orthodrive®

International
English

User Manual

DBZ-700

deSoutter
MEDICAL

E350308

MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14 IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 CAN/CSA C22.2 No. 60601-1-6:2011/AMD2:2021

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*  *. Risks associated with reuse include:*

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

WARNING: *when using this equipment, 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*

WARNING: *under certain circumstances, the applied part temperature may exceed 41°C. However, when the equipment is used for the purposes intended this poses no additional risks.*

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: *this equipment should only be used with the SB-704 battery*

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

NOTE: *the distal end of the handpiece and the compatible attachments are considered to be the applied parts*

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 replicate the function of a surgical mallet for impacting, insertion and removal of orthopaedic implants and other devices or for broaching bone or hard tissue.

There are no known contraindications.

NOTE: *The DBZ-70x is only available for use in the United States*

Disposal

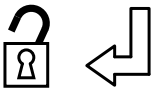
WARNING: *do not dispose of batteries by throwing them into a fire or immersing them in water*

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		Type BF protection
	Reciprocating Mode		Drive in the direction indicated
0	Safe mode (trigger locked)	1-4	Power level
	Pull and/or turn in the direction shown to unlock		Temperature limits to which the equipment can be exposed
	Pressure limits to which the equipment can be exposed		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		

Reprocessing - Sterilisable Equipment

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

- All Handpieces
- SB-xxx - Sterile Battery

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.*

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 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.

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

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) Ensure that sterile batteries are inverted (that is, contacts facing down).
   iii) Fit washing spacers and end caps as required.
   iv) 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 *(not suitable for batteries)*	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*

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

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-704	vacuum assisted	wrapped	3-4 minutes maximum at 134°C	12 minutes maximum
	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.

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.

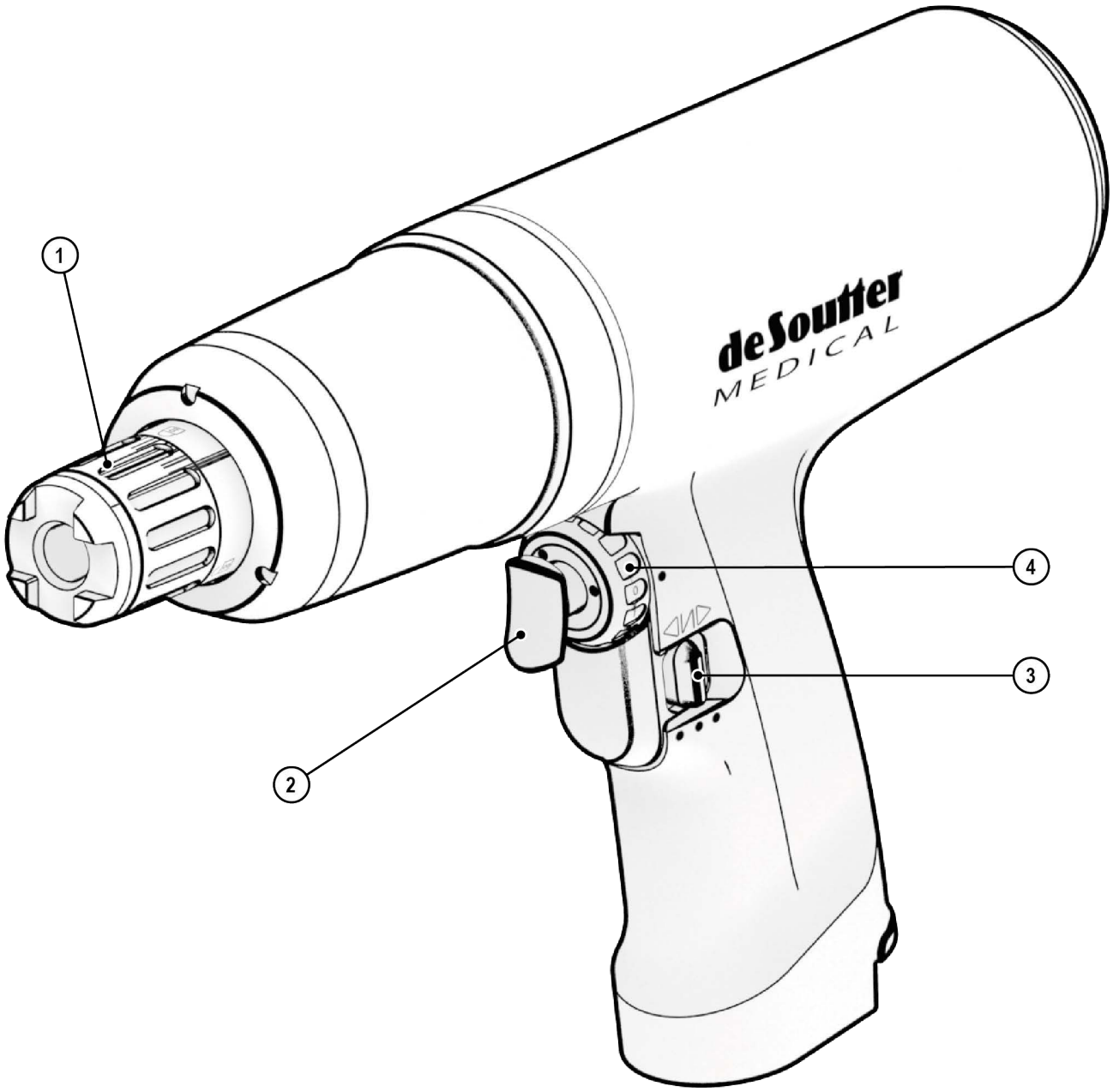
Sterrad sterilisation has been validated in accordance with ANSI/AAMI/ISO 14937.

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



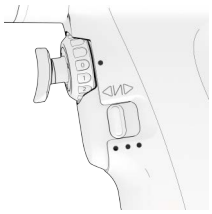
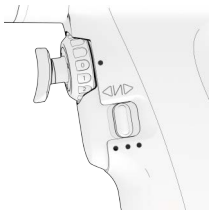
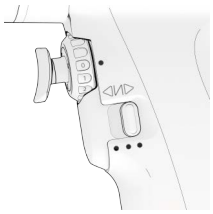
1) Attachment release ring
2) Trigger
3) Mode selector
4) Power selector (0 = SAFE Mode)

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*

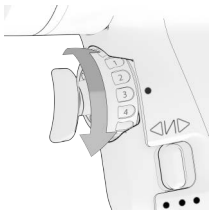
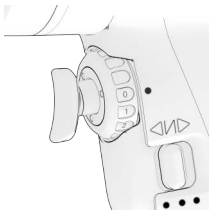
Slide the mode selector to choose the required mode.

		
Forward mode	Reciprocating mode	Reverse mode

NOTE: *SAFE mode is configured using the power mode selector*

Selecting the Power Level

Rotate the power selector to choose the required power level.

DBZ-70x	
	
Level 1 - 4	SAFE

Controlling the Handpiece

When the trigger is pressed, the handpiece will operate in the chosen mode.

NOTE: *to ensure optimum energy transfer, the handpiece should be pre-loaded before starting.*

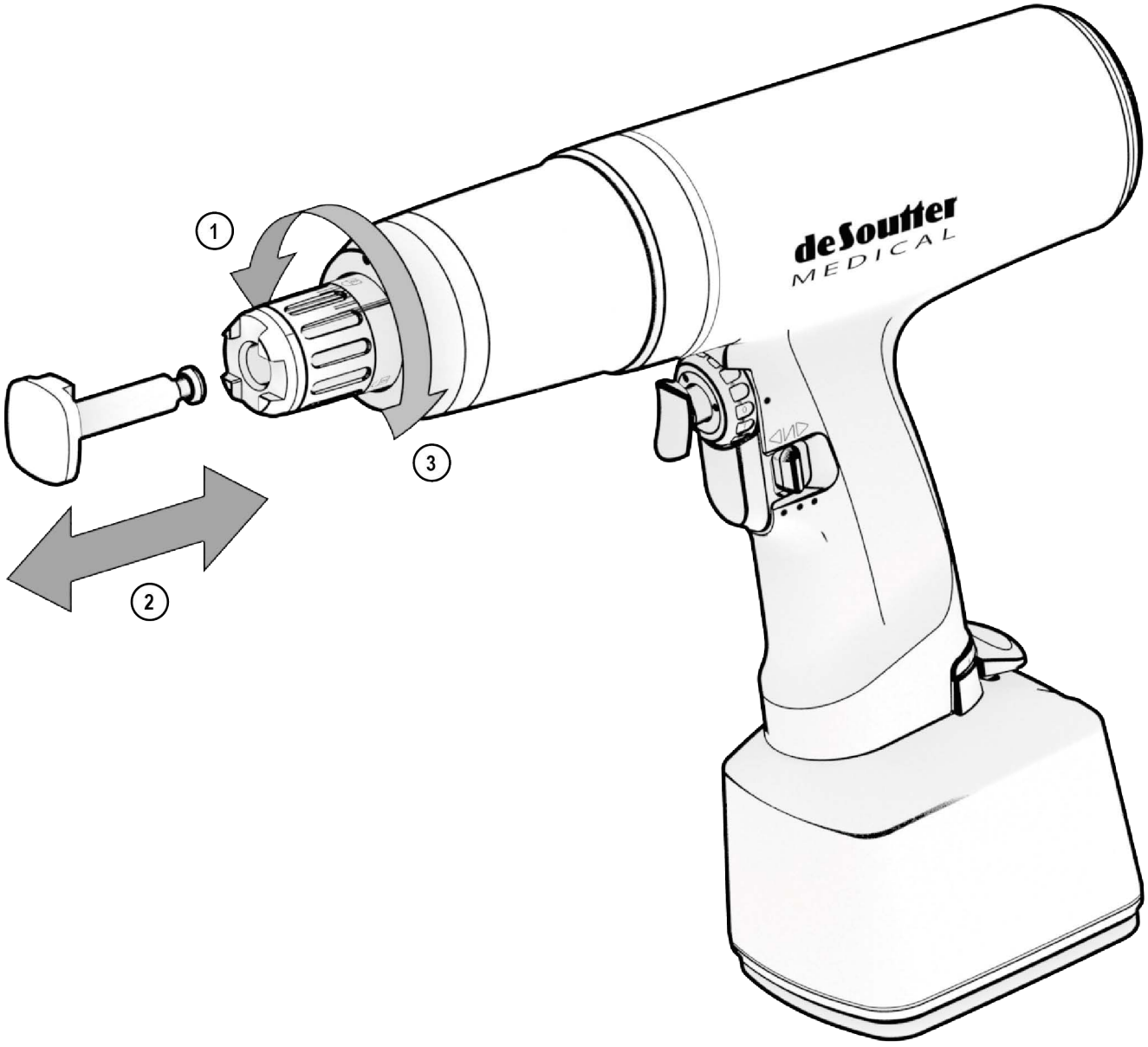
Using Attachments and Accessories

Fitting and 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. Rotate the release ring anti-clockwise
2. Fit or remove the attachment
3. Rotate the release ring clockwise to lock the attachment in position

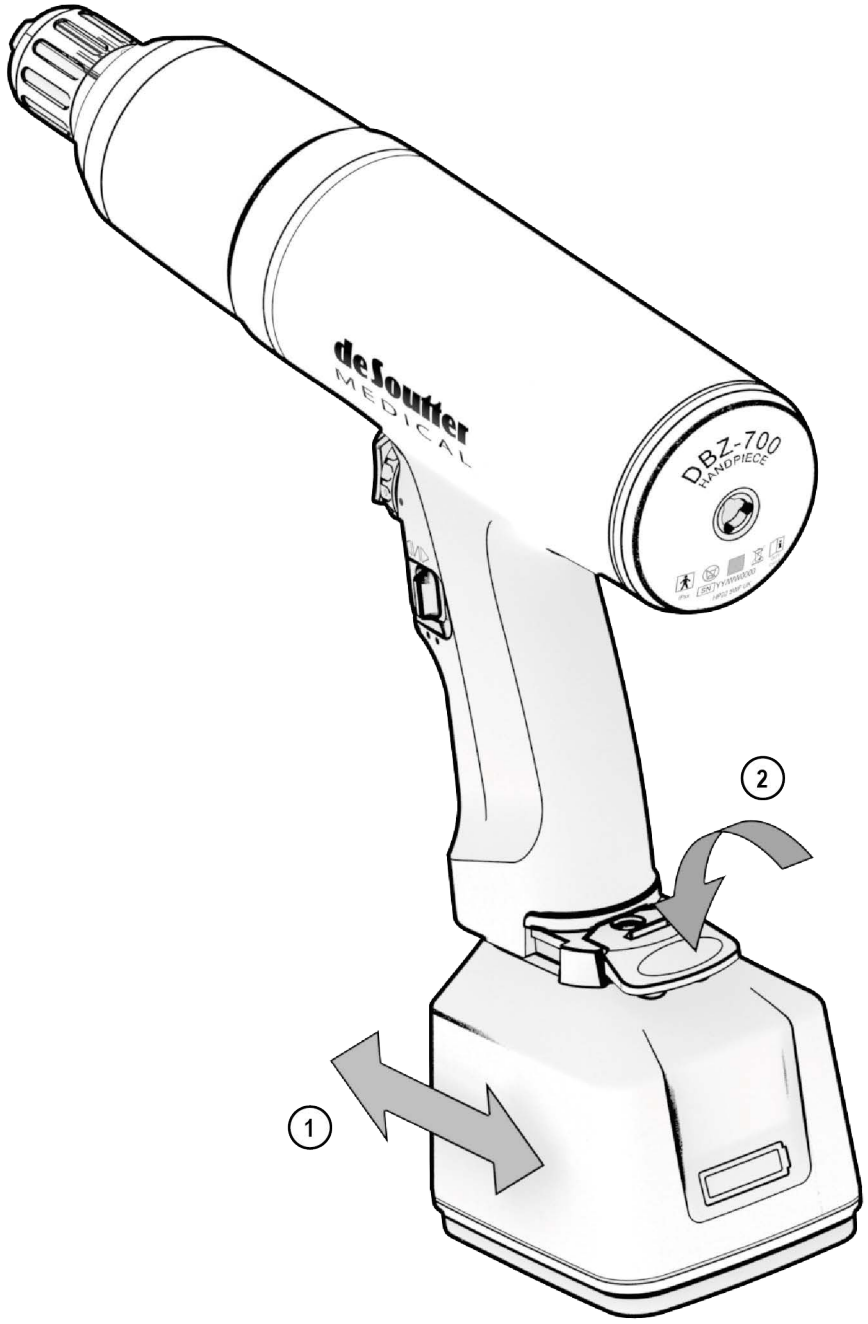
   NOTE: *ensure the attachment is secured in place*



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.



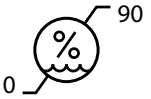
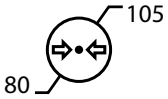
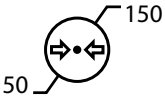
NOTE: *this procedure applies to all power options*

Technical and Ordering Information

Handpiece Specifications

Model	DBZ-700
Part no.	1295444
Frequency (Impacting)	6 Hz
Frequency (Broaching)	8 Hz
Duty Cycle	10s on / 10s off, 10 times with a 2 hour cooling period
Protection Type	 Type BF protection
Enclosure Protection	IPX0 - ordinary equipment

Environmental Conditions

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

Power Accessories

Battery Systems

The DBZ-70x is only suitable for use with Large lithium batteries.

Lithium Battery System

Model	Description	Voltage	Capacity	Part No.
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-706	SB-703, SB-704	1	17990

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

Sterilisation Accessories

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

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

Troubleshooting

Problem	Cause	Action
Handpiece does not run	Battery is discharged	Charge the battery
	Battery is expended	Replace the battery
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

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

EM Compliance (immunity)

This equipment complies with the tests and levels described.

Test	Test Standard	Compliance Level
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
Power frequency magnetic fields	IEC 61000-4-8	30 A/m, 50 or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	134.2 kHz & 13.56 MHz

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