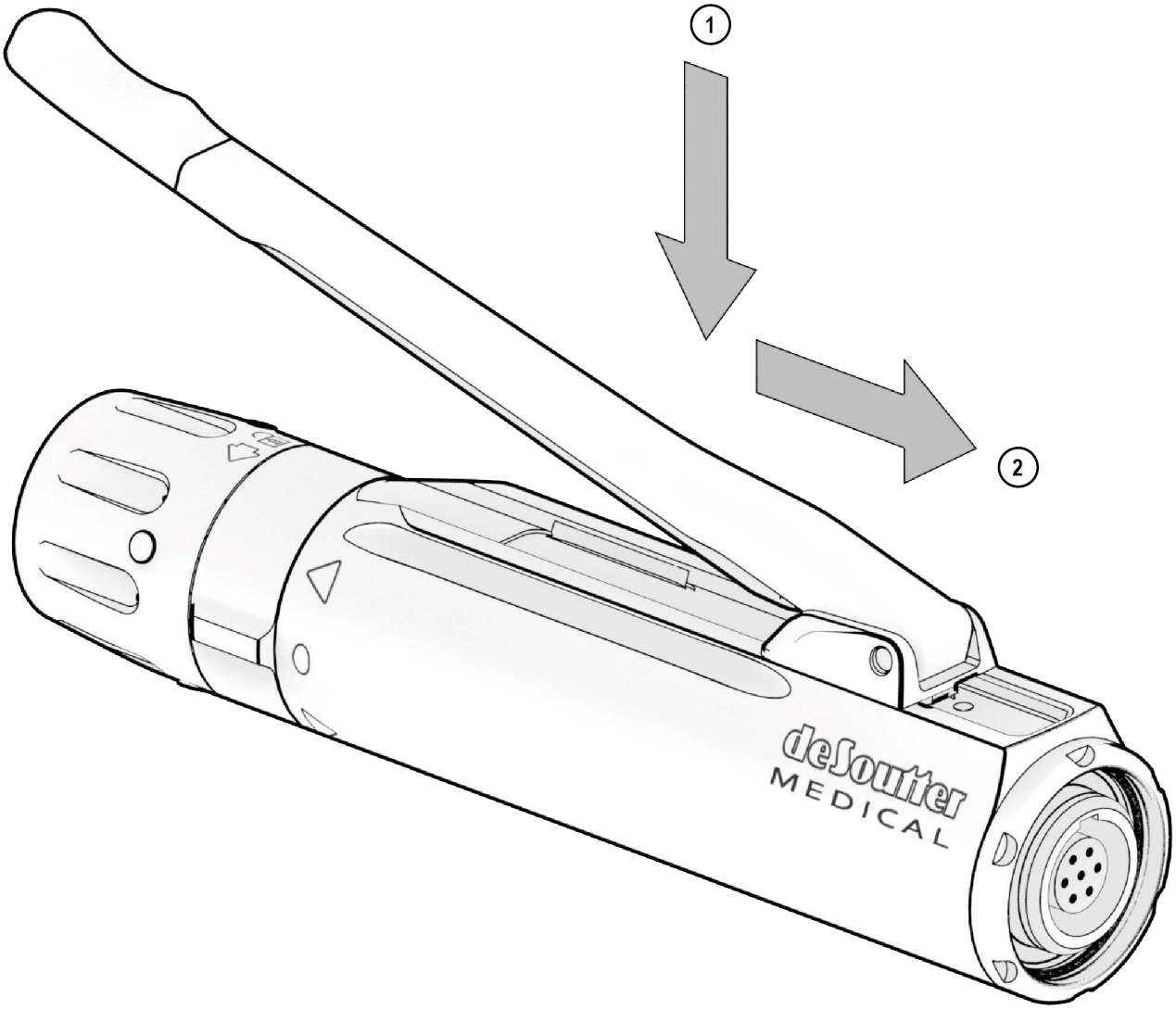
1) Lever extension
2) Lever
3) Release ring
4) Mode selector
5) Power connection

Configuring a Handpiece

Fitting a Lever

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. Press the lever into the slot on the handpiece.
2. Slide the lever towards the back of the handpiece
   NOTE: *ensure the lever is located securely in the location slots*

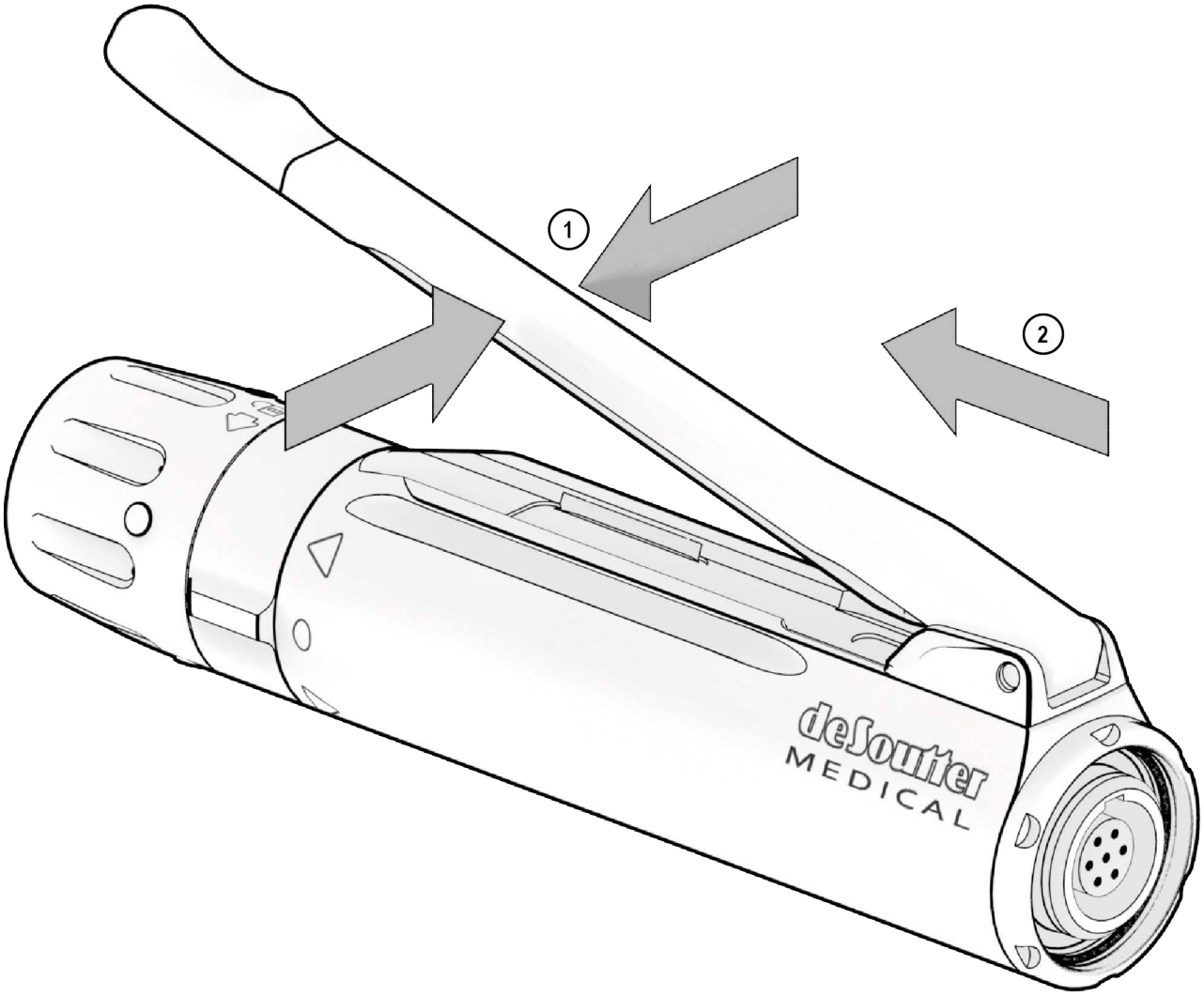


Removing a Lever

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: *if the lever and pedal are both connected, lever control will be activated. The lever must be removed to enable pedal control*

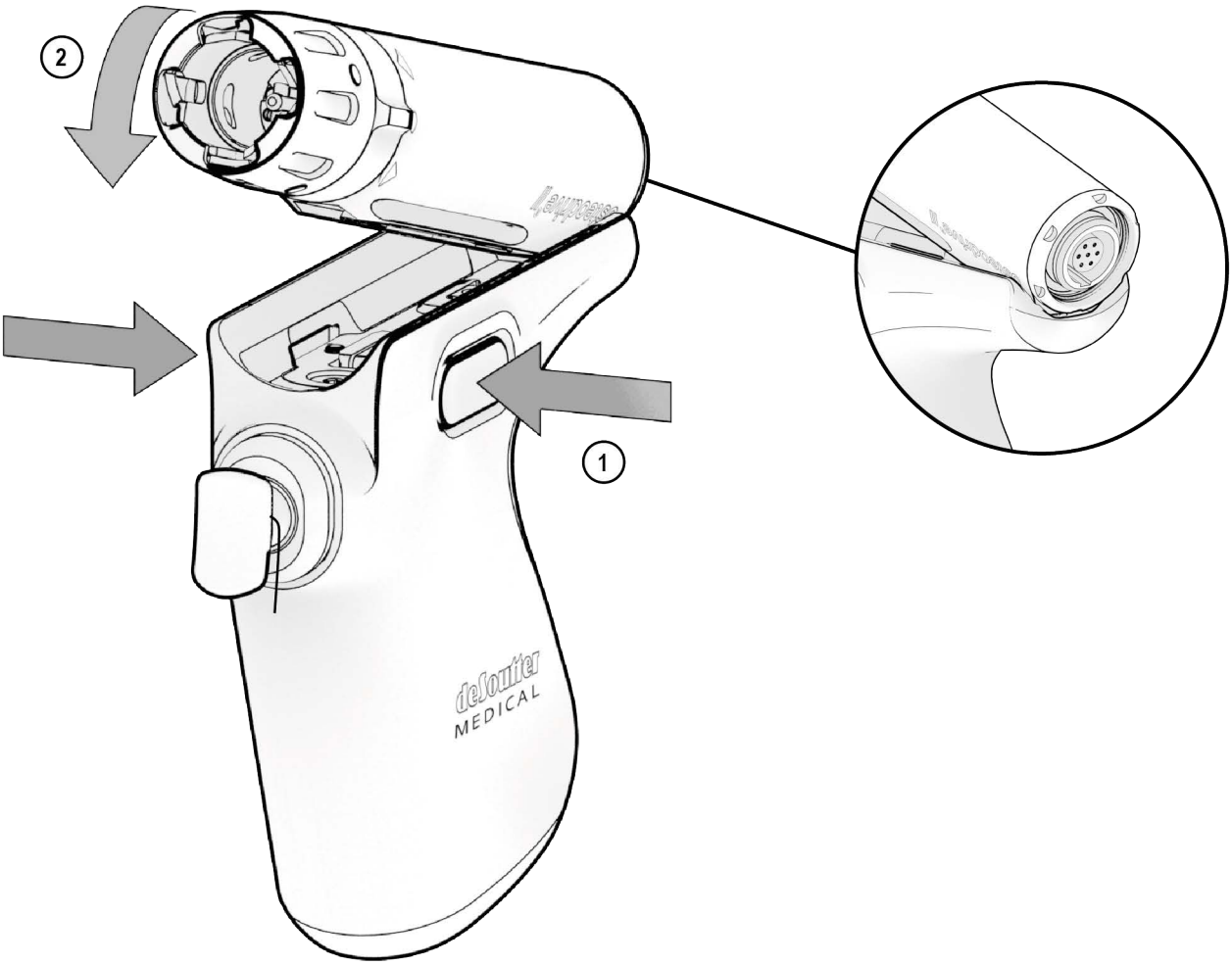
1. Grip the lever.
2. Slide the lever towards the front of the handpiece.



Fitting a Handle

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

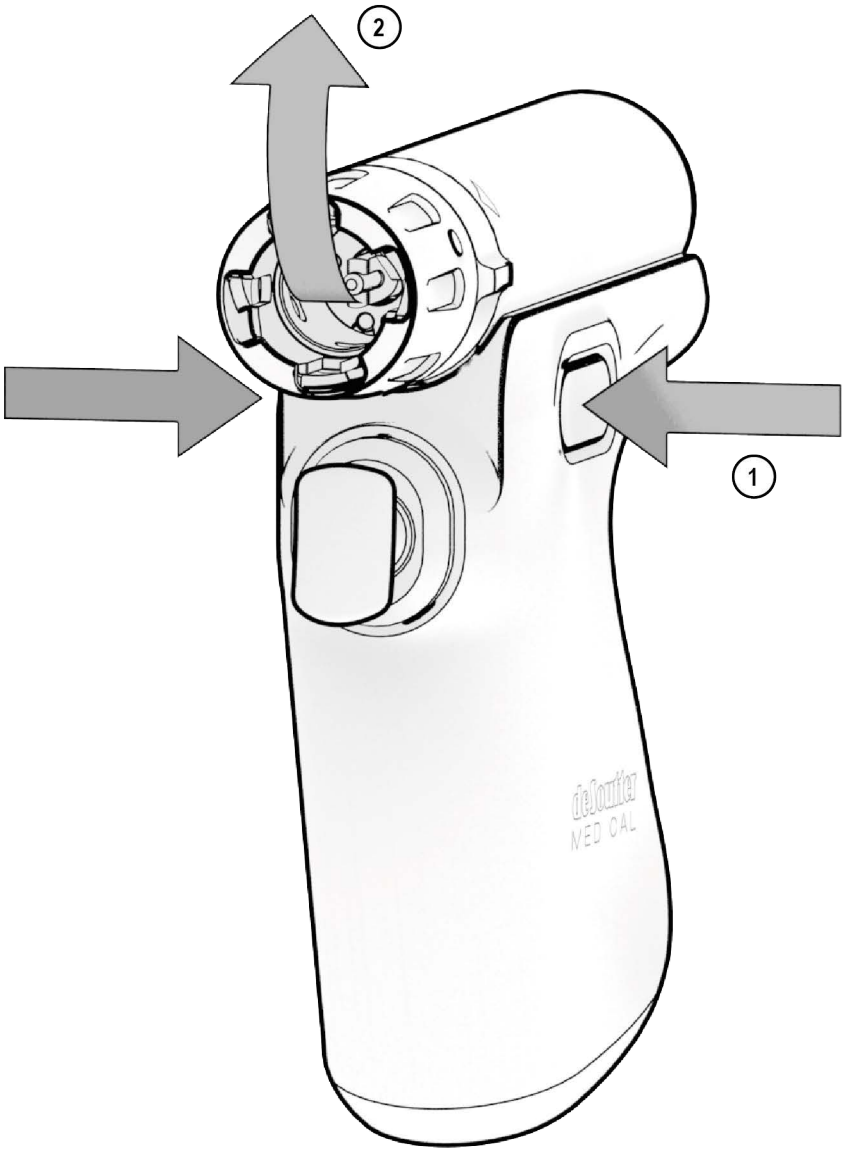
1. Press the handle release buttons until they click.
2. Align the handpiece on top of the handle and push the handpiece firmly down into place.
   NOTE: *ensure the handle is located securely*



Removing a Handle

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

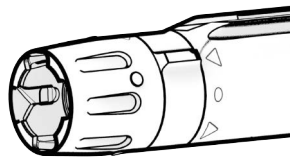
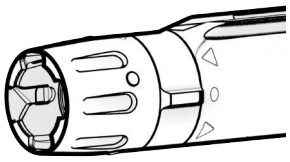
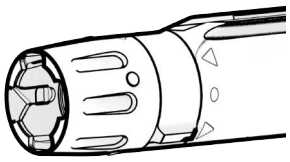
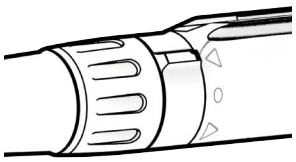
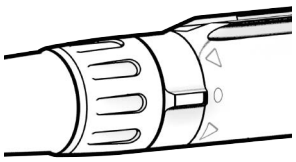
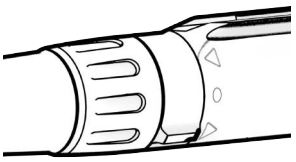
1. Press the handle release buttons until they click.
2. Remove the handpiece from the handle.



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*

Rotate the mode selector to choose the required mode.

MCI-280 / 281		
		
Forward	SAFE	Reverse
DCS-280		
		
Run mode	SAFE	Run mode

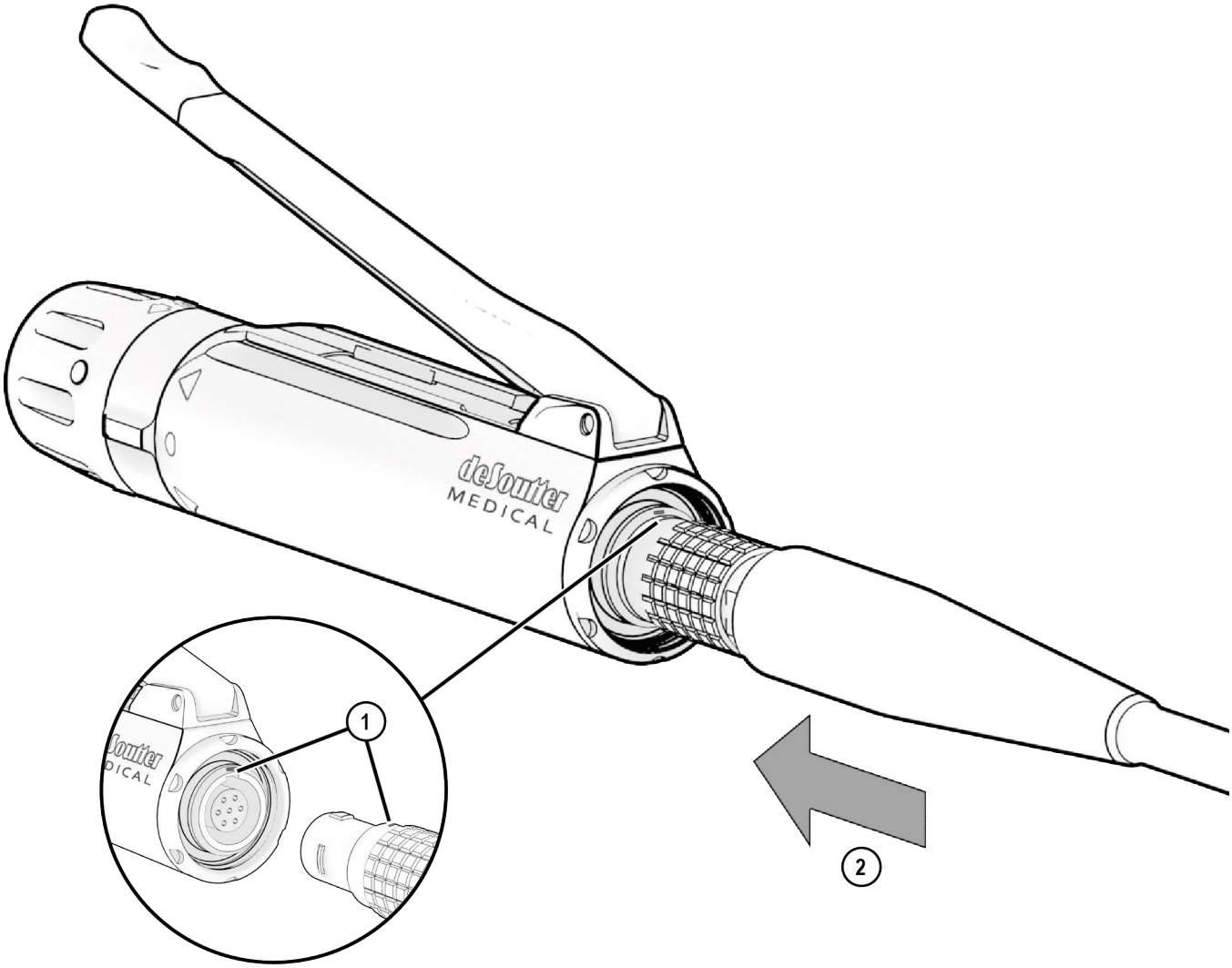
Controlling the Speed

The speed of the handpiece is controlled by progressively pressing lever or the foot pedal.

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*

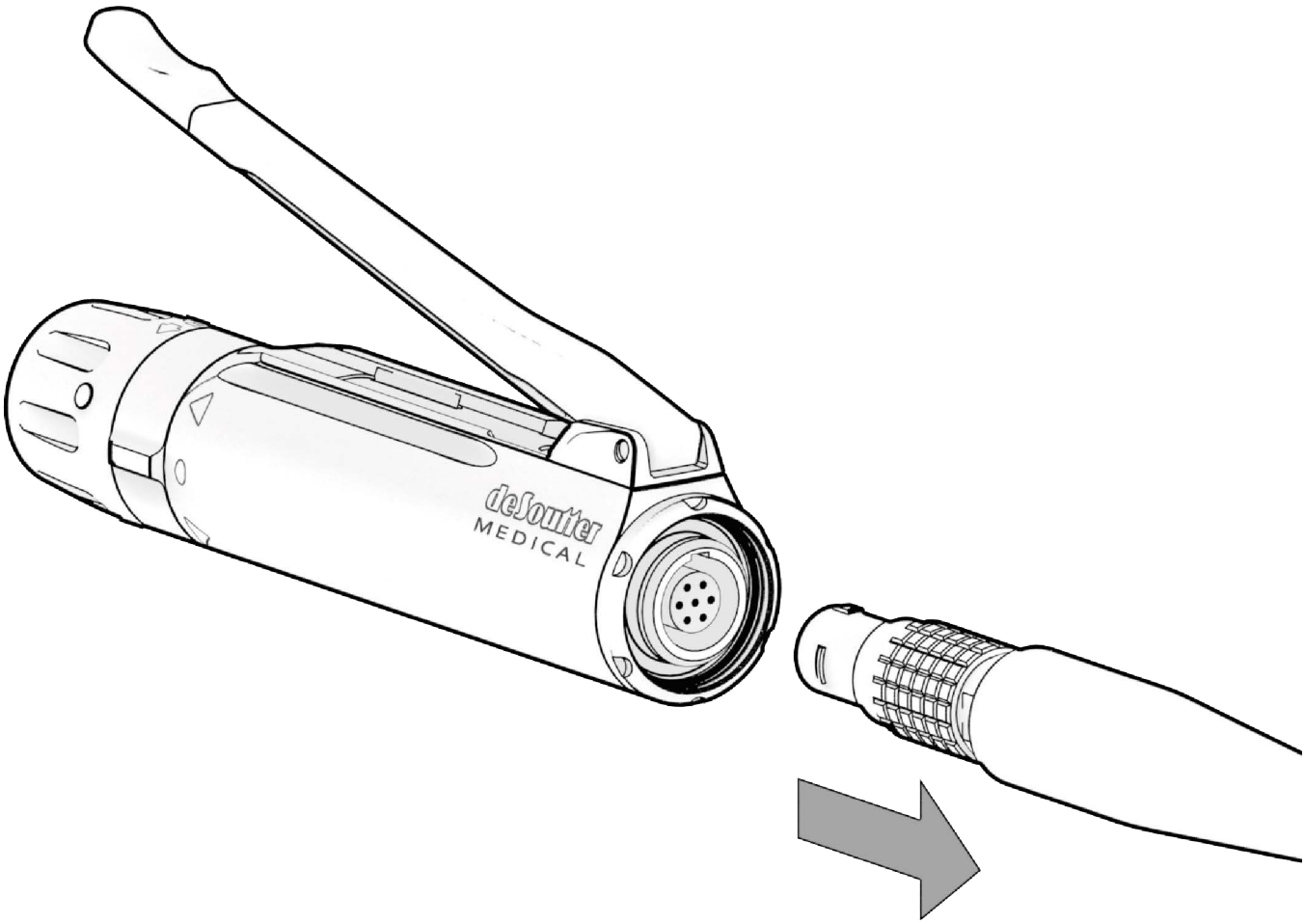


Disconnecting the Handpiece

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

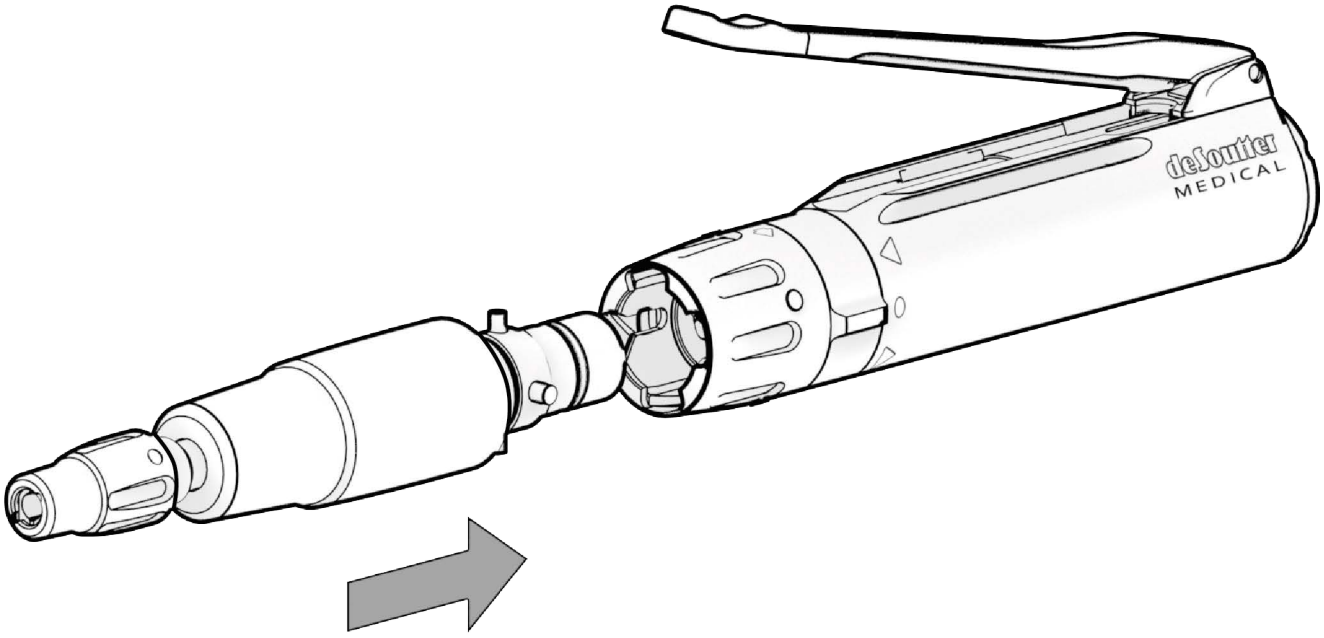
Fitting an Attachment

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

Push the attachment into the end of the handpiece, aligning the pins on the attachment with the corresponding slots in the handpiece.

NOTE: *ensure the attachment is secured in place*

NOTE: *attachments can be used in any of four angular positions*

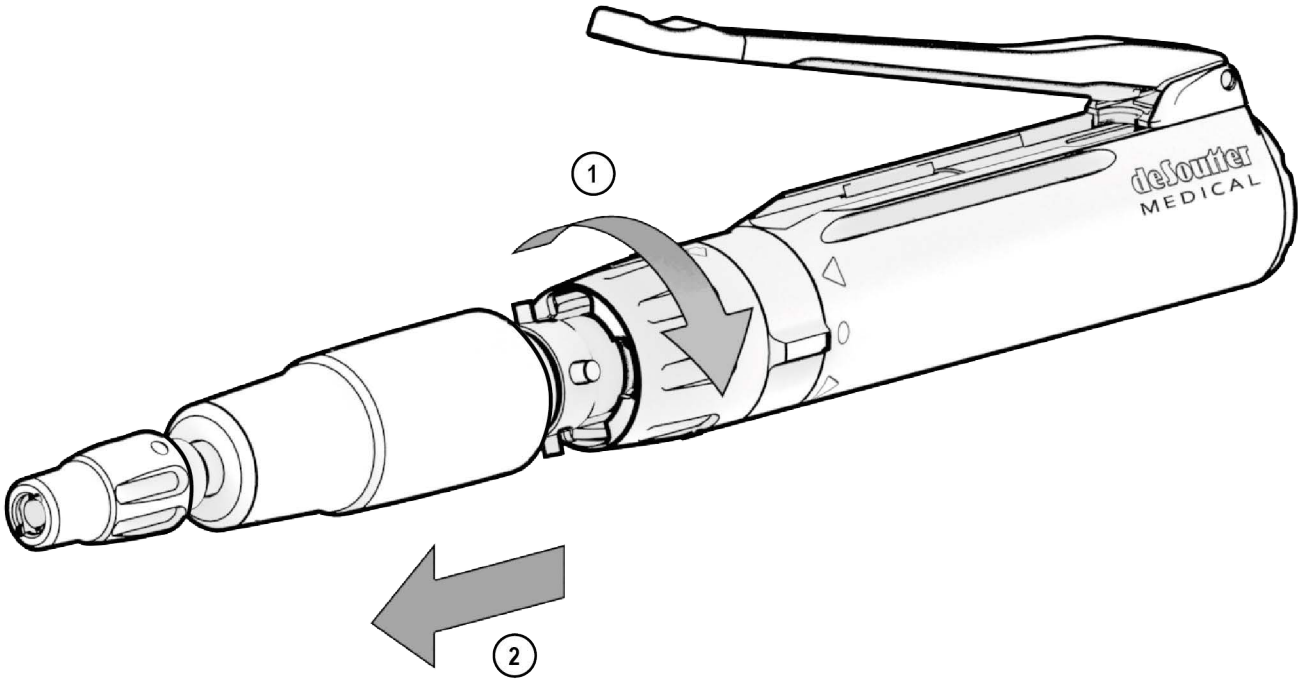


NOTE: *all attachments are fitted in the same way*

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.

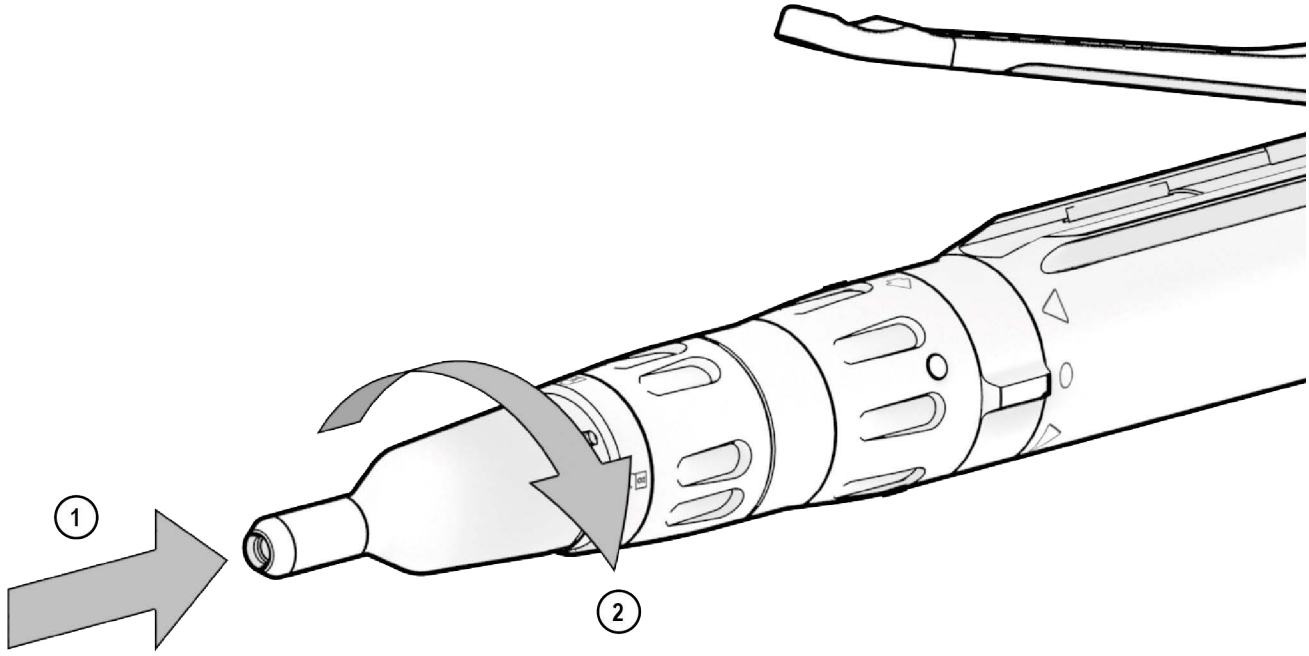


NOTE: *all attachments are removed in the same way*

Fitting a Bur Guard (BI-280/287)

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.

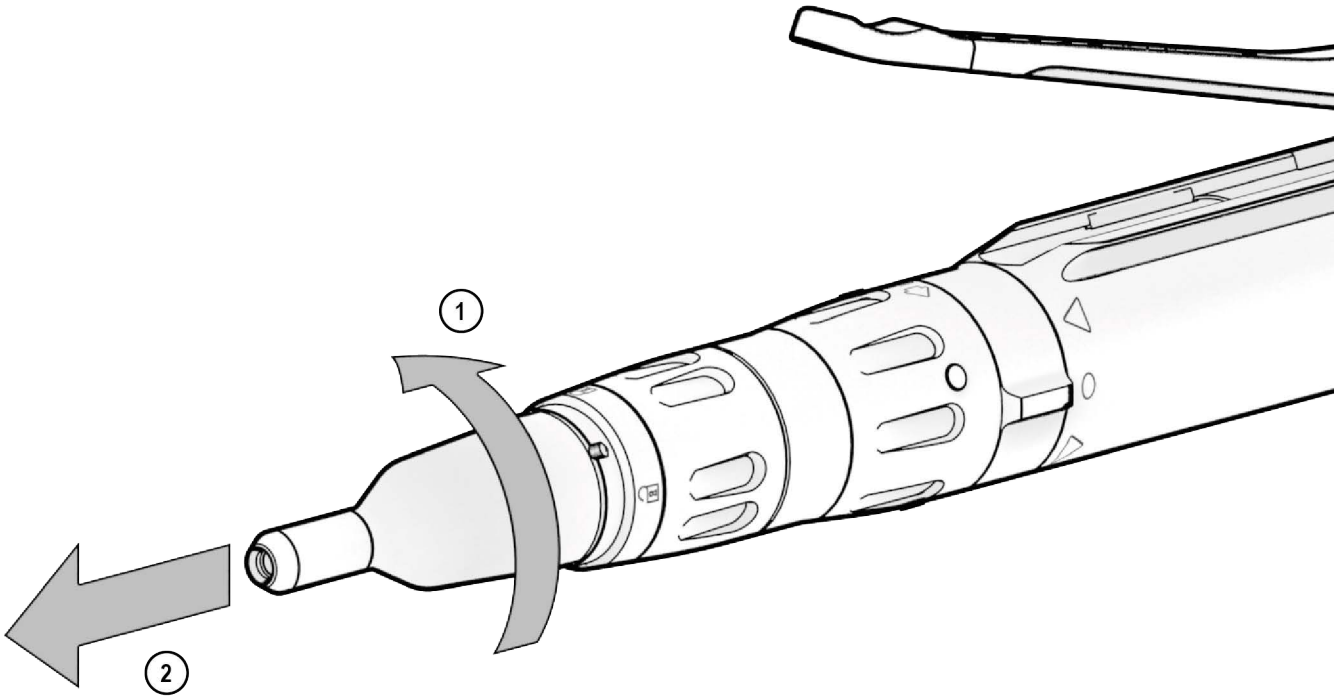


NOTE: *this procedure applies to the BI-280 and BI-287*

Removing a Bur Guard (BI-280/287)

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

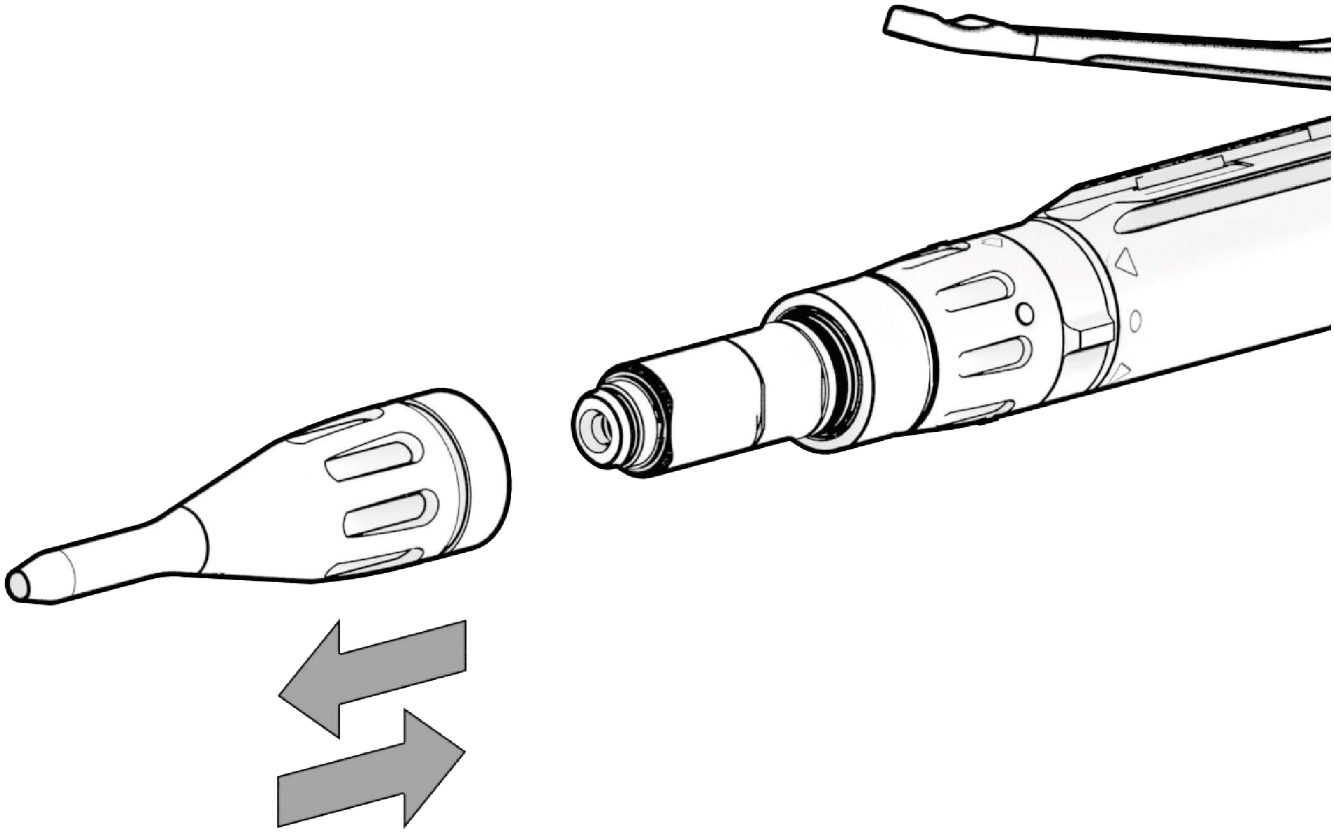


NOTE: *this procedure applies to the BI-280 and BI-287*

Fitting and Removing a Bur Guard (BI-281)

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 until it clicks in place.
2. Pull the bur guard away from the attachment.
   NOTE: *the bur guard must be in the unlocked position*



NOTE: *this procedure applies to the BI-281*

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*

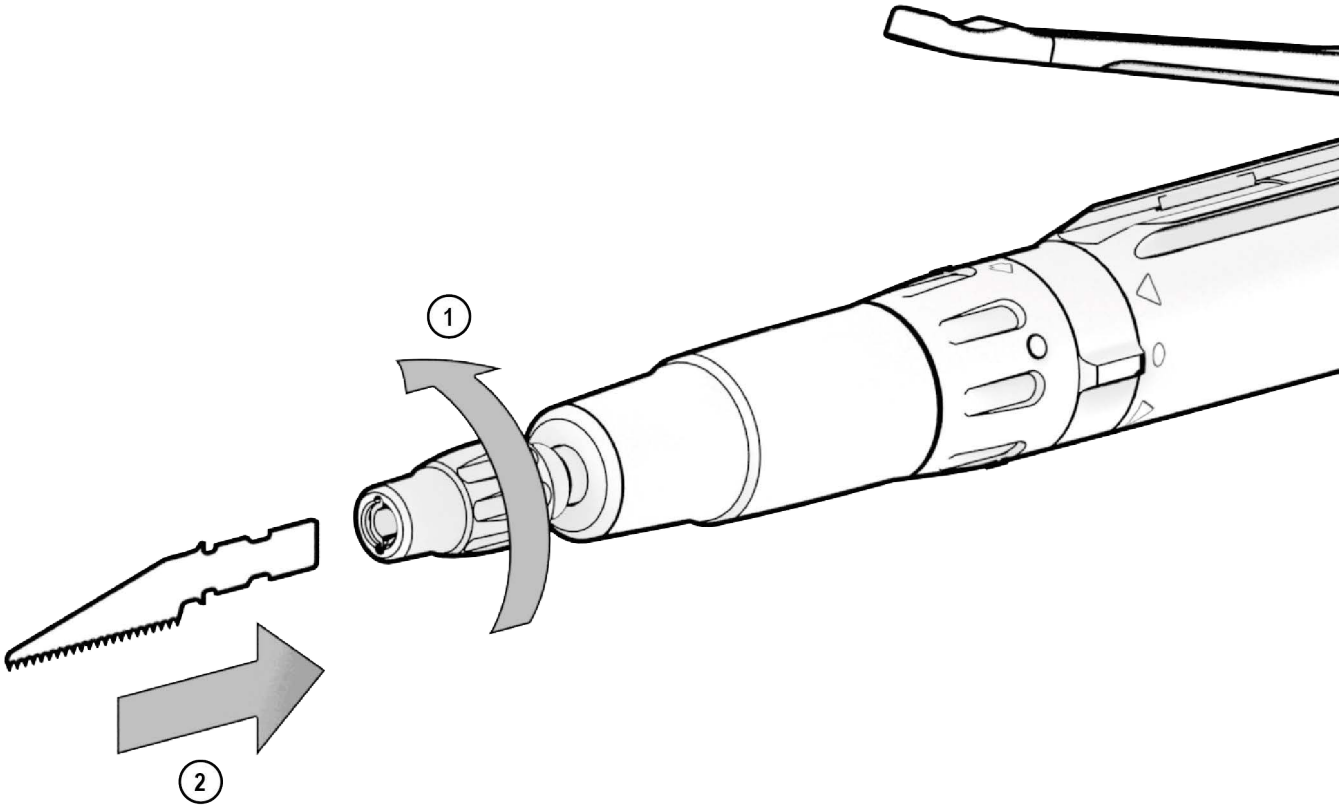
To secure or release the accessory, adjust the chuck according to the chuck type.

Chuck Type	Adjustment Instructions
Keyed	Use the chuck key
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 Small Reciprocating Blade (CI-280)

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

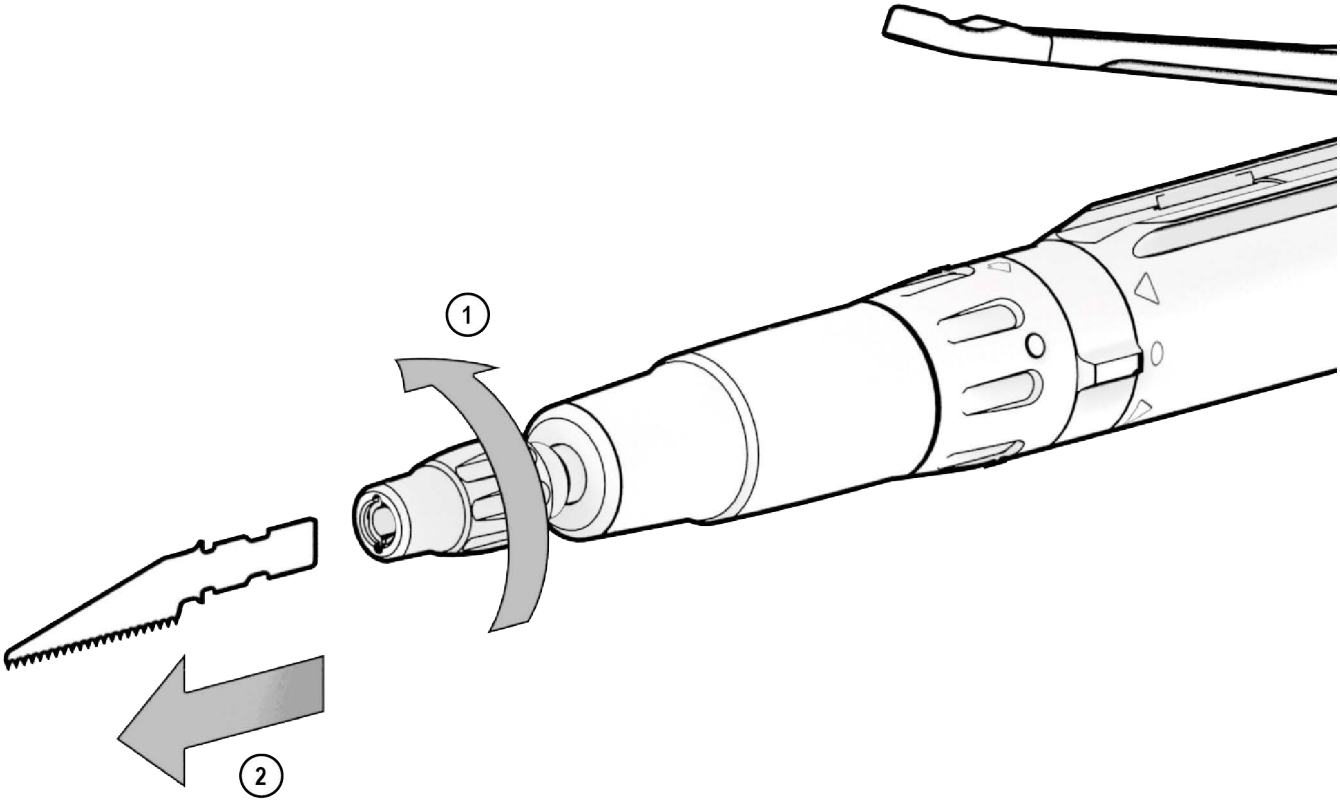
1. Rotate the locking sleeve anti-clockwise to unlock the blade clamp.
2. Insert the blade into the attachment and push the blade firmly until the blade clamp locks.
   NOTE: *ensure the blade is secured in place*



Removing a Small Reciprocating Blade (CI-280)

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

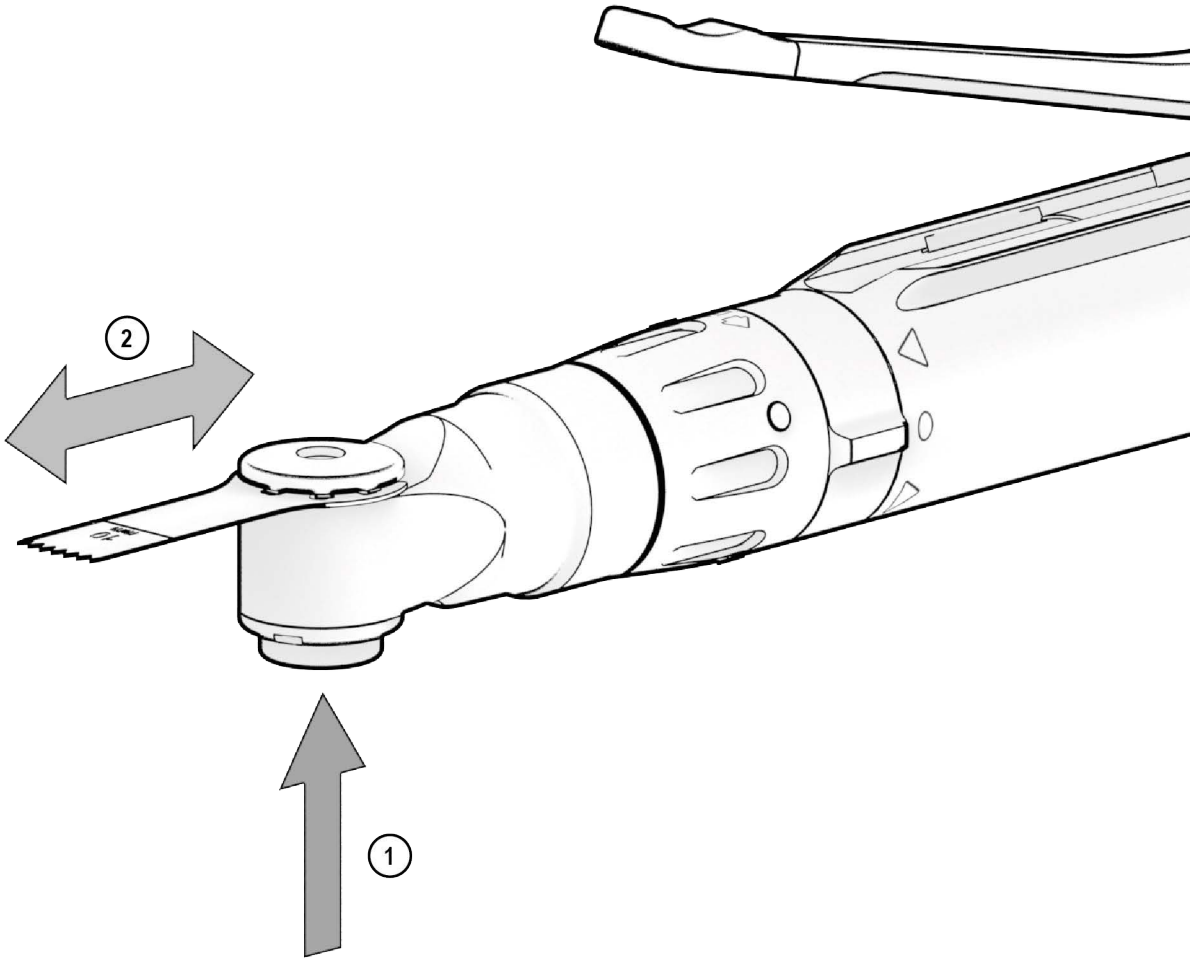
1. Rotate the locking sleeve anti-clockwise.
2. Remove the blade.



Fitting and Removing a Sagittal Blade (SI-280)

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

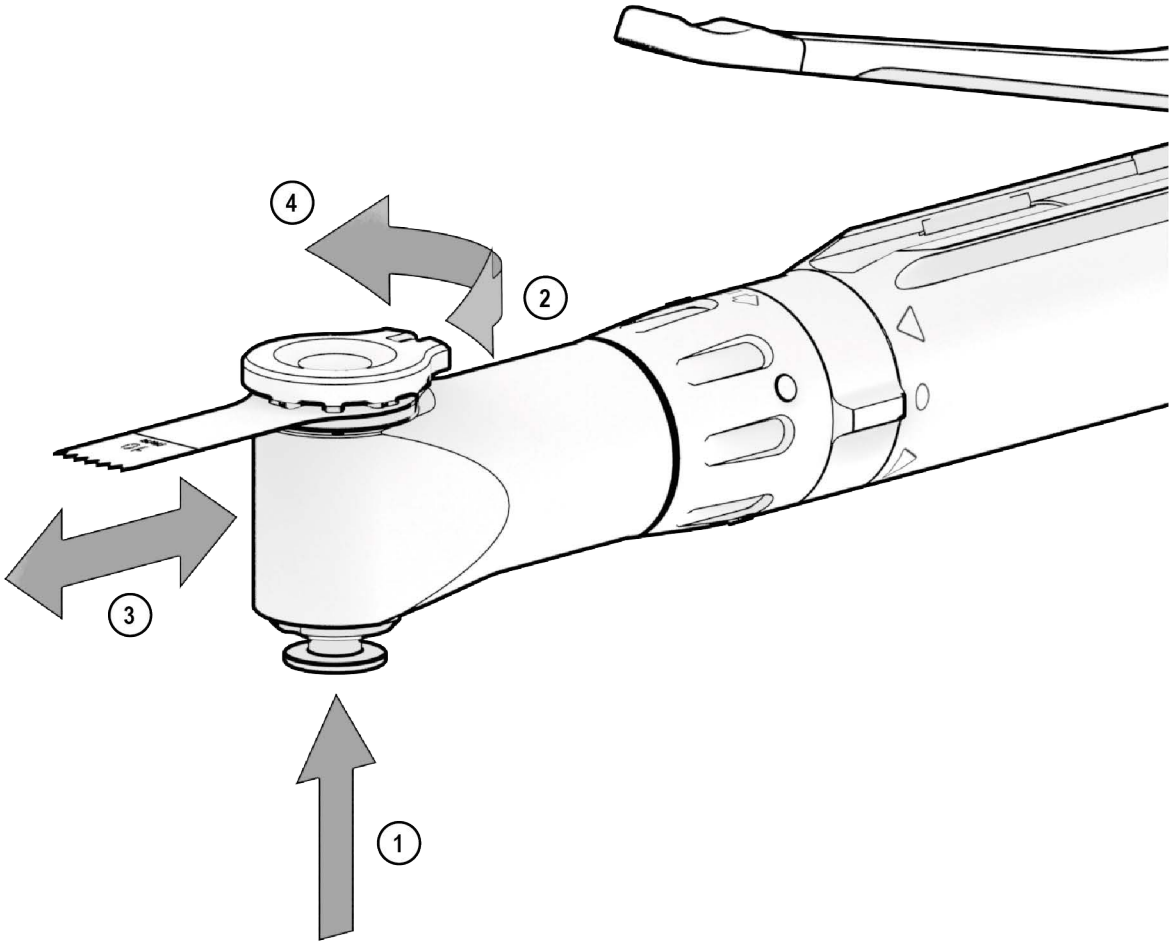
1. Push the bottom of blade clamp upwards.
2. Insert or remove the blade.
   NOTE: *ensure the inserted blade is securely clamped in place*



Fitting and Removing a Sagittal Blade (NI-280)

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. Rotate the top of the blade clamp clockwise or anti-clockwise.
   NOTE: *the blade clamp is now locked open*
3. Insert or remove the blade.
4. Rotate the top of the blade clamp until the blade clamp snaps back in place.
   NOTE: *ensure the blade is secure*

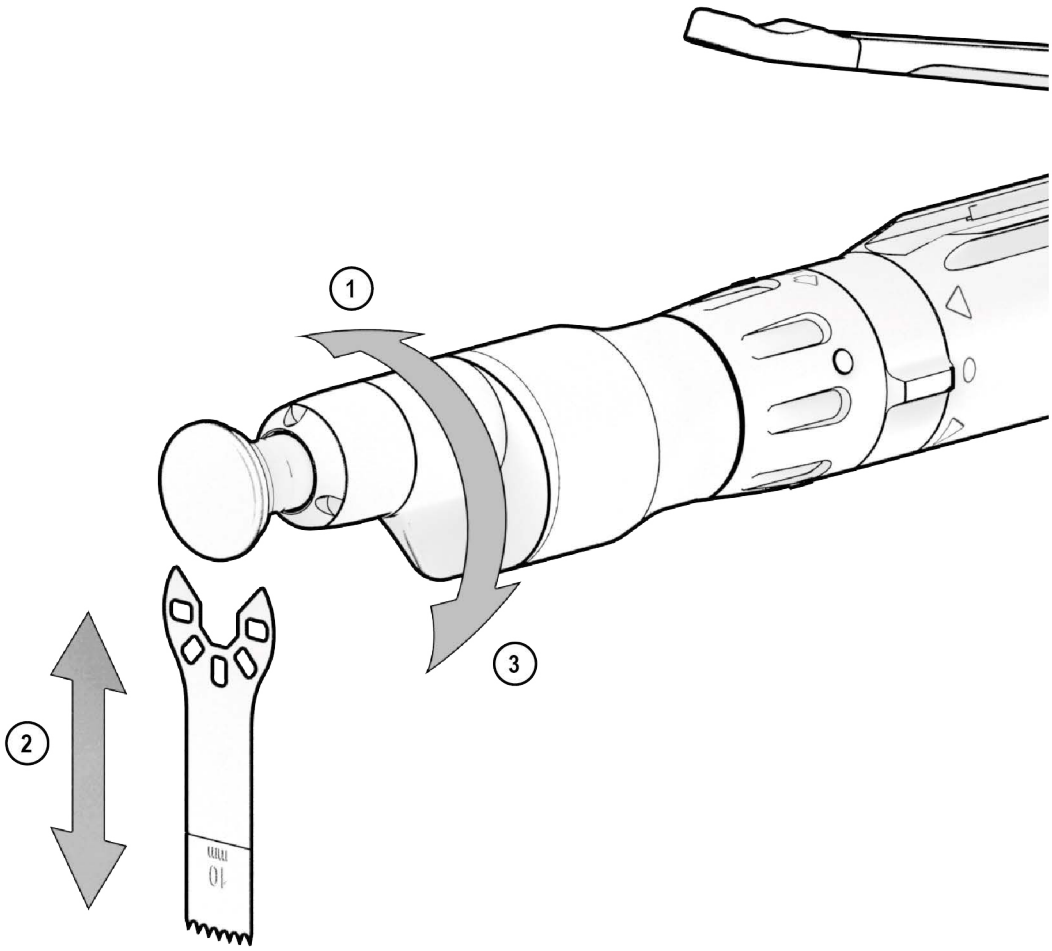


Fitting and Removing an Oscillating Blade (OI-280)

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.*

1. Rotate the locking sleeve anti-clockwise to the unlocked position.
2. Fit or remove the blade.
3. Rotate the locking sleeve clockwise to the locked position.



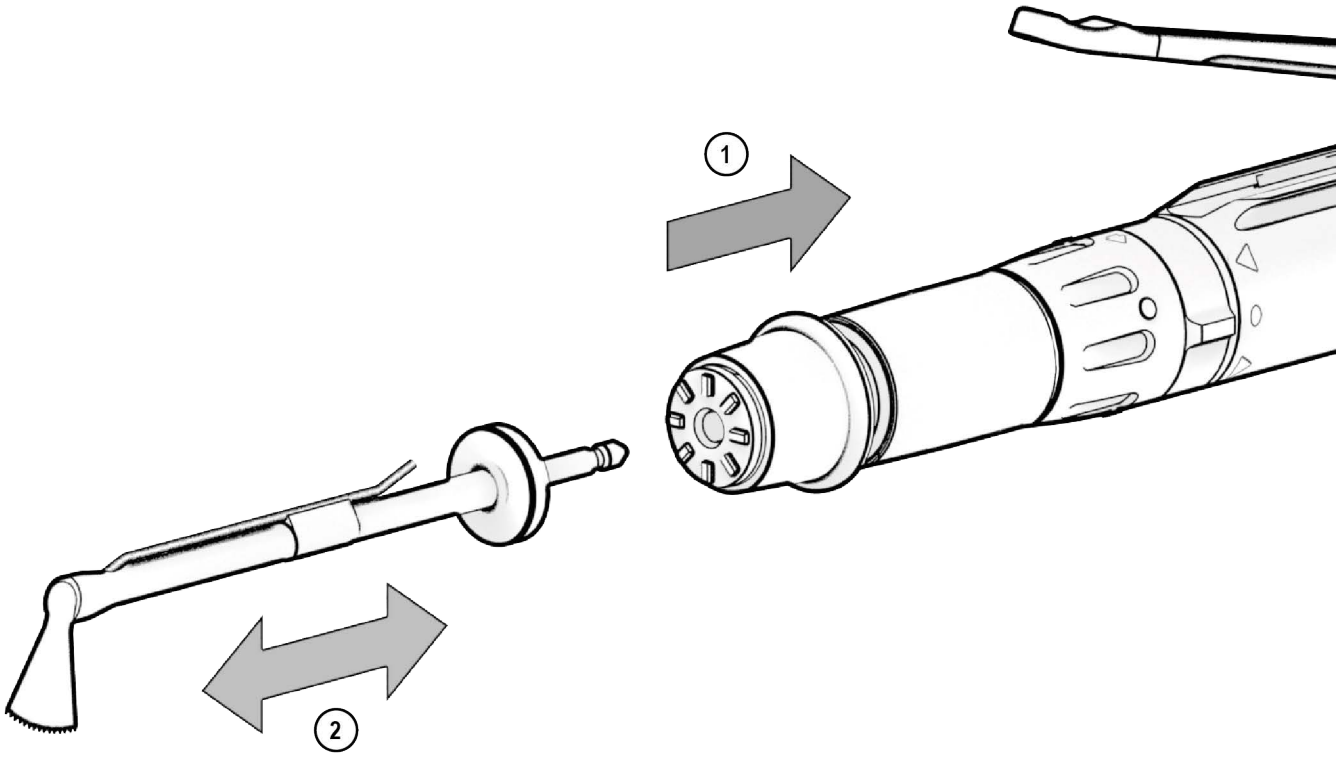
Fitting and Removing an Oscillating Blade (OI-281)

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*

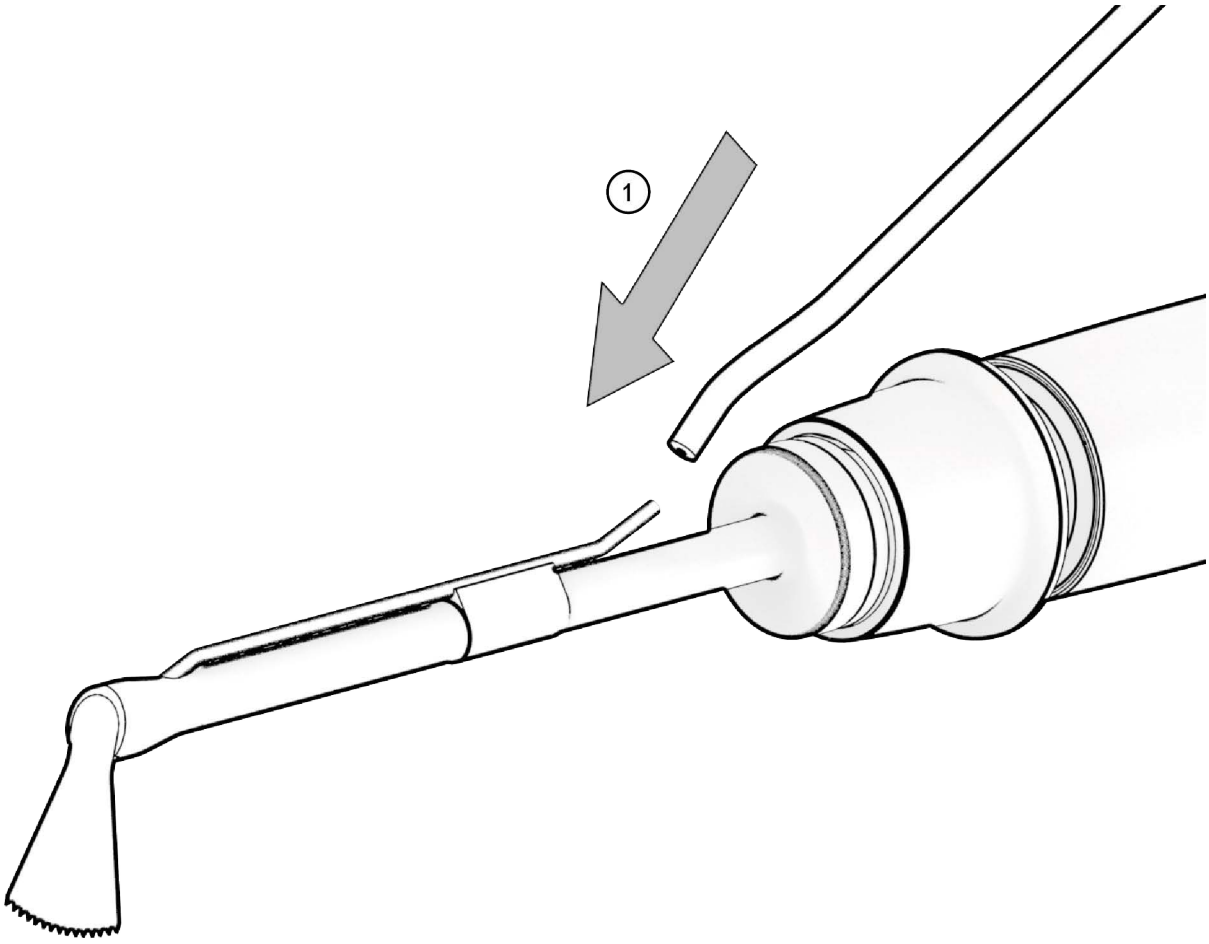
NOTE: *blades can be used in any of eight angular positions*



Fitting an Irrigation Kit (OI-281)

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 OI-281 and T20 irrigation kit*

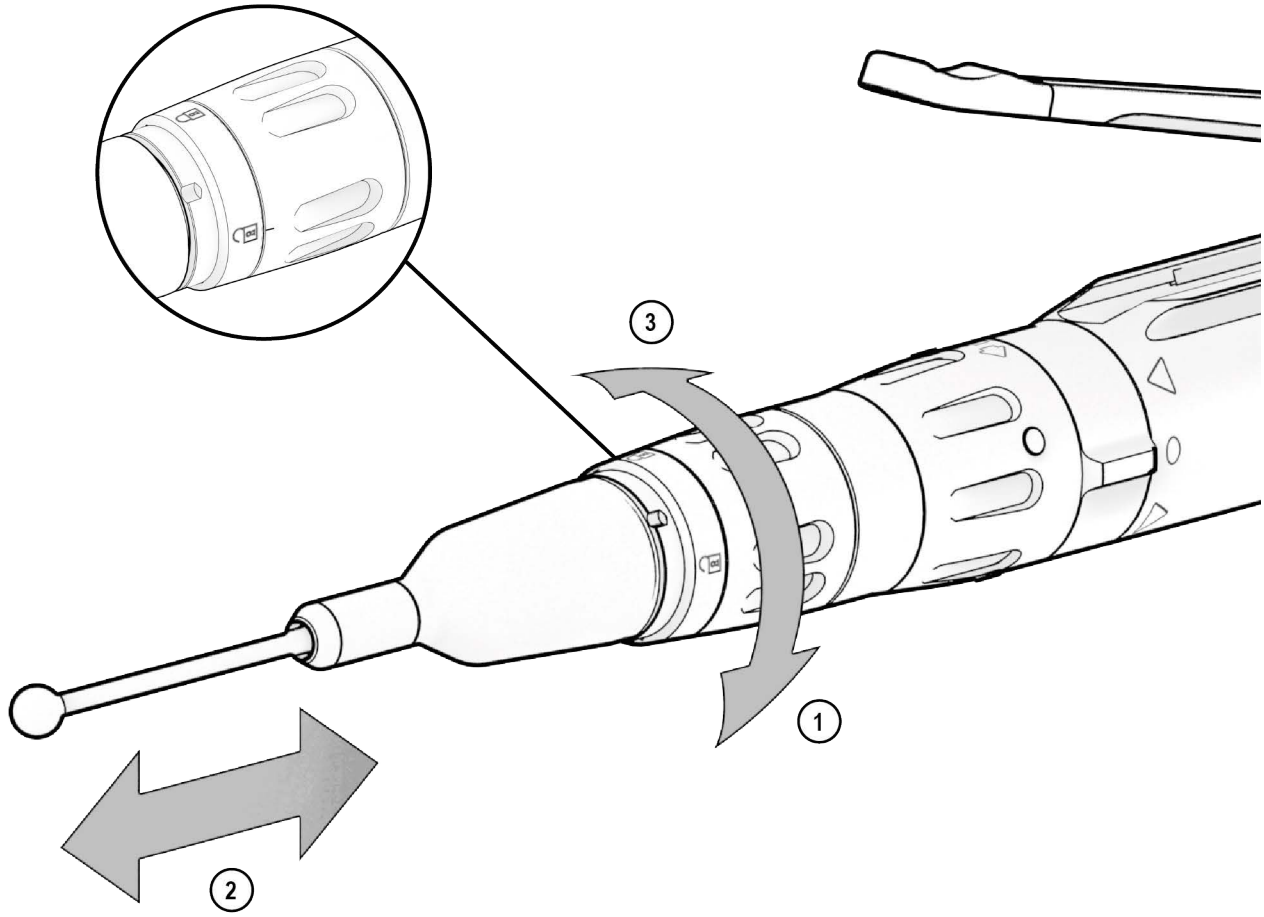
Fitting and Removing a Bur (BI-280/BI-287)

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*

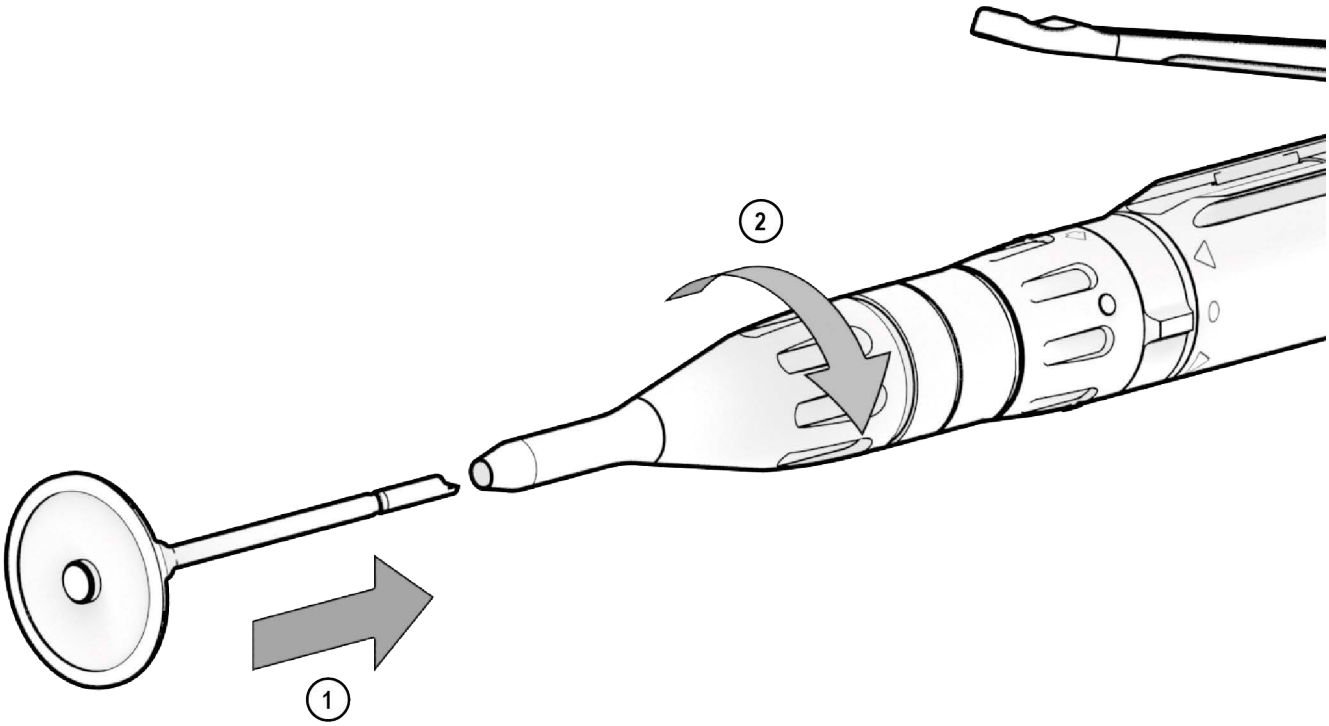


NOTE: *this procedure applies to the BI-280 and BI-287*

Fitting a Bur (BI-281)

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 bur into the attachment.
   NOTE: *the bur guard must be in the unlocked position*
2. Rotate the bur guard clockwise to the locked position.

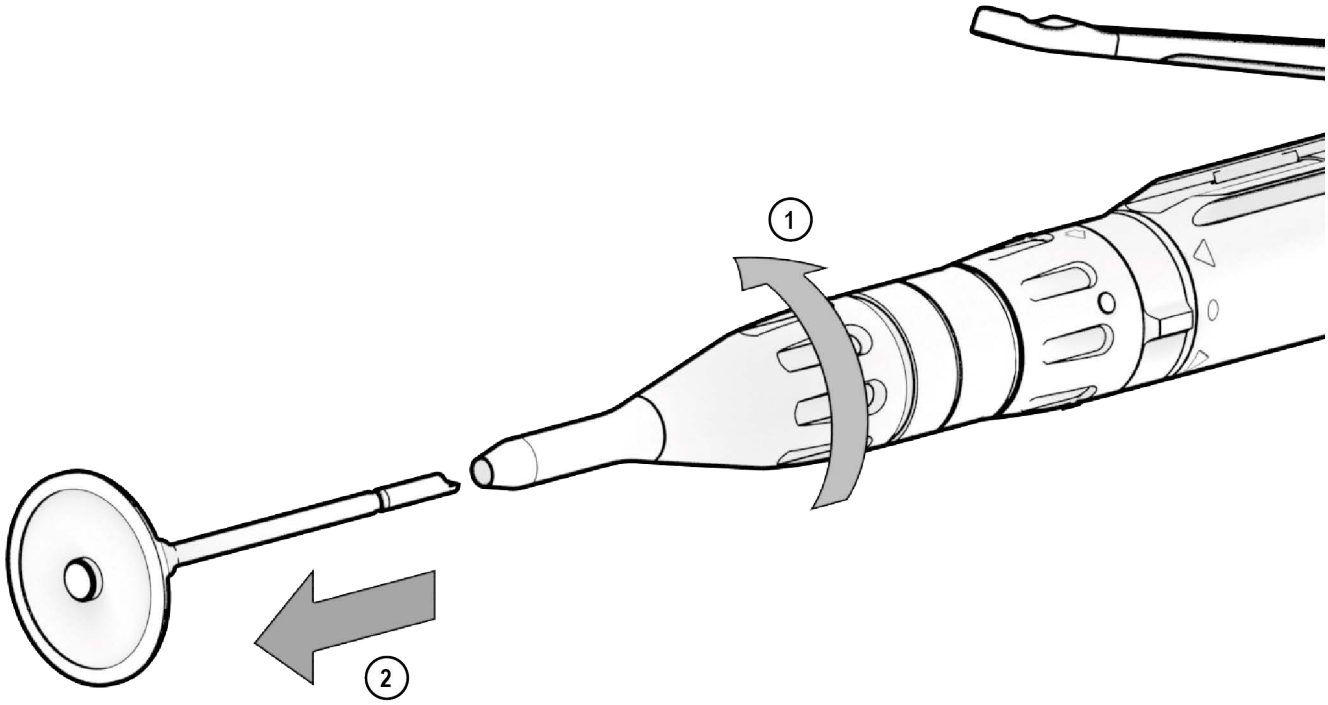


NOTE: *this procedure applies to the BI-281*

Removing a Bur (BI-281)

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 the unlocked position.
2. Remove the cutting accessory.

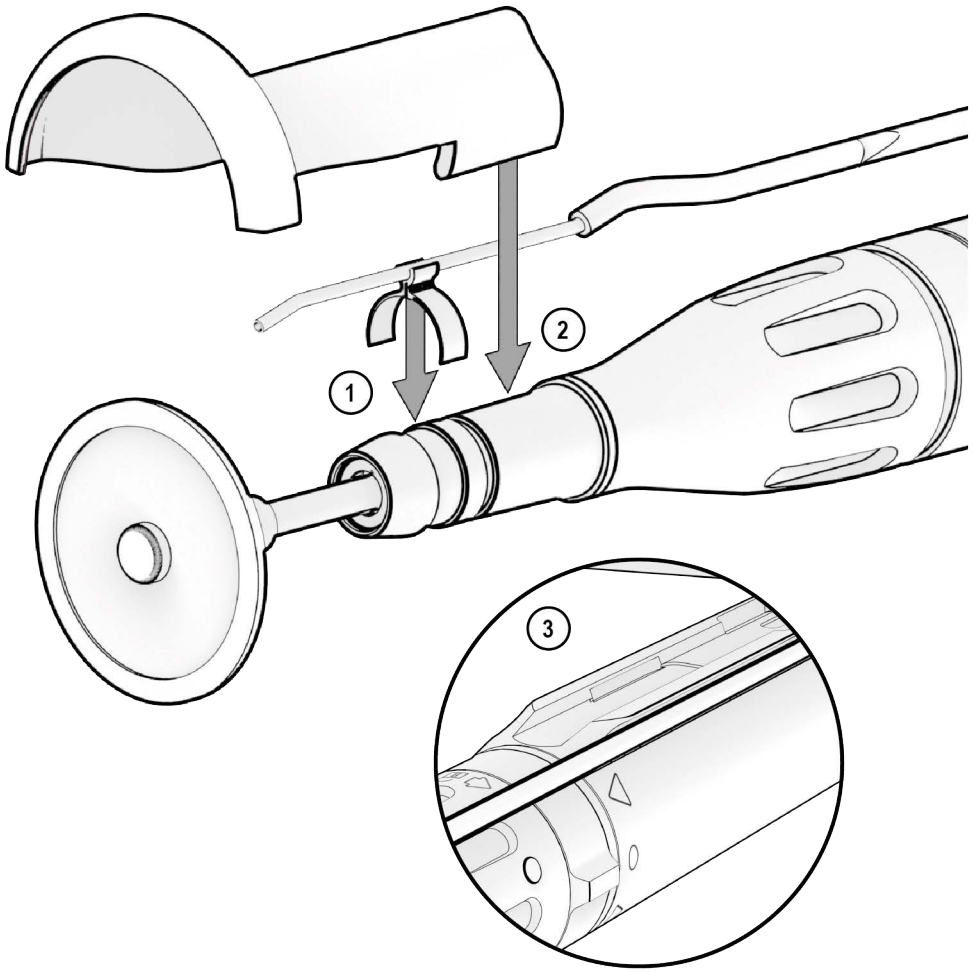


NOTE: *this procedure applies to the BI-281*

Fitting a Cutter Guard (BI-281)

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. Clip the irrigation nozzle into the groove on the front of the attachment.
2. Clip the splash guard, over the nozzle, into the groove on the attachment.
3. Clip the irrigation tube in the grooves on the side of the handpiece.



NOTE: *this procedure applies to the BI-281 and T20-101*

Fitting a Wire (WI-280)

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

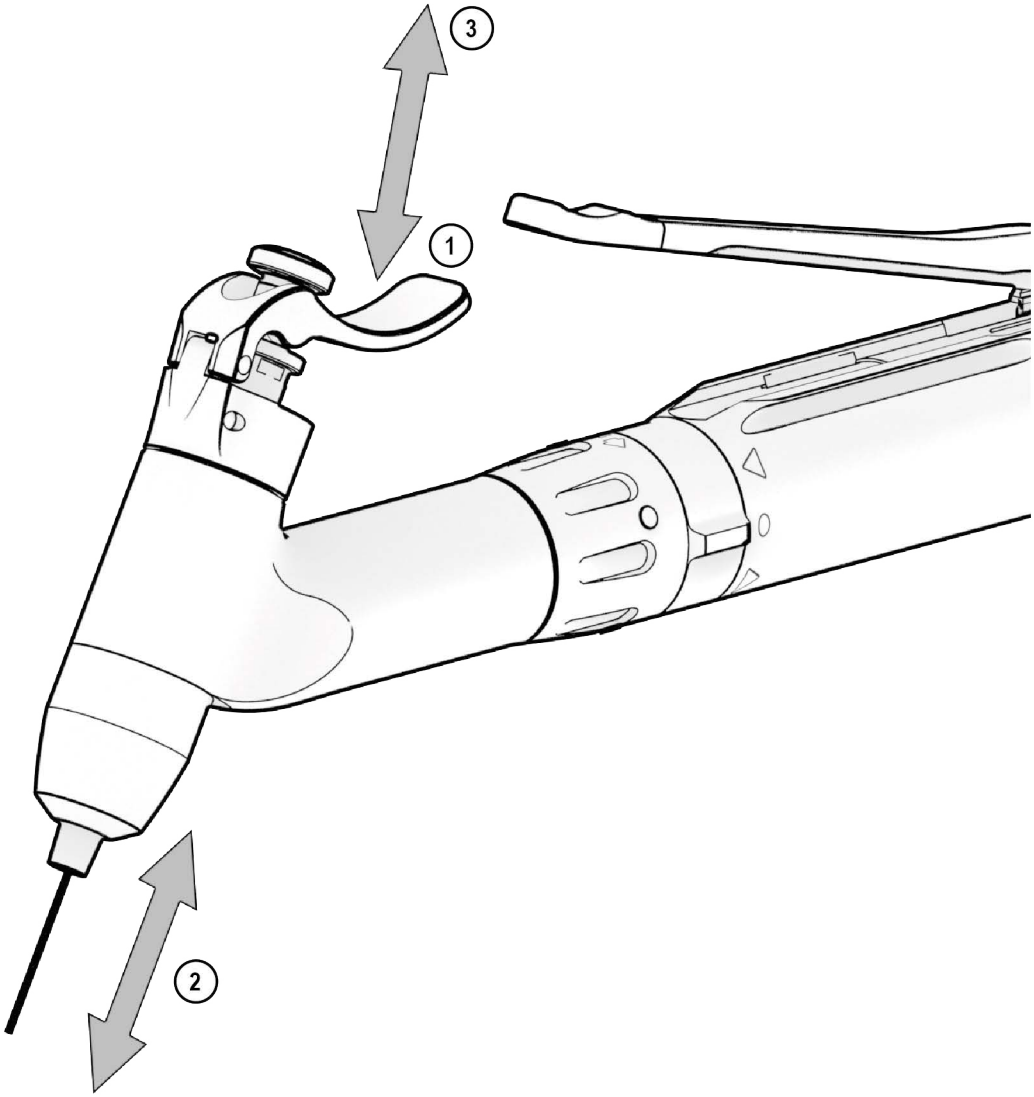
CAUTION: *if the wire is to be removed from the surgical site, ensure the wire is wiped clean before inserting into the attachment*

CAUTION: *do not use bent wires*

CAUTION: *ensure at least 15mm (5/8 inch) of the wire remains protruding from the surgical site if the wire is to be removed*

NOTE: *the lever can be rotated to any desired position*

1. Press the lever fully.
2. Insert the wire into the front of the wire driver until the wire is in the required position.
3. Release the lever to grip the wire.
   NOTE: *if additional grip strength is required (for example, if the wire slips) pull the lever back*



Fitting a Wire (WI-281)

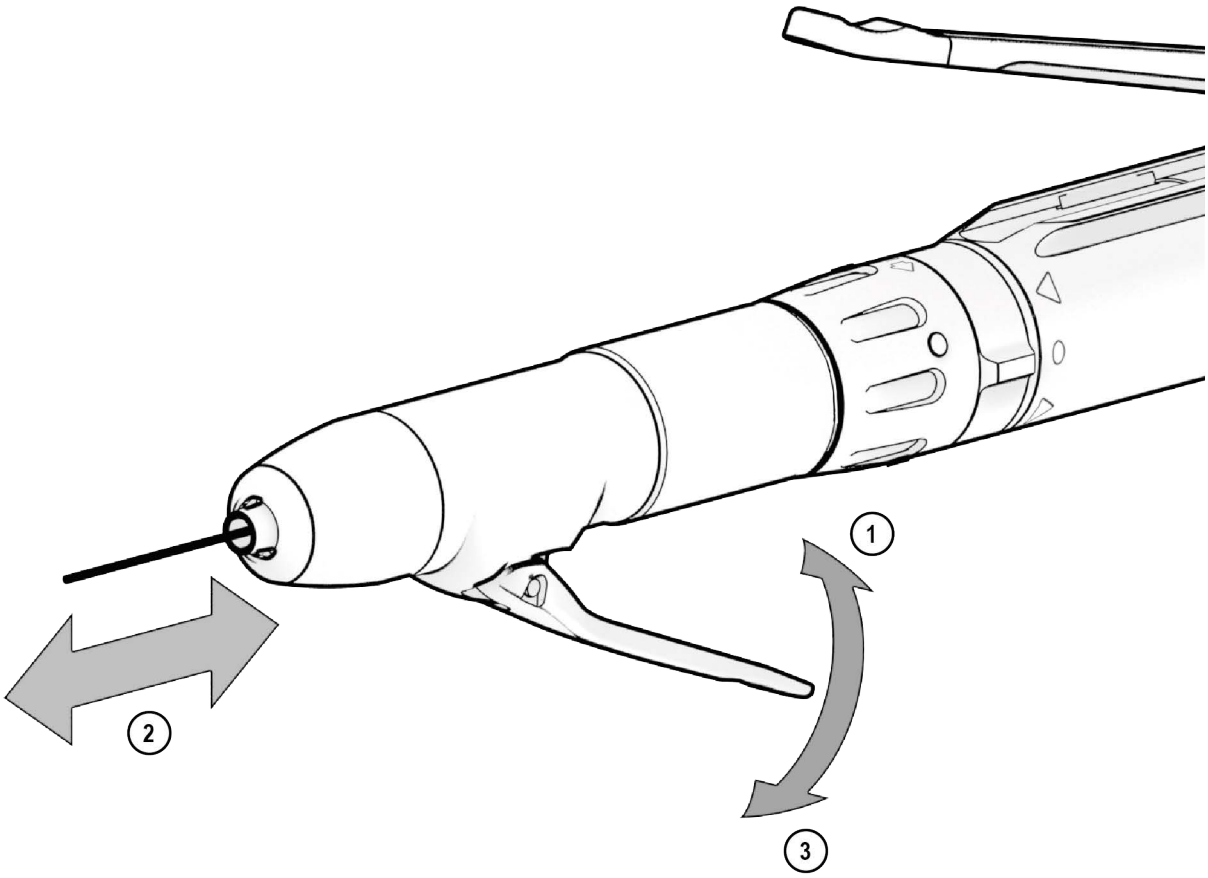
WARNING: *ensure the handpiece is set to SAFE mode before attempting to change the handpiece configuration, and before fitting or removing attachments and accessories*

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

CAUTION: *do not use bent wires*

CAUTION: *ensure at least 15mm (5/8 inch) of the wire remains protruding from the surgical site if the wire is to be removed*

1. Press the lever fully.
2. Insert the wire into the front of the wire driver until the wire is in the required position.
3. Release the lever to grip the wire.



Technical and Ordering Information

Handpiece Specifications

Model	MCI-280	MCI-281
Part no.	1294664	1294774
Speed	0 - 35,000 rpm	0 - 65,000 rpm
Protection Type	 Type BF protection	
Enclosure Protection	IPX0 - ordinary equipment	

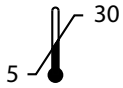
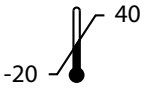
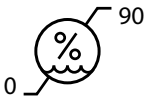
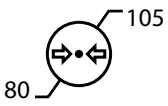
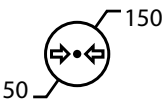
Model	DCS-280
Part no.	1294884
Speed	0 - 27,000 cpm
Protection Type	 Type BF protection
Enclosure Protection	IPX0 - ordinary equipment

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	Oscillating
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)		

Handpiece Accessories

Description	Part No.
4m Handpiece Cable	18570
Lever	20680
Minigrip	20650

Attachments

Drill Attachments

Model	Description	Capacity	Speed	Part No.
DI-280	Keyed	0.5 - 4.0 mm (5/32 inch)	0 - 1450 rpm	20690
DI-280	Offset keyed	0.5 - 4.0 mm (5/32 inch)	0 - 1450 rpm	20720
DI-280	Offset AO	2.4 mm cannulation	0 - 1450 rpm	20710
DI-280	In-line AO	-	0 - 1450 rpm	20700
DI-281	Angled AO	2.4 mm cannulation	0 - 1450 rpm	21240

Rotary Chuck Accessories

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

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.

Other Attachments

Model	Description	Speed	Blade / Capacity	Part No.
BI-280	Bur	0 - 35,000 rpm	De Soutter Medical R-Series	20740
BI-281	High Speed Bur	0 - 65,000 rpm	Zethon C-Series or D-Series[a]	20630
BI-287	Low Speed Bur	0 - 9,000 rpm	De Soutter Medical R-Series	20750
QI-280	Quick-release Medium Speed Drill	0 - 5,000 rpm	ISO 1797 Type 1	20730
CI-280	Small Reciprocating Saw	0 - 16,000 cpm	De Soutter Medical S83	20770
SI-280	Mini Sagittal Saw	0 - 27,000 cpm	De Soutter Medical S86	20550
NI-280	Large Sagittal Saw	0 - 22,000 cpm	De Soutter Medical S88	20760

Model	Description	Speed	Blade / Capacity	Part No.
OI-280	Oscillating Saw	0 - 22,000 cpm	De Soutter Medical S86	20780
OI-281	Oscillating Saw	0 - 20,000 cpm	De Soutter Medical S86-9xxx	20790
WI-280	Angled Wire Driver	0 - 1450 rpm	0.6 - 1.6mm	20800
WI-281	In-line Wire Driver	0 - 1450 rpm	0.6 - 1.6mm	20810
EI-280	E-Drive	0 - 35,000 rpm	-	21410

a. the bur size should be matched with the correct bur guard

Attachment Accessories

Description	Part No.
Bur guard - standard (for BI-280/287)	21120
Bur guard - long (for BI-280/287)	21130
Bur guard - extra long (for BI-280/287)	21140
Bur guard - 70mm (for BI-281 with Zethon C-Series)	20670
Bur guard - 100mm (for BI-281 with Zethon C-Series)	20660
Bur guard - metal cutting (for BI-281 with Zethon D-Series)	20460
Bur Attachment holder	19470

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 lever or pedal 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 lever or pedal. 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.

Patents

- US11464524B2
- GB2568215C
- AU2018269479

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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