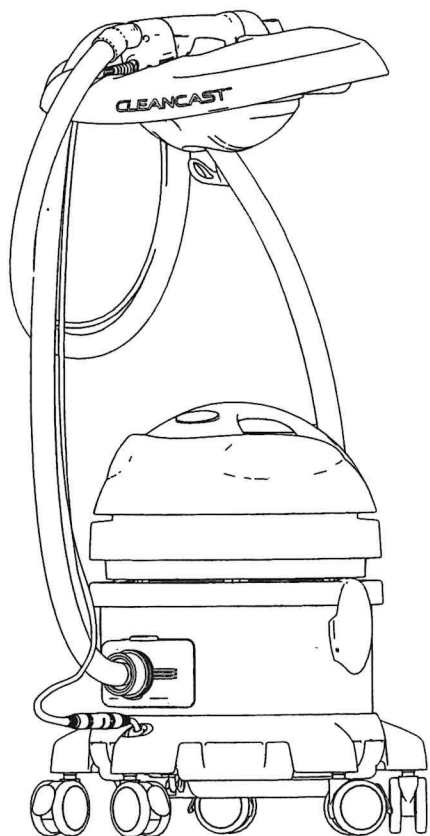


CLEANCAST™

International
English

User Manual

CC7
CC8



deSoutter
MEDICAL

CE

Contents

1	Important Information	1
	Safety Instructions	1
	Intended Use and Benefits	2
	Disposal	2
2	Symbols	3
	General	3
	Extractor	3
	Power Supply	3
	Cast Saw	4
3	Reprocessing - Non-sterilisable Equipment	5
	Limitations on reprocessing	5
	Safety Instructions	5
	Manual Cleaning	5
4	Overview	6
	Cast Saw	6
	Extractor	7
5	Configuring the Extractor	8
	Fitting the Castor wheels	8
	Fitting the Tray	9
	Fitting and Removing the Hose from the Cast Saw	10
	Fitting the Hose to the Extractor	11
	Removing the Hose from the Extractor	12
	Selecting the Mode	13
6	Configuring the Cast Saw	14
	Connecting a Saw Cable	14
	Disconnecting a Saw Cable	15
7	Using Accessories	16
	Fitting a Wall Mount	16
	Replacing the Dust Bag	17
	Fitting and Removing a Blade	18
8	Technical and Ordering Information	19
	Cast Saw Specifications	19
	Extractor Specifications	19
	Power Supply Specifications	19
	Accessories	20
	Saw Blades	21
9	Troubleshooting	23
	Further Help	23
	Service and Repair Information	24
	Guarantee and Liability	24
10	EMC Information	25
	General Information	25
	EM Compliance (emissions)	25

EM Compliance (immunity)25

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Important Information

Save this user manual. This user manual contains important safety and operating instructions for this equipment.

Throughout this user manual, the words WARNING, CAUTION and NOTE are used to highlight important information.

WARNING: *WARNING information identifies conditions or practices that could result in injury*

CAUTION: *CAUTION information identifies conditions or practices that could result in damage to the equipment or system*

NOTE: *NOTE information is provided to clarify or supplement procedural information*

Safety Instructions

WARNING: *do not attempt to use this equipment until this user manual and all cautionary markings have been studied and understood*

WARNING: *this equipment should only be used by personnel with appropriate training*

WARNING: *inspect all equipment before use and do not use suspect, damaged or worn equipment*

WARNING: *do not use this equipment to cut wet plaster*

WARNING: *do not use this equipment with wet hands*

WARNING: *do not expose this equipment to rain or use near water*

WARNING: *ensure the voltage rating of the electrical supply corresponds with the voltage rating stated on the equipment label*

WARNING: *this equipment must only be connected to a supply with a protective earth*

WARNING: *do not position the equipment so that it is difficult to disconnect from the mains supply*

WARNING: *this equipment is not intended for use in an oxygen rich environment or in the presence of flammable gases*

WARNING: *do not attempt to dismantle or modify this equipment, except as directed in this user manual*

WARNING: *do not allow the blade to contact the skin*

WARNING: *ensure the equipment is disconnected from all power sources before cleaning*

WARNING: *do not exert excessive pressure on the cast when cutting. Excessive cutting pressure will cause the blade to overheat which may result in injury to the patient*

WARNING: *when using cast saws, 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: *always use extraction when operating the CC7 cast saw*

WARNING: *apply the brakes when the extractor is not in transit*

CAUTION: *do not immerse any part of this equipment in fluids*

CAUTION: *ensure the vent is not obstructed*

CAUTION: *only reprocess this equipment as directed in this user manual*

CAUTION: *do not clean this equipment in an automatic washer-disinfector*

CAUTION: do not clean any part of this equipment in an ultrasonic cleaner

CAUTION: ensure this equipment is regularly serviced. Refer to the service and repair information section of this user manual.

CAUTION: only use De Soutter Medical approved accessories

CAUTION: only use sharp cutting accessories

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.

NOTE: if electro-magnetic interference occurs, causing undesirable operation, increase the distance between the interfering devices and if possible, connect the items of equipment to separate power outlets

Intended Use and Benefits

The equipment described in this user manual intended for use by a clinical professional, within an approved clinical setting. The equipment is intended to provide an efficient means of removing orthopaedic casts.















There are no known contraindications or limitations on patient target group.

Disposal



All equipment should be recycled or disposed of, in accordance with local regulations.

Symbols



General

Symbol	Meaning	Symbol	Meaning
	Refer to the user manual		Dispose of in accordance with local regulations
	Type BF protection	SN YY/000000	The first two digits (YY) indicate the year of manufacture
	Alternating current		Do not immerse
	Humidity limits to which the equipment can be exposed		Temperature limits to which the equipment can be exposed
	Pressure limits to which the equipment can be exposed		Transport - keep away from rain
	Transport - fragile, handle with care		Transport - this way up
	Manufacturer		EC authorised representative
	Medical Device		


Extractor

Symbol	Meaning	Symbol	Meaning
	Off	I MAN	Manual extraction mode
I AUTO	Automatic extraction mode		Warning. Refer to the accompanying text

Power Supply

Symbol	Meaning	Symbol	Meaning
	Direct current		Input

Cast Saw

Symbol	Meaning	Symbol	Meaning
	Stand-by		

4

9

Reprocessing - Non-sterilisable Equipment

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

- Extractor
- PSx - Power Supply
- CCx - Cast Saw

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: inspect all equipment before use and do not use suspect, damaged or worn equipment

CAUTION: do not immerse any part of this equipment in fluids

CAUTION: do not clean this equipment in an automatic washer-disinfector

CAUTION: do not clean any part of this equipment in an ultrasonic cleaner

CAUTION: do not sterilise this equipment

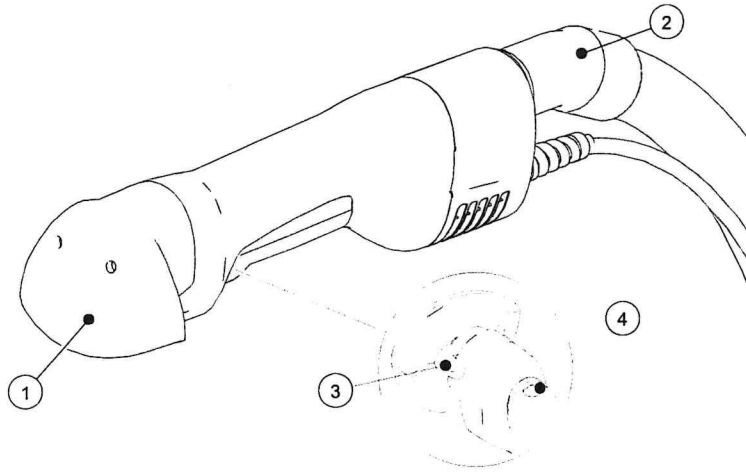
Manual Cleaning

NOTE: cannulations, blind holes, recesses, and other surfaces which are hard to reach, require particular attention during reprocessing

1. Remove any attachments and accessories.
2. Using a soft brush, clean the air vents and blade area to remove any dust or debris.
3. Wipe the surfaces of the equipment with a clean, soft cloth, slightly dampened with a mild pH balanced detergent or alcohol.
NOTE: avoid fluid ingress
4. Wipe the surfaces of the equipment with a clean, soft cloth, slightly dampened with distilled or sterilised water.
NOTE: avoid fluid ingress
5. Dry the equipment with a clean, soft, dry cloth.

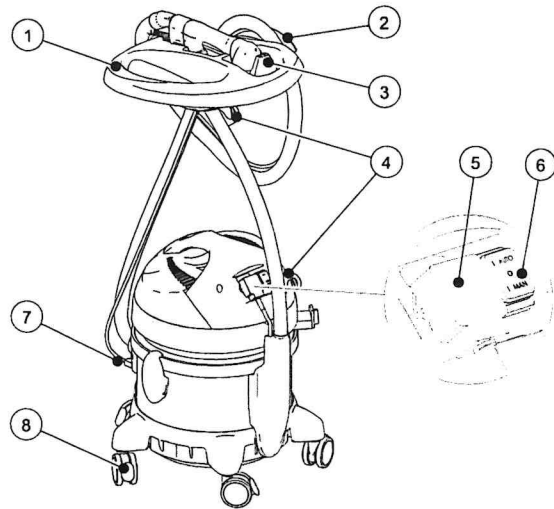
Overview

Cast Saw



- 1) Extraction Hood (CC7 only)
- 2) Extractor Hose (CC7 only)
- 3) Blade clamp lever
- 4) Stand-by button

Extractor



- 1) Tray
- 2) Extraction hose stowage
- 3) Vacuum nozzle
- 4) Cable stowage
- 5) Auxiliary outlet (for power supply)
- 6) Mode selection switch (mains isolation)
- 7) Cast saw connector
- 8) Brakes

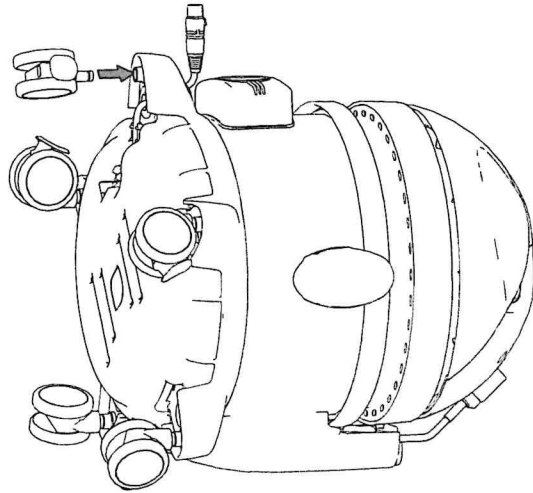
Configuring the Extractor

NOTE: before initial use, the castor wheels and tray must be fitted to the extractor base.

Fitting the Castor wheels

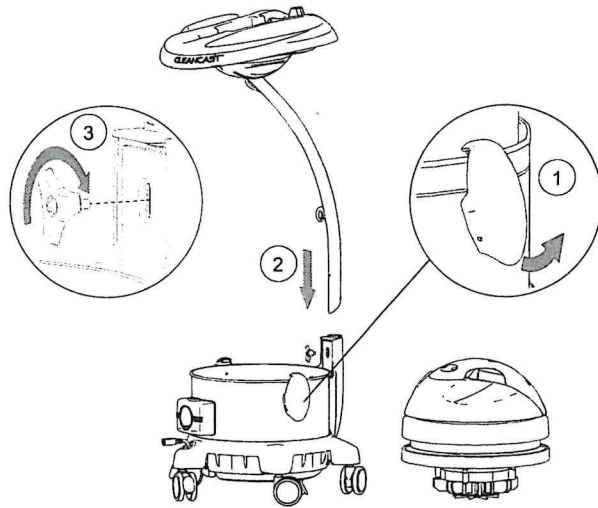
Push the castor wheels into the base of the extractor until they click into place.

NOTE: ensure the castor wheels are securely fitted



Fitting the Tray

1. Open the catches on each side of the extractor and place the extractor head to one side.
NOTE: ensure the auxiliary plug is removed before placing the extractor head to one side
2. Insert the tray into the extractor base.
3. Secure in place with the wing nut provided.



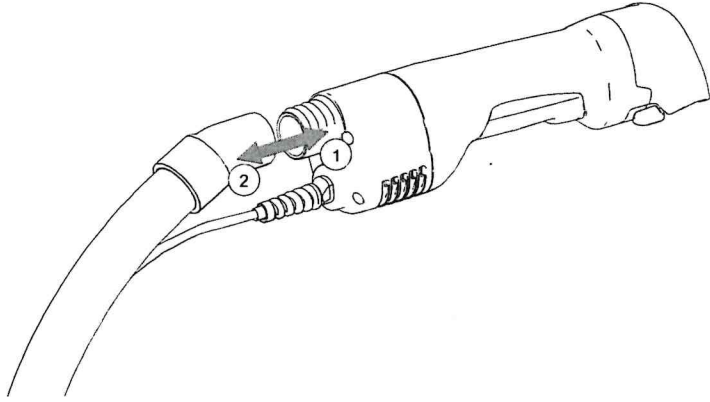
Fitting and Removing the Hose from the Cast Saw

WARNING: ensure the equipment is switched off

1. To fit: push the hose over the barbed connector on the cast saw.

NOTE: ensure the hose is secured in place

2. To remove: pull the hose away from the cast saw.

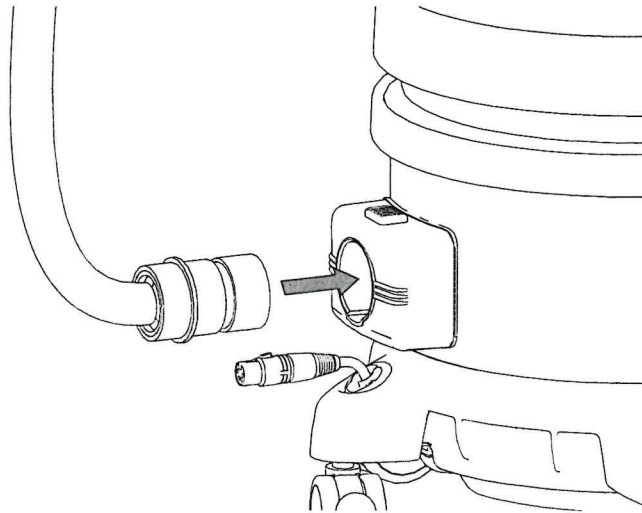


Fitting the Hose to the Extractor

WARNING: ensure the equipment is switched off

Push the hose into the extractor inlet until it clicks into place.

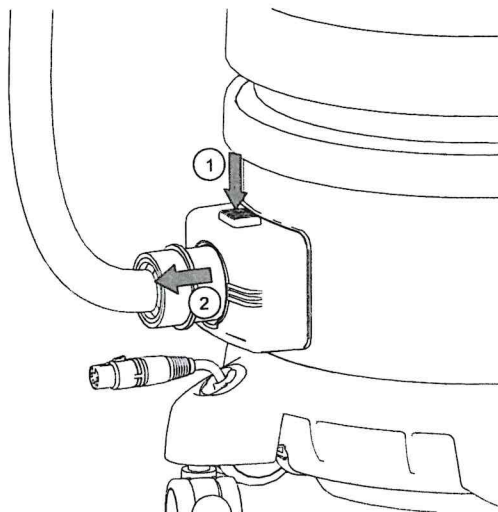
NOTE: ensure the hose is secured in place



Removing the Hose from the Extractor

WARNING: ensure the equipment is switched off

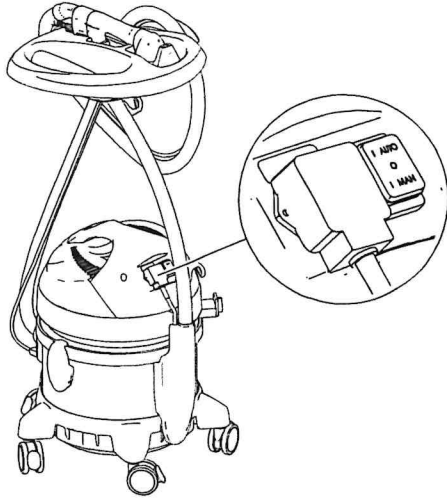
Press the release button and pull the hose away from the extractor.



Selecting the Mode

Set the mode selection switch to the required mode.

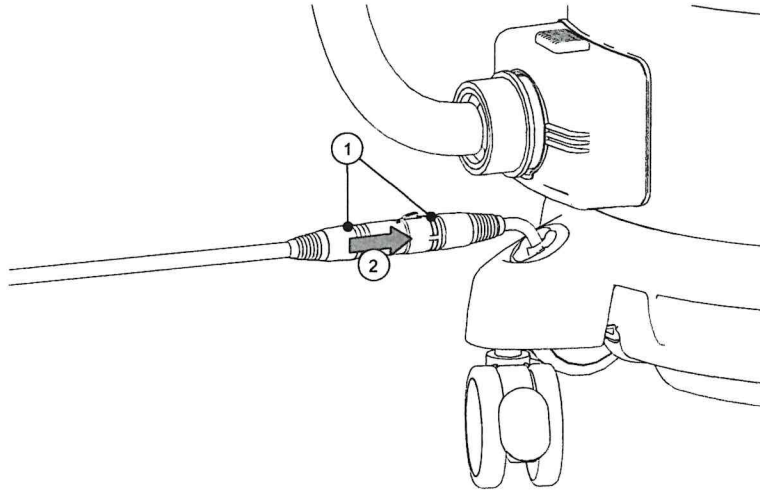
Mode	Description
I AUTO	The extractor will automatically switch on with the cast saw, and turn off a few seconds after the cast saw has stopped
O	Off
I MAN	The extractor is on and the cast saw is disabled



Configuring the Cast Saw

Connecting a Saw Cable

1. Align the arrow on the plug with the catch on the socket.
2. Push the plug firmly into the socket.
NOTE: ensure the plug is securely fitted
3. Use the clips provided to attach the saw cable to the hose (CC7 only).

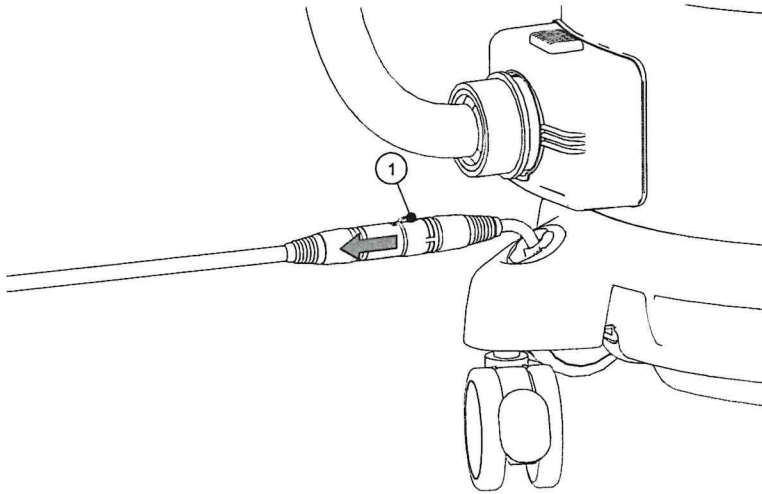


NOTE: this procedure applies to the CC7 and the CC8

Disconnecting a Saw Cable

1. Press the catch on the socket.
2. Pull the plug away from the socket.

NOTE: do not attempt to disconnect the saw by pulling the cable



NOTE: this procedure applies to the CC7 and the CC8

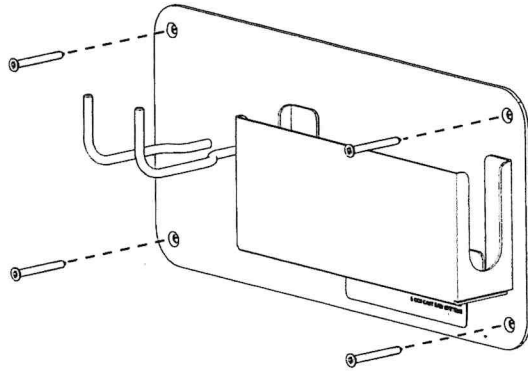
Using Accessories

Fitting a Wall Mount

WARNING: do not position the wall mount more than 1m from the ground

WARNING: the wall plugs provided are only suitable for solid walls

Using the screws and wall plugs provided, fix the wall mount to the wall.



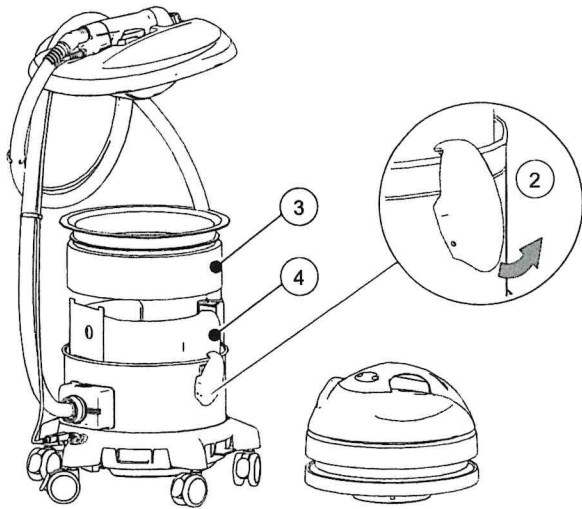
Replacing the Dust Bag

To ensure optimum efficiency, replace the dust bag regularly.

WARNING: ensure the equipment is switched off and the mains supply is disconnected

1. Unwind the mains cable fully and unplug the auxiliary socket.
2. Open the catches on each side of the extractor and place the extractor head to one side.
3. Replace the permanent filter, as required.
4. Replace the dust bag.
5. Re-fit the extractor head into its original position and secure the catches.
NOTE: ensure the extractor head is securely held in place
6. Re-fit the auxiliary plug.

CAUTION: do not attempt to pull the auxiliary plug and cable out of the base



Fitting and Removing a Blade

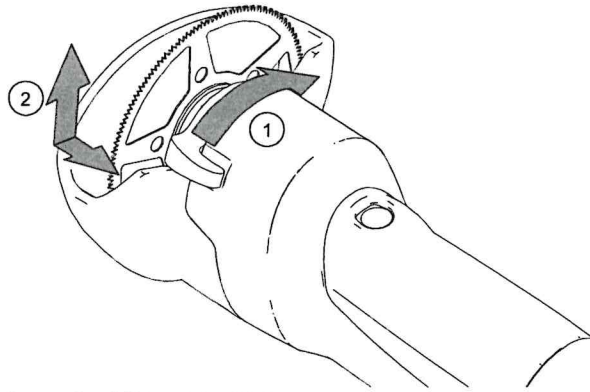
WARNING: ensure the equipment is switched off and the mains supply is disconnected

1. Operate the blade clamp lever to open the blade clamp.
2. Fit or remove the blade as necessary.

NOTE: a circular blade can be fitted in any of 5 positions, allowing the full circumference of the blade to be used

3. Release the blade clamp lever to secure the blade in place.


NOTE: ensure the blade is securely clamped in place and that the blade clamp lever has returned to its original position



NOTE: this procedure applies to the CC7 and the CC8

Technical and Ordering Information

Cast Saw Specifications

Model	CC7		CC8	
Cable length	2m	4m	2m	4m
Part no.	1292554	1293224	1292664	1293334
Maximum Speed	19,000 cpm	18,300 cpm	19,000 cpm	18,300 cpm
Protection Type	 Type BF protection			
Enclosure Protection	IPX0 - ordinary equipment			
Mode of Operation	Continuous		4 min on / 15 min off	

Extractor Specifications







Model	CC7 Extractor			
Part no.	1292884 (UK)	1292994 (EU)	1293114 (AU)	1293004 (US)
Supply Voltage	230 Vac			120 Vac
Supply Frequency	50 - 60 Hz			
Input Current	7A maximum			
Protection Class	Class I			
Enclosure Protection	IPX0 - ordinary equipment			
Mode of Operation	Continuous			

Power Supply Specifications

Model no.	PS8 ^a
Part no.	19770
Supply Voltage	100 - 240 Vac
Supply Current	2.0 - 1.0 A
Supply Frequency	50 / 60 Hz
Output Power	138 W max.
Output Voltage	12 Vdc
Protection Class	Class I
Enclosure Protection	IPX0 - ordinary equipment
Mode of Operation	Continuous

a. for use with the CC8 cast saw or the CC7 cast saw with centralised extraction

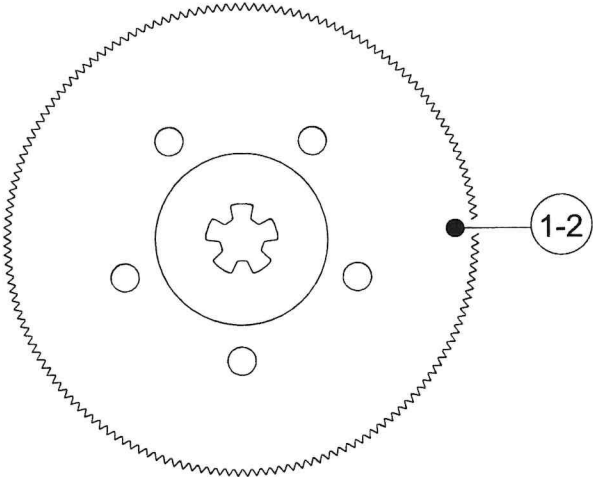
Environmental Conditions

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

Accessories

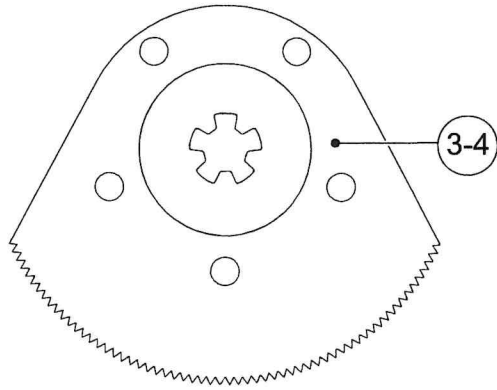
Description	Part No.
Large, two-handed, cast spreader	5130
Small, single-handed, cast spreader	5120
Plaster shear	7680
Under-padding scissors	15150
HEPA dust bags (pack of 10)	670123
Dust filter	670113
Wall mount kit	19850
Extractor hose kit (2m)	19600
Extractor hose kit (4m)	19800
Hose kit for centralised extraction (2m)	19930
Hose kit for centralised extraction (4m)	19940
Vacuum nozzle	670733

Saw Blades
Circular Saw Blades



	Type	Diameter (mm)	Part No.
1	PTFE	64	19610
2	Zirconium carbo-nitride	64	19660

Segmented Blades



	Type	Radius (mm)	Part No.
3	Segmented PTFE	32	19670
4	Segmented zirconium carbo-nitride	32	19730

Troubleshooting

Problem	Cause	Action
Saw cuts slowly	Blade is not securely fitted	Refit the blade
	Blade is worn	Rotate the blade to a new position Replace the blade
	Incorrect blade is being used	Use a blade suitable for the material being cut Replace the blade
Cast saw cuts out during use	Temperature protection has activated	Allow the handpiece to cool
	Power supply overload has activated	Ensure the blade is not worn Adjust the cutting technique, allowing the blade to cut at its own rate Restart the saw
Extractor is noisy/suction is poor	Dust bag is full	Replace the dust bags
	Filters are blocked	Replace the filters
Saw does not run but extractor functions	Extractor is in manual mode	Select auto mode
Extractor does not stop	Extractor is in manual mode	Turn off the extractor manually Select auto mode

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. User servicing of the parts described in this user manual is possible. Servicing of all other parts must be carried out by De Soutter Medical or an authorised repair centre.

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.

Guarantee and Liability

De Soutter Medical guarantees all equipment to be free from defects in material and workmanship for one year from the date of purchase. The following exceptions apply:

- Sterile packed consumables are guaranteed for single-use only.
- New batteries are guaranteed for a period of six months from the invoice date.
- Non-sterile consumables are guaranteed for their normal expected working life.

De Soutter Medical is not liable by warranty or otherwise in the case of any of the following:

- abuse, misuse or use in a non-surgical environment
- disassembly, alteration or unauthorised repair
- use of the product in an unreasonable manner or, a manner which is not in full compliance with these written instructions or with the equipment's intended use.

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

EMC Information

General Information

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

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

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

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

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

EM Compliance (emissions)

This equipment complies with the tests and levels described.

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

EM Compliance (immunity)

This equipment complies with the tests and levels described.

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

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



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