



Securos Surgical

Oscillating TPLO Saw electroCUT

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Securos Surgical electroCUT TPLO Saw



1 Safety remarks

Our products are exclusively intended for professional use by appropriately trained and qualified personnel and may only be acquired by them.

All safety remarks in these operating instructions are marked with the symbol **!**.



Before using the saw, carefully read through these operating instructions and the valid national occupational safety regulations and act accordingly.

- *Please keep these operating instructions for later reference and always include them if the device is sold or passed on to third parties.*



Application in accordance with the intended application:

This device is intended for cutting bone for TPLO osteotomies in veterinary medicine.



Never rivet or screw signs or symbols onto the device, as this can render the protective insulation ineffective. We recommend using adhesive signs.



Only ever use undamaged plugs and cables. Check cables and plugs regularly.



The line voltage and specified voltage rating shown on the device must agree.



Only use original accessories.



Wear personal protective gear such as safety goggles, hearing protectors and gloves.



This device may only be used in veterinary hospitals, practices and orthopedic centers. The device must not be operated in areas at risk from explosion.

Manufacturer's guidelines - Electromagnetic emissions

The product is intended for use in the environment specified below. The customer or the user should assure that the product is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The product uses RF energy only for its internal function. Therefore, its RF emission is very low and is unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The product is suitable for use in facilities other than residential areas and those directly connected to the public power supply network, which also supplies buildings used for residential purposes, provided that the following warning is observed: Warning: The product is intended for use by medical professionals. In residential areas, this product may cause radio interference, in which case it may be necessary to take appropriate remedial measures, such as new orientation, new arrangement or shielding of the product, or filtering the connection to the site.
Harmonic emissions IEC 61000-3-2	Class A	
In accordance with IEC 61000-3-3 *Emission of voltage fluctuations / flicker emissions*		

Manufacturer's guidelines - Electromagnetic immunity


The product is intended for use in the environment specified below. The customer or the user should assure that the product is used in such an environment.

Immunity test	IEC 60601 test level	In accordance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Yes	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Yes	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Yes	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T *; ½ period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T *; 1 period and 70 % U_T *; 25/30 periods Single phase: at 0 degrees 0% U_T *; 250/300 periods	Yes	Main power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power main interruptions, it is recommended that the product is powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Yes	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

*NOTE: U_T is the mains voltage prior to application of the test level.

Guidelines and manufacturer's declaration - Electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V _{eff} 150 kHz to 80 MHz	Portable and mobile radios should not be used at a distance (including wires) less than the recommended protective distance of 30 cm from the device.
Radiated RF IEC 61000-4-3	6 V _{eff} ^a in ISM-Frequency bands 150 kHz to 80 MHz	6 V _{eff} ^a in ISM-Frequency bands 150 kHz to 80 MHz	The field strength of stationary radio transmitters determined during an on-site investigation should be below the compliance level at all frequencies. ^b
	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Interference may occur in the vicinity of equipment marked with the following symbol: 

Note These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a The ISM bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz, 13,553 MHz to 13,567 MHz, 26,957 MHz to 27.283 MHz and 40.66 MHz to 40.7 MHz.

^b The field strength of stationary transmitters, such as base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot theoretically be predicted exactly. In order to assure the proper electromagnetic environment with regard to stationary transmitters, a site investigation should be considered. If the measured field strength at the site where the equipment is used exceeds compliance levels, proper functioning of the device should be observed. In case of unusual operating behavior, additional measures may be necessary, such as a change in alignment or another location for the device.

Recommended separation distances between portable and mobile RF telecommunications equipment and the models listed

Determination against high-frequency wireless communication devices

Frequency band (MHz)	Test frequency (MHz)	Modulation	Compliance level (V/m)
380-390	385	Puls ^a – 18 Hz	27
430-470	450	FM ± 5 kHz stroke or Puls ^a – 18 Hz	28
704-787	710, 745, 780	Puls ^a – 18 Hz	9
800-960	810, 870, 930	Puls ^a – 18 Hz	28
1700-1990	1720, 1845, 1970	Puls ^a – 217 Hz	28
2400-2570	2450	Puls ^a – 217 Hz	28
5100-5800	5240, 5500, 5785	Puls ^a – 217 Hz	9

Note A minimum protective distance of 30 cm should be maintained between portable RF telecommunications equipment transmitting in the given frequency band and the equipment. This includes mobile phones, WLAN and RFID and Bluetooth devices. Failure to do so may result in degradation of the device's performance.

^a The pulse modulation is defined as a square wave signal with 50% duty cycle.

2 Scope

A hand-held electric-driven device (AC) to cut bone for TPLO osteotomies in veterinary medicine.

2.1 Intended Use

TPLO saws electric; Accessories, Saws: A hand-held, power-driven (AC) product for cutting bone for TPLO osteotomies in veterinary medicine.

When sawing bone, don't put too much pressure on the saw blade. Sawing works best with the saw's own weight so that the saw blade can oscillate freely. The saw cuts as the electric motor in the handle oscillates the blade. The cut is done by rotating or vibrating rather than by sawing.

2.2 Contraindications

There are no known contraindications.

3 Inserting / Removing



Danger of injury due to unintentional activation. Disconnect the plug before changing the saw blade. If applicable use thick gloves to prevent injury when handling the saw blade.

3.1 Inserting the saw blade on the electroCUT 3 TPLO Saw, "Triangle Hub".

1. Place the TPLO saw on a stable surface.
2. Apply hex wrench to hex screw on the connector shaft. (see fig.1).
3. Loosen the hex screw using the hex wrench without completely removing the hex screw.
4. Insert the TPLO saw blade.
5. Tighten the hex screw using the hex wrench. Do not over tighten.

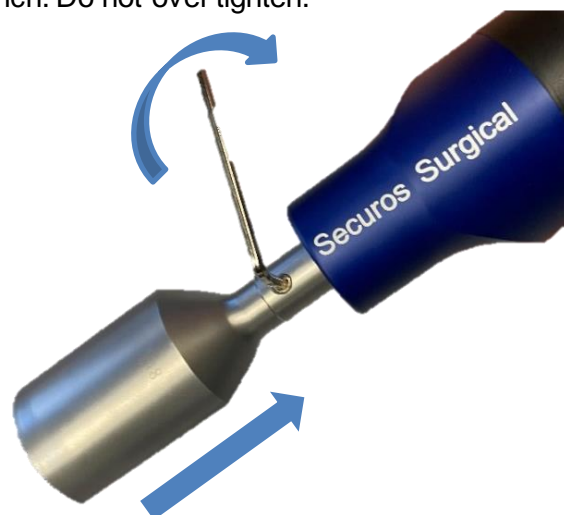


fig. 1:
Tighten the hex screw

3.2 Inserting the saw blade on the electroCUT 4 TPLO Saw, “4-Point Hub”.

1. Place the TPLO saw on a stable surface.
2. Position the new saw blade.

Important!

The notches in the saw blade must be positioned flush against the spigots of the drive shaft.

3. Position the washer. The notches in the washer must point toward the saw and positioned against on the spigots (see fig. 2).
4. Tighten the screw by hand.
5. Use the fork wrench to hold the shaft while tightening the blade assembly with the T-handle wrench (see fig. 2.1).

The tightening torque is 6 - 7 Nm. Caution! Do not over tighten.

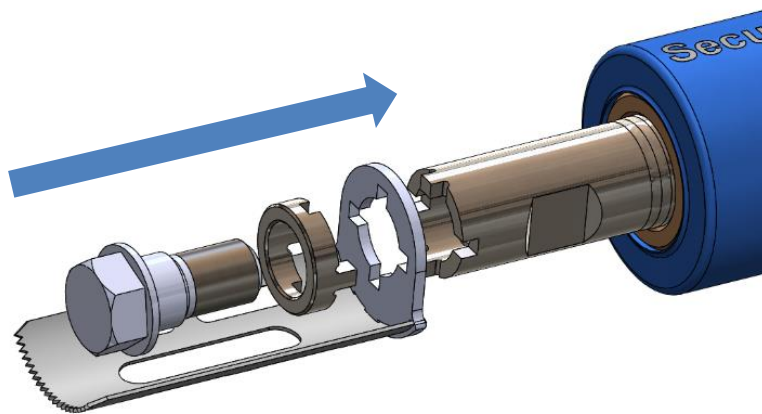


fig.2:
Assembling the parts of the 4-point hub (screw + washer + saw blade)

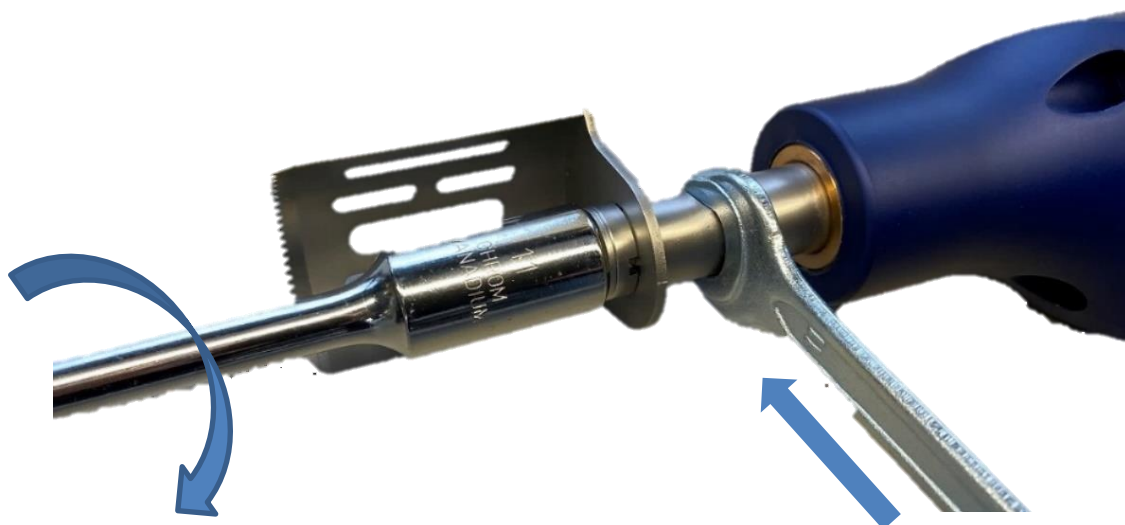


fig.2.1:
Tightening the screw

3.3 Removing the saw blade on the electroCUT 3 TPLO Saw, “Triangle Hub”.

1. Place the saw on a stable surface.
2. Apply hex wrench to hex screw on the connector shaft. (see fig.3).
3. Loosen the hex screw using the hex wrench without completely removing the hex screw.
4. Pull out the TPLO saw blade.

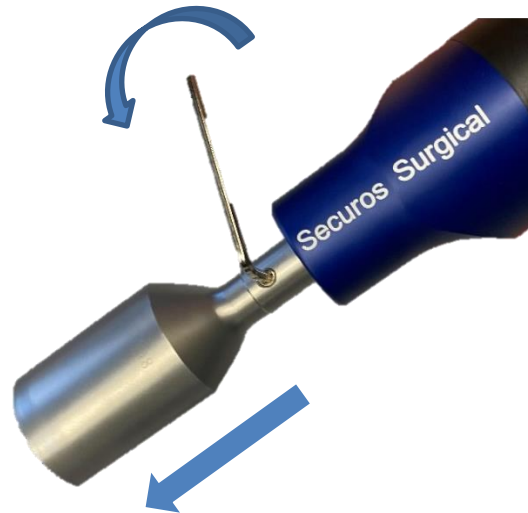


fig.3:
Loosening the hex screw

3.4 Removing the saw blade on the electroCUT 4 TPLO Saw, “4-Point Hub”.

1. Place the saw on a stable surface.
2. Apply the fork wrench to the drive shaft behind the saw blade and the T-handle wrench at the front on the screw (see fig. 4).
3. Hold the fork wrench firmly and loosen the screw using the T-handle wrench.
4. Remove the screw and the washer. Ensure that you do not lose any components.
5. Remove the saw blade.

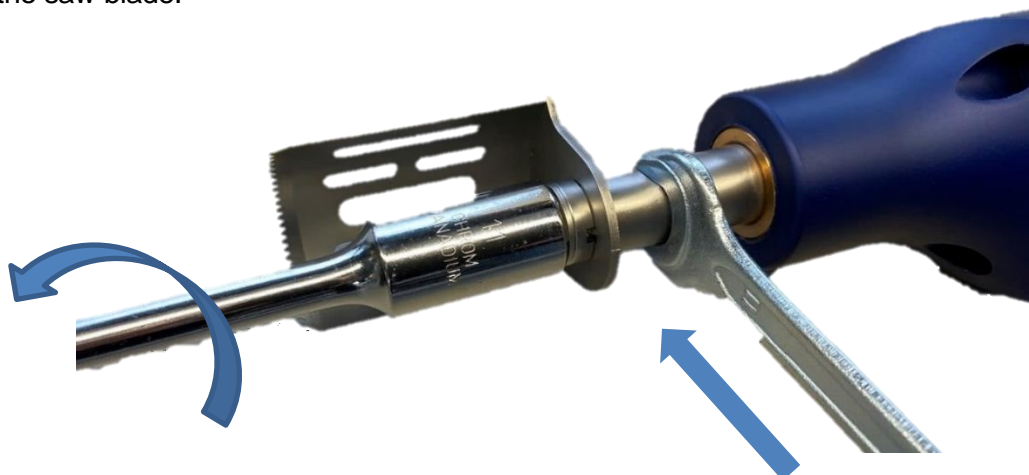


Fig. 4:
Loosening the screw

4 System Setup

Switching the saw on and off (see fig. 5)

Switching on: Slide finger forward against touch sensitive power switch from OFF to ON (I)

Switching off: Slide finger back against touch sensitive power switch from ON to OFF(0)



fig. 5

Setting the oscillating frequency (see fig. 6)

Use the electric cable to connect the saw to the electric console. Once connected, select the speed (oscillating frequency) on the electric console while the motor is running.

Numbered speed settings:

- (1) 9,000 rpm
- (2) 9,830 rpm
- (3) 10,670 rpm
- (4) 11,500 rpm
- (5) 12,330 rpm
- (6) 13,170 rpm
- (7) 14,000 rpm



fig.6

Recommended use:

We recommend a maximum continuous operation of 8 minutes. This saw is not ventilated due to its structural design and is sealed to enable sterilization.

Thereafter, a cooling time of 30-40 minutes is necessary for the saw to reach a comfortable temperature.

4.1 Operation of optional foot pedal

Connect the foot pedal to the electric console (see fig.7+7.1). The on/off switch on the hand piece and the speed (oscillating frequency) settings on the electric console will not operate the saw while the foot pedal is connected to the electric console. Use the pressure-sensitive foot pedal to control the speed of the saw while it is connected.



fig. 7
Electric Console with foot pedal



fig. 7.1
Plug with push/pull

5 Cleaning, maintenance and sterilization



Danger of injury through unintentional activation. Disconnect the plug before any cleaning or maintenance work.

The electroCUT TPLO saw (800109/800105) and the electric cable (800108) between the hand piece and the electric console are waterproof and can be cleaned and sterilized as follows:

On the basis of international standards (EN ISO 15883) and national directives, only validated machine cleaning and disinfection methods may be used.

The chemical cleaning should take place at 40°C -60°C / 104°F-140°F for at least 5 minutes. We recommend products with a pH-value within 9-10. MediClean forte from Dr.Weigert

The thermal disinfection should take place at temperatures of between 80-95°C / 176-203°F, with an exposure time as outlined in EN ISO 15883.

Ensure adequate drying by the cleaning and disinfection device or using other suitable measures. The drying temperature should not exceed 95°C / 203°F to avoid material-related ageing processes.

Prior to sterilization, products must undergo cleaning and disinfection, be rinsed off without residue using demineralized water and subsequently dried. Use a validated steam sterilization process (e.g. sterilizer in compliance with EN 285 and validated in accordance with DIN EN ISO 17665-1).

Maintenance

Wipe disinfection is suitable for motor housing, cable, power plug and all accessories, such as saw blades and an open-end wrench. For this purpose, we recommend products with a pH-value within 9-10, e.g. MediClean forte from Dr. Weigert. It is important to ensure that the device is disconnected from the power supply and the disinfecting liquid does not enter the interior of the power supply.

Otherwise no further maintenance is necessary.

Sterilization Parameters

Pre-Vac Steam

Steri-Time	3 minutes	3 minutes
Min. Temperature	132°C - 134°C / 270 °F - 273°F	132°C - 134°C / 270 °F - 273°F
Min. Dry Time (Vac-Drying)	20 minutes	40 minutes
Materials	no wrapping	single or double wrap

Gravity-Displacement Steam

Steri-Time	4 minutes	4 minutes
Temperature	134°C / 273°F	134°C / 273°F
Min. Dry Time	60 minutes (slightly open door for cool down)	60 minutes (slightly open door for cool down)
Materials	no wrapping	single or double wrap

Information on instrument preparation and sterilization:

- Use cleaning and/or disinfection agents with a pH-value within 9-10.
- Please observe manufacturer instructions regarding dosage, exposure time and renewal of solutions.
- Do not use hard brushes or coarse abrasive cleaners.
- Never leave instruments in cleaning or disinfection agents for longer than the specified time.
- Only used demineralized water for rinsing.
- Observe manufacturer instructions of cleaning and sterilizing equipment.

Disinfection wipers are suitable for power supply and power cord. For this purpose, we recommend products with a pH-value within 9-10, e.g. MediClean forte from Dr. Weigert.

6 TPLO Saws & Accessories

800114	electroCUT 3 TPLO Saw System (Saw with Triangle Hub, Cable, Console, Foot Pedal) & EU Wall Plug
800116	electroCUT 3 TPLO Saw System (Saw with Triangle Hub, Cable, Console, Foot Pedal) & UK Wall Plug
800104	electroCUT 3 TPLO Saw System (Saw with Triangle Hub, Cable, Console, Foot Pedal) & US Wall Plug
800113	electroCUT 4 TPLO Saw System (Saw with 4-Point Hub, Cable, Console, Foot Pedal) & EU Wall Plug
800115	electroCUT 4 TPLO Saw System (Saw with 4-Point Hub, Cable, Console, Foot Pedal) & UK Wall Plug
800103	electroCUT 4 TPLO Saw System (Saw with 4-Point Hub, Cable, Console, Foot Pedal) & US Wall Plug
800109	electroCUT 3 TPLO Saw, Triangle Hub
800105	electroCUT 4 TPLO Saw, 4-Point Hub
800106	Foot Pedal
800108	Electric Cable
800107	Electric Console
800110	Wall Plug - US
800111	Wall Plug - EU
800112	Wall Plug - UK
800117	Hex Screw for Triangle Hub (Included with saw)
800118	Hex Wrench 2.5mm for Triangle Hub (Included with saw)
800119	Screw & Washer for 4-Point Hub (Included with saw & blade adapter)
800120	Wrench set for 4-Point Hub (Included with saw)
800101	Plastic Carrying Case, Non-Sterile
800102	fineCUT TPLO Blade Adapter (Fits TPLO saws with standard triangle hub.)

7 Servicing

The electroCUT TPLO saw should be sent to Securos Surgical every year for annual servicing, or 20 hours of operation, whichever comes first.

DO NOT LUBRICATE.

8 Warranty


The electroCUT system is warranted to be free from defects in material and workmanship to the original purchaser for a period of one year from the date of purchase. Warranty is limited to repair or replacement (at the discretion of the manufacturer) of the product without charge. Securos Surgical reserves the right to void the manufacturer's warranty in the event of abuse, misuse, disassembly, alteration, neglect, unauthorized repair, non-recommended usage and/or non-compliance per the Operating Instructions furnished by Securos Surgical. All other expressed or implied warranties are excluded and Securos Surgical shall have no liability of any kind for incidental or consequential damages.

9 Environmental protection

Any packaging materials, disused devices and accessories should be sent for environmentally friendly recycling or disposal. Electrical devices may not be disposed of with household waste but taken to the local disposal and recycling facility for electrical devices.



10 Specifications

Model	# 800105 and # 800109
Mains connection	110-240 Volt, 50/60 Hz.
Rated current consumption	105 Watt
Current type mains connection	1 ~
Current type handle	32 V =
Oscillations	ca. 9000 - 14000 min ⁻¹ / rpm
Weight	0,7 kg / 1,543 lbs
Classification Applied Parts	BF 
IP Code	IP67
Noise level (A-graded)	50-60 dB (A).
Hand-arm vibration	Typically, lower than 2.5 m/s ² or 492,145 Feet/Minute Measured values determined in accordance with EN 50 144.

11 Securos Surgical service contact information

United States

FISKDALE, MASSACHUSETTS

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