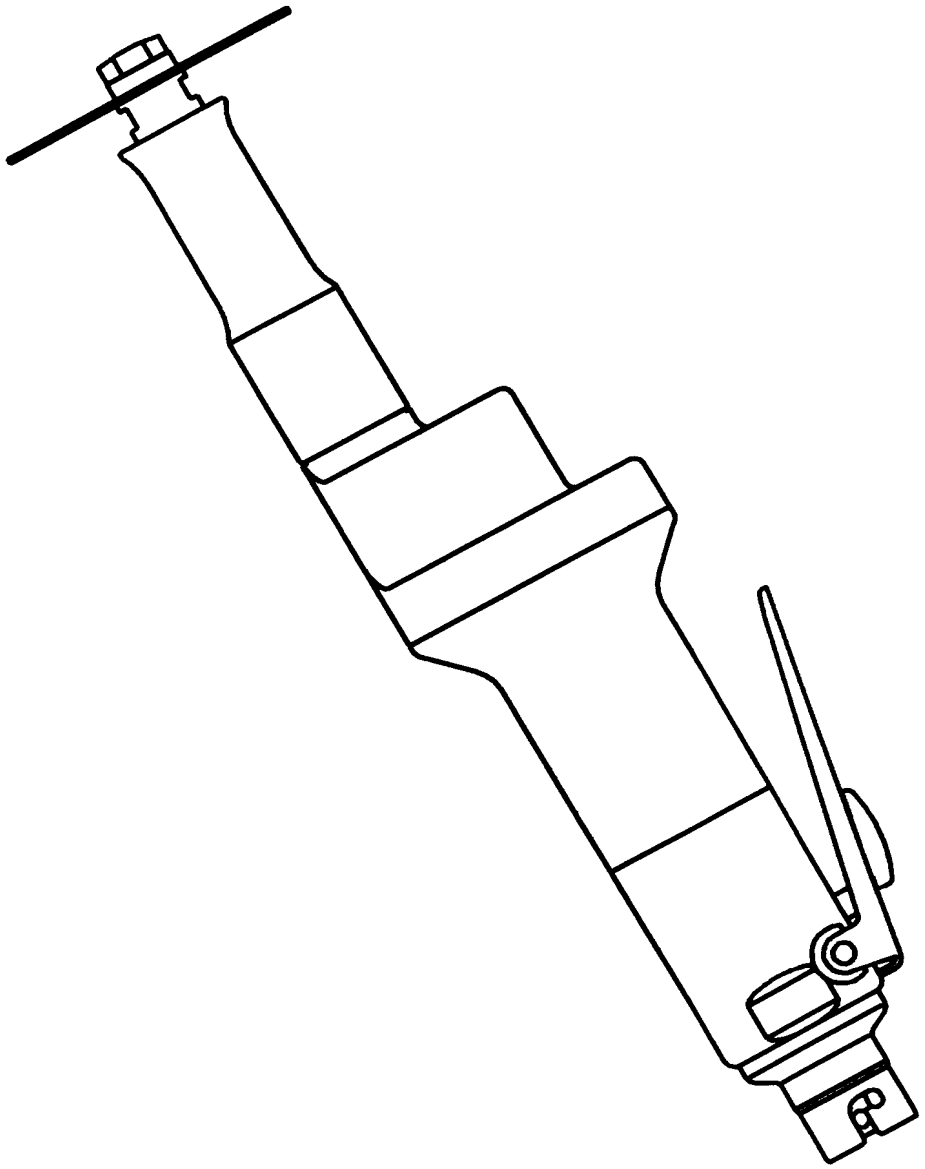
Operating Instructions

International
English

Sternum Saw
DPX–170



Pneumatic
Oscillating Saw

deSoutter MEDICAL

De Soutter Medical DPX-170 Pneumatic Oscillating Sternum Saw

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Warnings & Safety Rules

Failure to follow these instructions may result in serious injury to the patient or operating staff.

Do not attempt to use the equipment until all the instructions have been studied and understood.

Never permit untrained personnel to use this instrument system.
Always operate the instrument at the correct air pressure as specified in these instructions.
Always ensure that the hose is securely connected prior to use.
Always inspect all equipment and accessories before use. Do not use suspect, damaged or worn equipment.
Always ensure accessories are correctly connected to the instrument before use.
Always set the instrument safety catch to the **SAFE** position when changing accessories or when not in use.
Always use eye protection when cutting to prevent injury from flying debris.
Do not allow loose articles to be caught by the moving parts of the instrument.
Never drop the instrument or it's accessories; always handle with extreme care.
Always allow the instrument to stop before removing from the surgical site.
Only clean and sterilise the instrument and accessories as directed in these instructions.
Do not immerse the instrument in fluids.
Always use Stericut or De Soutter Medical approved accessories.

Product Description

The DPX-170 is a pneumatic surgical oscillating saw.

Air Supply

Use only 99.97% pure, dry compressed air or nitrogen filtered to 5 microns.
Lower pressures may be set for lower speed requirements.

Operating Pressure:	6 bar (87psi)
Flow Rate:	3.3l/s (7 cu.ft./min)

Never exceed 7 bar (100psi) pressure.

Reprocessing Instructions

Warnings:	
Limitations on reprocessing:	**Do not** immerse the handpiece in water other than when automatic reprocessing, and only then, when fitted the correct washing caps. **Do not** exceed temperatures 140 °C. **Do not** clean any part of the equipment in an ultrasonic cleaner. **Long narrow cannulations and blind holes require particular attention during cleaning.** Repeated processing has minimal effect on these instruments. End of life is normally determined by wear or damage during use.
Instructions	
Point of Use	Do not operate the equipment while still warm
Containment and transportation:	It is recommended that instruments be reprocessed immediately following surgical use. The handling, collection and transportation of soiled equipment should be strictly controlled to minimise risks.
Preparation for cleaning:	Remove all attachments and accessories for cleaning, wash separately, or dispose of as per instructions.
Manual Cleaning	**Equipment:** Manual cleaning should only be carried out where automatic washer/disinfection is not available. It should be conducted in a dedicated area by trained personnel wearing protective clothing e.g. gloves, waterproof apron and goggles or visor. Use Neutral pH Enzymatic detergents such as Klerzyme™ and Nylon scrubbing brushes. Dedicated sinks with temperature controlled water, ideally de-ionized or distilled and a Lint-free cloth for drying. **Method:** 1. Wash off excess contaminant with running water (maximum 35 °C) avoiding fluid ingress via the air hose inlet. Scrub the components thoroughly using a neutral pH enzymatic detergent and nylon brushes to remove all visible traces of contaminant. Pay attention to recesses, blind holes and cannulations. Note: Manually open and close chucks and blade clamps. Use suitable nylon brushes to reach difficult surfaces and inside cannulations. Flush through these areas to ensure any trapped contaminants are removed. 2. Rinse off all traces of the detergent with de ionized or distilled running water (45-65 °C). 3. Shake off excess water and dry surfaces with a lint-free cloth. 4. Visually inspect each item to verify that all contaminants are removed in accordance with local reprocessing guidelines.

Automatic Cleaning	**Equipment:** Automatic Washer/Disinfector capable of meeting relevant national and international cleaning and disinfection standards i.e. BS2745 and HTM2030; Neutral pH Enzymatic detergent such as HAMO Liquid 52 ™. **Method:** 1. Large contaminant deposits should be removed manually using the method described in Manual Cleaning:- item 1. Pay particular attention to recesses, blind holes, chucks, clamps and cannulations. 2. Place the handpiece, attachments and accessories onto the wire basket. Ensure all items are separated and washing caps are securely fitted to the handpiece and air supply hose. <u>Note:</u> The placement of item in automatic washer/disinfector baskets can be a critical factor in achieving effective cleaning. Selection of the basket type and position of the items to be cleaned should be done by suitably trained personnel in accordance with the manufacturer's instructions for the washer/disinfector. 3. Follow manufacturers loading instructions and select the appropriate cycle recommended. The cycle should include: ▪ Pressurized cold water rinse (maximum 35 °C). ▪ Hot water wash (minimum 55 °C) using a neutral pH enzymatic detergent. ▪ Warm water rinse. ▪ Disinfection rinse (minimum 80 °C for 1 minutes). ▪ Drying cycle 4. Remove disinfected instruments from the washer/disinfector to a clean area. Remove the washing caps. 5. Visually inspect each item and verify the cleaning process is complete and all contaminants have been removed in accordance with local reprocessing guidelines.
Disinfection:	Thermal disinfection is recommended and included in the automatic washer/disinfection cycle. See above.
Maintenance:	Lubrication of the motor is not essential but will enhance the life and performance of the instrument. 1. Apply 3 drops of surgical instrument oil (part no. 30982- Non-sterile) into the instrument air inlet after cleaning. 2. Connect the instrument to an air supply and run for at least 20 seconds to ensure adequate dispersal of lubricant. 3. Lubricate collets, chucks and hose connectors using mineral oil such as Blitz™.
Inspection and Function Testing:	Ensure the handpiece, attachments and non-cutting accessories are in good working order. Note any unusual sounds, vibrations or operating speeds. If operating difficulties are experienced and are not already

	covered in these operating instructions, refer to the Repair and Servicing Information section of this manual. **Re useable cutting accessories (saw blades, drill bits, reamer shells etc.).** Inspect for damage and wear. Cutting edges should be sharp and free from damage. Discard worn or damaged cutting accessories into a suitable sharp's disposal bin. **Single use accessories (Sterile saw blades, burrs, K wires etc.).** (2) Accessories marked for single use only must not be re used. Dispose of these items in a sharp's bin or other suitable disposal method.
Packaging:	Place cleaned instruments, attachments and accessories into the DPX Sterilization case (part No. 9350). If wrapping is used, material conforming to EN868 allowing rapid penetration of steam should be used.
Sterilization:	Wrapped or Unwrapped. Vacuum steam autoclave, minimum 3 minutes @ 134°C (+3°C/ -0°C). The equipment is capable of withstanding a standard drying cycle.
Storage:	Wrapping sterilized instruments in accordance with EN868 is recommended to preserve sterility. The material should present a barrier to micro-organisms and particulate contamination.
Additional Information:	Automated cleaning was validated in accordance with HTM 2030 using an automated washer/disinfector and Neutral Ph enzymatic detergent. Sterilization was validated in accordance with HTM2010 using a 134 °C (+3°C/ -0°C) vacuum steam autoclave. **Note: Manual cleaning: Not validated for reasons of non-repeatability.**
The instruction's provided above have been validated by De Soutter Medical Ltd. as being capable of preparing a device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process. Likewise any deviation by the preprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. (07/2002)	

Accessories

Description	**Part No.**
Washing cap	608073
Hose Washing Cap	8950
Sterilisation Case	9350

Air Supply Hose

The air supply hose is self sealing when disconnected from the instrument. The hose connects to the instrument with a quick release bayonet connection.

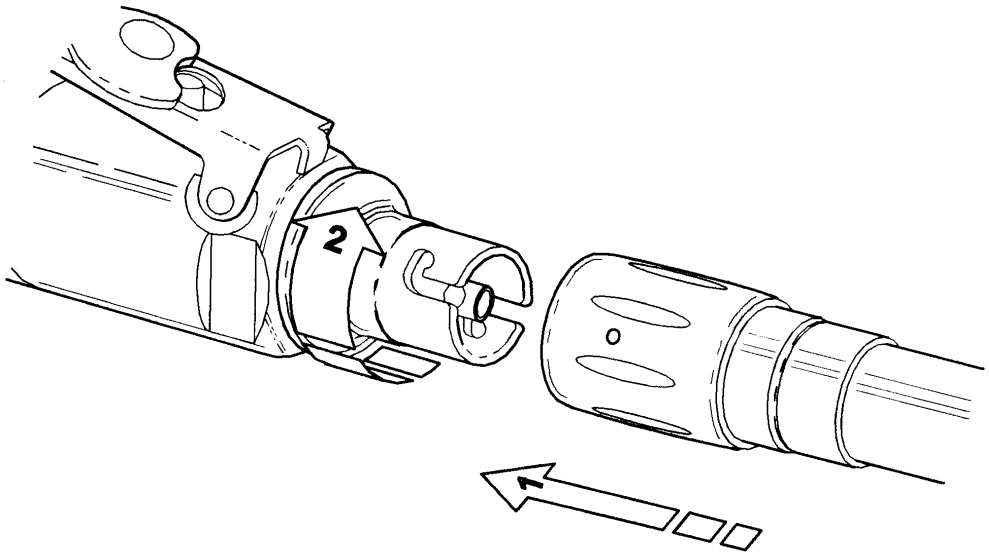
To attach the hose:

- Grip the hose connector and push it on to the instrument spigot.
- Twist the connector clockwise. The connector will come to a stop - the hose is now connected.
- Pull gently on the hose to check that the hose is securely connected to the instrument.

To remove the hose:

- Hold the instrument and grip the hose connector.
- Twist the hose connector anti clockwise, pushing the hose connector towards the instrument.

Refer to the diagram.



Optional Accessories

Air Supply Hoses

Type	3m length	4m length	5m length
BOC MA7	5300	5310	5320
A. O.	5330	5340	5350
AGA	5360	5370	5380
Draeger	5390	5400	5410

Blades
Stericut saw blades are sterile packed in packs of 5 blades.

Part No.	Blade Thickness (mm)	Cut Thickness (mm)	Tooth Pitch (mm)	Depth of cut (mm)	Blade Radius (mm)
S81-100	0.5	1.0	1.5	16	25
S81-101	0.5	1.0	1.8	23	32
S81-102	0.5	1.0	1.5	29	38
S81-103	0.5	1.0	1.5	13	22
S81-104	0.5	1.0	1.5	42	51
S81-105	0.5	1.0	1.8	23	32
S81-106	0.5	1.0	1.4	15	25

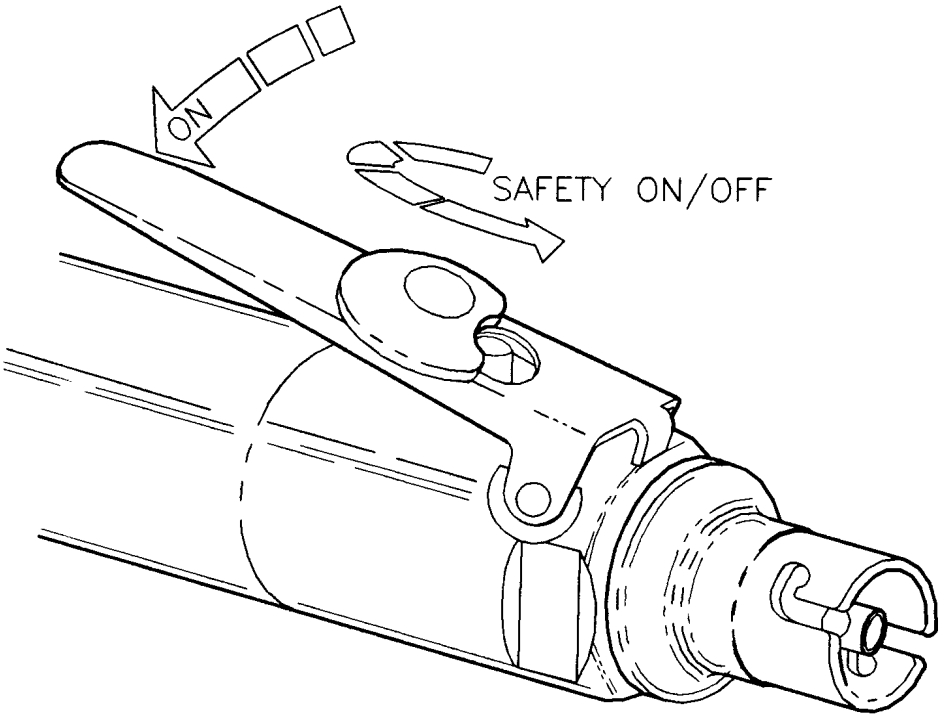
For full details of suitable saw blades refer to Stericut data sheets.

Controls

Lever - The lever control has a progressive throttle action, increasing the saw speed as it is depressed.

Safety catch - The lever can be made inoperable by rotating the safety catch so the cut out is positioned above the hole in the lever. In this position the tool can not run

Refer to the diagram.



Blade Clamp Operation

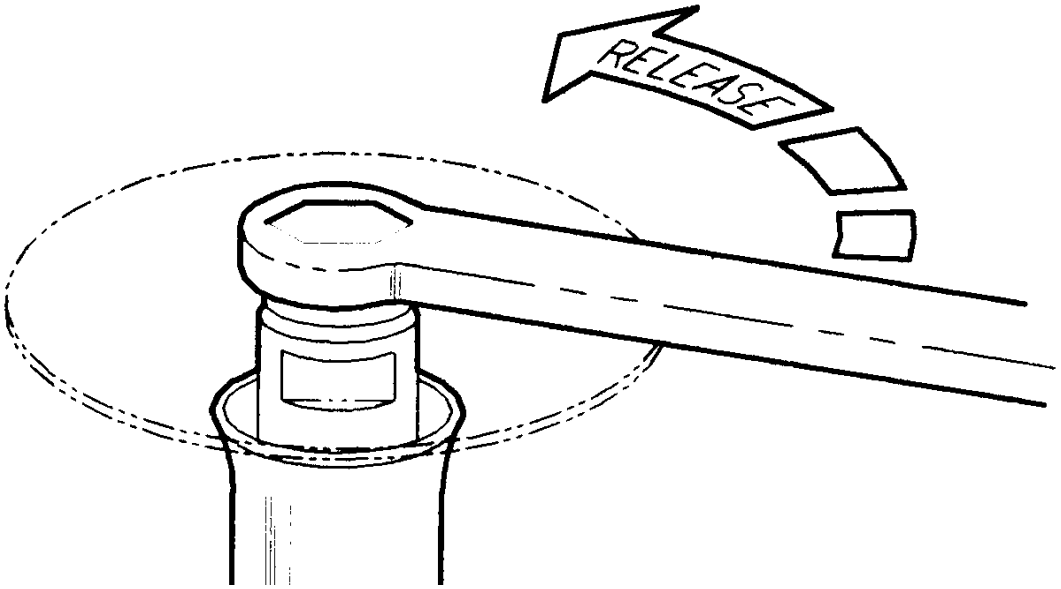
Assembly:

- Using the spanner provided, remove the clamp nut on the end of the oscillating shaft in an anti clockwise direction.
- Insert the blade onto the oscillating shaft, and locate the splined hole in the blade over the spline on the shaft.
- Replace the clamp nut and tighten

Removal:

- Using the spanners provided, remove the clamp nut on the end of the oscillating shaft in an anti clockwise direction.
- Remove the blade.
- Replace the clamp nut.

Refer to the diagram below.



Conditions for Transport & Storage

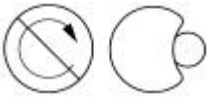
Temperature:	-20ºC to +40ºC
Relative Humidity:	90% maximum.
Atmospheric Pressure:	1.5 atmospheres maximum.

Explanation of Symbols

Refer to the Operating Instruction Manual

Vacuum Steam Sterilise.

Do Not Immerse



Safe

Fault Finding

Fault:	Possible Cause:	Remedy:
Instrument does not run.	Air supply faulty	Check air supply Check hose connections
	Lever Mode Selector set to Safety	Rotate Lever Mode Selector to run position
Instrument runs slowly, or seems to lack power	Insufficient lubrication	Refer to Lubrication section of manual
	Insufficient air supply pressure and/or flow rate	Check air supply pressure at regulator (bottled air only). Check hose for possible restriction.
	Regulator malfunctioning.	Check air supply regulator.
Blade will not fit onto oscillating shaft	Debris inside blade clamp	Clean with small brush
	Blade is damaged	Replace the blade. **Do Not** force a damaged blade onto the oscillating shaft
Instrument seems to cut slowly	Worn accessory	Replace accessory.

If any problem persists then contact De Soutter Medical Ltd.

Repair & Service Information

All powered instruments `should be periodically checked and cleaned. Annual servicing is recommended for normal use. Due to the specialist techniques used in the manufacture and maintenance of De Soutter instruments, user servicing is not possible. For service and repair please contact your nearest De Soutter Medical Authorised Service Centre.

To return an instrument for repair:

- Record the serial number of the instrument being returned. Enclose a brief statement describing the reason for returning the instrument.
- Enclose the purchase order number for the instrument if warranty is being claimed. It will be helpful to include a contact name.
- Pack the instrument securely and send to the address below.

Please ensure that the instrument has been properly decontaminated and sterilised.

Guarantee & Liability

De Soutter Medical guarantees all instruments, attachments and accessories to be free from defects in material and workmanship for one year from the date of purchase. De Soutter Medical is not liable by warranty or otherwise in the case of any of the following:

- Abuse, misuse or use in other than a surgical environment;
- Disassembly, alteration or unauthorised repair;
- If the product has not been used in a reasonable manner and in full compliance with the written instructions.

This guarantee does not affect your Statutory Rights in accordance with 1999/44/EEC

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