Electric Dermatome Instruction Manual

INDICATIONS FOR USE

The Zimmer® Electric Dermatome is a skin grafting instrument that is intended to provide variable graft thickness and width capabilities.

DESCRIPTION

The Zimmer Electric Dermatome (See Fig. 1) is an electrically-powered surgical skin grafting instrument. The thickness control adjustment ranges from 0 to 0.030 in. (0.75 mm) in 0.002 in. (0.050 mm) increments. Individual graft widths of 1 in., 1.5 in., 2 in., 3 in. and 4 in. (2.5 cm, 3.8 cm, 5.1 cm, 7.6 cm, 10.2 cm) are obtained with five width plates. Two stainless steel machine screws secure the plates to the underside of the instrument. The plates are easily fastened and removed with the screwdriver provided. The dermatome is powered by an ironless rotor, low inertia motor, which provides nearly vibration-free power.

SPECIFICATIONS

I. POWER SUPPLY

I. Physical: Weight: 2.6 lb. (1.18 kg); Length: 9.12 in. (23.2 cm); Height: 5.44 in. (13.8 cm); Width: 6.69 in. (17.0 cm)

II. Electrical: Power Requirements: 100–240 V~ (Auto Switching; 150 VA, 50/60 Hz; Single Phase; Power Output: 14.5 V, 4.3 A Maximum ; Protection Class: Class 1; Degree of Protection Against Electrical Shock: Type BF

II. HANDPIECE

I. Physical: Weight: 2.1 lb. (.95 kg); Width: 8.5 in. (21.6 cm); Length: 5.2 in. (13.2 cm); Vibration and Shock: Standard Commercial Practice; Nominal Speed: 4,500–5,500 cycles/minute

II. Electrical: Power Requirements: 14.5 V , Fully Regulated and Isolated, 4.3 A Maximum

III. Operational: Nominal Speed: 4,500-5,500 cycles/Minute

UL 60601-1 Classification:

Type of protection against electric shock:	Class I
Degree of protection against electric shock:	Type BF applied part
Classification according to the degree of protection against ingress of water:	IPXO
Mode of operation:	Continuous operation
Maximum operating ambient:	88°F (31°C)

Emissions / Immunity:

The Electric Dermatome complies with EMC criteria set forth in EN 60601-1-2.

POWER SOURCE

The unit is shipped with a 0.25 in. $(6.35 \text{ mm}) \times 1.25 \text{ in}$. (31.75 mm) fuse drawer installed. A separate fuse drawer is supplied for 0.197 in. $(5 \text{ mm}) \times 0.787 \text{ in}$. (20 mm) fuses. To replace input fuses, disconnect the power supply from the power source. Remove the fuse drawer by lifting up on the tab using a tool and pulling the drawer outward. (See Fig. 6.) Replace the fuse drawer with the correct fuses installed.

FUSES

Input fuses are located in the fuse drawer in the power entry module at the rear of the power supply. 250 V \sim 1.25 A time lag/delay.

WARNINGS AND PRECAUTIONS

To avoid serious injury to the patient and operating staff while the Zimmer Electric Dermatome is in use, the user must be thoroughly familiar with its function, application, and instructions for use.

To avoid injury, use extreme caution when handling the blade or when handling the dermatome with the blade installed.

Use caution when inserting blade to avoid nicking it, which may result in an uneven cut. To avoid blade damage, place dermatome blade side up when not in use.

The throttle must be in the SAFE position before changing blades, when connecting power to the instrument, or when the instrument is not in use. Accidental activation of the instrument during these procedures may injure the patient or operating staff. To ensure that the instrument is in the SAFE position, the safety lock on the throttle should be toward the blade end of the dermatome and only the word SAFE should be visible.

Handle the Zimmer Electric Dermatome carefully. Should it be inadvertently dropped or damaged, it should be serviced. Do not use.

Use only Zimmer Dermatome Blades (REF 00-8800-000-10). The Zimmer Dermatome Blade has been specifically designed and engineered for use with the Zimmer Electric Dermatome. Other blades may not fit properly in the dermatome and may cause serious injury. Use of non-Zimmer Dermatome Blades can cause the dermatome to take grafts deeper than what the user has selected. Never connect the Zimmer Electric Dermatome Handpiece to any source other than the Zimmer Electric Dermatome Power Supply. It has been factory calibrated to provide optimum cutting performance and maximum safety. It is also designed to meet or exceed specific medical electrical safety standards.

Ground reliability can only be achieved when the power cord is connected to a receptacle marked "HOSPITAL GRADE". Use only the power cord marked "HOSPITAL GRADE" supplied or one that complies with all local and electrical requirements but does not exceed 10 feet (3.05 meters).

For continued protection against fire hazard, replace only with the same type and rating of fuse. Refer to FUSES section.

Possible explosion hazard exists if this instrument is used in the presence of flammable anesthetics or gasses.

Never sterilize the power supply. Disconnect the dermatome handpiece from the power supply before sterilization.

The user and operating staff must always pay close attention to the CLEANING PRECAUTIONS and CLEANING INSTRUCTIONS FOR THE DERMATOME. Failure to follow these instructions may damage the dermatome.

IMPORTANCE OF THE NEED TO ADHERE TO A CARE REGIMEN

The handpiece and accessories must be inspected prior to each use.

• Visually inspect for damage and/or wear.

• Always inspect the handpiece carefully for possible scratches, nicks, or burrs caused by extended use or mishandling.

- Inspect the dermatome's cord for cuts or missing insulation caused by extended use or mishandling.
- Check the action of moving parts to ensure smooth operation throughout the intended range of motion.

• Annual calibration checks are strongly recommended to verify continued accuracy. Note: If damage or wear is noted that may compromise the function of the instrument, do not use.

SETUP INSTRUCTIONS

• Observe sterile field precautions per hospital protocol.

• Connect the Zimmer Electric Dermatome to the power supply by inserting the connector plug into the connector receptacle. (See Fig. 7.) Remove any kinks or twists from the cord. Align the connector plug to the receptacle by rotating the plug while gently pushing inward. When aligned, push in until the plug clicks into the receptacle.

Note: Older Zimmer Dermatomes and Power Supplies were equipped with a metal connector plug and receptacle. The metal connectors have been upgraded to plastic connectors for ease of use. The older metal connectors are not compatible with the plastic connectors.

• Before connecting the power supply to a power source, be sure that the switch on the front of the power supply is in the OFF (O) position and that the safety lock on the Zimmer Electric Dermatome is in the SAFE position. Connect to a power source via the "IEC" connector in the rear of the power supply.

• Turn power on by moving the rocker switch on the front of the power supply to the ON (I) position. The rocker switch should illuminate. Activate the dermatome by completely depressing the throttle lever with the safety lock in the ON position. Return the safety lock to the SAFE position, when not in use.

• During set-up procedure, visually inspect for damage and/or wear. If damage or wear is noted that may compromise the function of the instrument, do not use.

BLADE INSTALLATION (See Fig. 5.)

• Use a new sterile blade for each procedure. Use only Zimmer Dermatome Blades (REF 00-8800-000-10).

• To install blade:

- Place the throttle in the SAFE position. To place the dermatome in the SAFE position, slide the safety lock on the throttle toward the blade end of the instrument to the SAFE position. Only the word SAFE should be visible.
- Using a screwdriver, loosen width plate screws approximately two turns. Do not remove screws from handpiece.
- Place a new blade in slot on the handpiece. If replacing a blade, remove the used blade before inserting a new one. Refer to BLADE REMOVAL section.
- Mate the drive pin with the hole in the blade. Note: "INSERT WITH THIS SIDE UP" message.
- Lubrication of the blade is not necessary because the backing of the blade is a self-lubricating plastic.
- Choose proper width plate to satisfy cutting requirements. Place width plate over blade and tighten screws. Do not overtighten. Ensure the printing on the width plate is facing out. (See Fig. 5.)

CUTTING THE GRAFT

• Skin should be prepared in routine manner.

• It is not necessary to lubricate the skin; however, lubricating the donor site with sterile mineral oil may ease travel of the Zimmer Electric Dermatome.

• Set control lever adjustment knob pointer to desired graft thickness. Factory calibrations indicate 0.002 in. (0.050 mm). Do not insert any instrument between the blade and the control lever as this may damage or knick the blade causing a poor cut. Further, it may compromise the calibration of the instrument. (See Fig. 8.)

• Hold the handpiece on the donor site at a $30^{\circ} - 45^{\circ}$ angle. (See Fig. 10, 11.)

• To activate the dermatome, place the power supply in the ON (I) position. Lift the throttle lever and slide the safety lock back from the SAFE position toward the hose coupling. The word ON should be visible. (See Fig. 9.) For optimum results, it is recommended that the dermatome operate at full speed. To ensure that full speed is achieved, completely depress the throttle control with the safety lock in the ON position.

• Depress the throttle to start the cut. Guide the unit forward using a slight downward pressure to ensure that the cutting edge remains continuously firmly in contact with the donor site.

- Two methods of graft removal from the instrument may be used:
 - Method I

Allow the cut graft to accumulate in the pocket of the handpiece. Lift the handpiece away from the donor site to end the graft. Return the throttle to the SAFE position and carefully remove the graft. (See Fig. 10)

Method II

Use tissue forceps to gently lift the graft as it emerges from the pocket area. Do not stretch or pull the graft as this causes irregular edges and nonuniform cuts. Lift the handpiece away from the donor site to end the graft. Return the throttle to the SAFE position. (See Fig. 11.)

• Do not run the Zimmer Electric Dermatome without cutting for an extended time. Release the on/off lever and return the safety lock to the SAFE position between cuts to remove the graft.

AFTER THE PROCEDURE

• Unplug from wall receptacle.

• To remove the Zimmer Electric Dermatome connector plug from the power supply, pull outward on the outer sleeve of the plug to separate the plug from the receptacle.

• Remove the used blade and dispose of properly in designated sharps container or per hospital protocol.

• Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.

• Return and secure instrument and width plates to instrument case for transport and cleaning.

BLADE REMOVAL

• Loosen the width plate screws. Do not remove the screws.

• To remove the width plate, hold both sides and lift. Do not lift the width plate from the front as this will cause contact with the blade and possible injury.

• Remove the blade carefully lifting from the side.

• Dispose of used blade in a sharps container or per hospital protocol.

CLEANING PRECAUTIONS

All subsequent cleaning and sterilization steps are facilitated by not allowing blood, tissue debris, or disinfectants to dry on used instruments.

Handle the Zimmer Electric Dermatome carefully. Should it be inadvertently dropped or damaged, it should be serviced.

Refer to NEED TO ADHERE TO CARE REGIMEN section.

Do not lubricate the Zimmer Electric Dermatome. Lubrication may cause extensive damage to the motor.

Never immerse the dermatome in any solution. Some solutions will corrode the metal and delicate moving parts and also break down the internal lubricants.

Never immerse the dermatome in liquid chemical disinfectant.

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Saline solution has a corrosive effect on stainless steel and should not be used.

Do not process the dermatome handpiece or accessories in an automatic washer/sterilizer.

Never clean in an ultrasonic cleaner. Ultrasonic cleaning will dislodge oil from the bearings and render the instrument inoperative. Ultrasonic cleaning may affect calibration of the Zimmer Electric Dermatome.

Never sterilize the power supply or immerse it in any solution.

Steam sterilize the Zimmer Electric Dermatome and accessories (except power supply). Follow instructions in STERILIZATION RECOMMENDATIONS.

CLEANING INSTRUCTIONS FOR THE DERMATOME

• Ensure the Zimmer Electric Dermatome has been fully disconnected from the power supply.

• Use caution when handling the dermatome to determine that the used blade has been removed. If not, safely dispose of all used blades in accordance with hospital policy for contaminated waste and sharps.

• Never let water or detergent enter the handpiece. Permanent damage may result. (See Fig. 13.)

• Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.

Universal precautions for handling contaminated/biohazardous materials should be observed.

• Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

• Prepare cleaning agents at the use-dilution and temperature recommended by the manufacturer.

• Thoroughly scrub the instrument with a soft-bristled brush and a pH neutral detergent. If desired, a neutral pH enzyme solution may be used prior to scrubbing with the detergent. Use the soft-bristled brush to gently clean the instrument, paying particular attention to any crevices and other hard-to-clean areas until all visible soil has been removed. (See Fig. 12.) Note: the cleaning solution should be changed if it becomes grossly contaminated (bloody and/or turbid).

• The thickness control lever should be moved during cleaning to release any debris which may be trapped under the lever or in the notches.

• The cavity which housed the oscillating drive pin should be rinsed clean and the water shaken out. This will prevent the accumulation of deposits in this cavity.

• Rinse all detergent from the instrument. Purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) is recommended. (See Fig. 13.)

• If there continues to be blood or soil in the rinse stream, repeat proceeding two steps with freshly prepared cleaning solution.

• Dry the instrument with a clean, disposable, absorbent, non-shedding wipe. (See Fig. 14.)

• Carefully inspect each instrument to ensure that all visible blood and soil has been removed.

• Visually inspect for damage and/or wear.

• Check the action of moving parts to ensure smooth operation throughout the intended range of motion. Note: If damage or wear is noted that may compromise the function of the instrument, do not use.

• Steam sterilize only. Follow instructions in STERILIZATION RECOMMENDATIONS.

CLEANING INSTRUCTIONS FOR THE POWER SUPPLY

- Ensure the power supply has been fully disconnected from the power source.
- Clean the power supply with a damp, lint-free cloth using a pH neutral detergent.
- An alcohol wipe may be used to disinfect the surface of the power supply.
- Never immerse the power supply.

STERILIZATION RECOMMENDATIONS

Steam sterilization is safe and effective, and is the only recommended method for the dermatome. There are no contraindications for sterilizing the Zimmer Electric Dermatome and accessories.

Ethylene oxide sterilization is not recommended because reliable outgassing times are difficult to determine for lubricated powered instruments.

Never sterilize the power supply. Disconnect the dermatome from the power supply before sterilization.

- Place cleaned instruments in an instrument tray or fully perforated autoclave case. The Zimmer Dermatome Autoclave Case (REF 00-8801-003-00) is recommended. (See Fig. 18.)
- Do not kink or crimp the dermatome's cord when closing the case lid.
- If the Zimmer Dermatome Autoclave Case is used, the instruments are to be wrapped, two double thicknesses of #140 thread count wrappers, or equivalent. If sterilization wraps are used, they must be free of detergent residues. Foam sheets should not be reused. They may have trapped impurities from the steam supply, and subsequently may form deposits on the instruments. Textiles that have been scorched by overheating also may form deposits on instruments. Exposure times are the same for wrapped or unwrapped instruments.
- Follow instructions in RECOMMENDED STEAM STERILIZATION PARAMETERS.
- Do not immerse in liquid to cool. Cool by exposure to room temperature or cover with a cold, sterile towel.

RECOMMENDED STEAM STERILIZATION PARAMETERS

СусІе Туре	Minimum	Pressure ₆	Minimum Exposure Time ₇		Minimum
	Temperature		Wrapped 8,9	Unwrapped ₁₀	- Dry Time 3,11
Prevacuum/ Pulsating Vacuum 1,3	134°C 273°F	3bar 28.5 psi	3 min	3 min	
Prevacuum/Pulsating Vacuum 2,3	132°C 270°F	1.86bar 27 psi	4 min	4 min	8 minutes
Prevacuum/Pulsating Vacuum 3,4	134°C 273°F	3bar 28.5 psi	18 min	18 min	
Prevacuum/Pulsating Vacuum 5	132°C 270°F	1.86bar 27 psi	8 min	8 min	
Gravity/Gravity Displacement	Not recommen practical.	ded due to exc	essively long sterili	zation cycles whic	h are not

1. Minimum validated steam sterilization time required to achieve a 10-6 sterility assurance level (SAL). 2. Minimum validated steam sterilization temperature required to achieve a 10-6 sterility assurance level. 3. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table. 4. Disinfection /steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination. 5. For Universal Instrument Cases without defined load configurations. 6. Sea level. 7. AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable. 8. Medical grade steam sterilization compatible wrap equivalent to four thicknesses of 140-thread-count muslin. 9. Rigid sterilization container that complies with ANSI/AAMI ST46. 10.Flash (unwrapped) sterilization by exposure at 132°C/270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled. 11. Drying times vary according to load size and should be increased for larger loads.

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

Flash sterilization (10-minute exposure in a gravity displacement sterilizer in an open tray at 270°F [132°C]) is not recommended for the Zimmer Electric Dermatome as this method may not provide sterility throughout the instrument.

STORAGE CONDITIONS

–40 to +85°C.

ACCESSORIES (See Fig. 15–22.)

Description: Blades (10 per box)

REF: 00-8800-000-10

Description: Zimmer Electric Dermatome Complete (includes: 00-8821-001-00, 00-8801-003-00, 00-8821-006-00)

REF: 00-8821-000-00

Description: Zimmer Electric Dermatome Handpiece (includes: 00-8802-001-00, 00-8802-002-00, 00-8802-003-00, 00-8802-004-00, 00-8803-000-00)

REF: 00-8821-001-00

Description: Power Supply (includes: Fuse drawer, 5 mm x 20 mm; Fuses, 1.25 A (QTY 2) Fuses, 800 mA (QTY 2); Power Cord)

REF: 00-8821-006-00

Description: Autoclave Case

REF: 00-8801-003-00

Description: 1 in. (2.5 cm) Width Plate

REF: 00-8802-001-00

Description: 1.5 in. (3.8cm) Width Plate

REF: 00-8802-015-00

Description: 2 in. (5.1 cm) Width Plate

REF: 00-8802-002-00

Description: 3 in. (7.6 cm) Width Plate

REF: 00-8802-003-00

Description: 4 in. (10.2 cm) Width Plate

REF: 00-8802-004-00

Description: Screwdriver

REF: 00-8803-000-00

Description: Width Plate Screws (10 per pack)

REF: 00-8803-001-10

TROUBLESHOOTING GUIDE

PROBLEM	ACTION
Dermatome not operating. Power light off.	Check input fuses. Check power cord connections.
	Have unit serviced.
Dermatome not operating. Power light on.	Check blade fit. Check handpiece connection to
	power supply. Have unit serviced.
Dermatome operating too slowly.	Check dermatome for damage. Check blade for
	damage. Have unit serviced.
Erratic speed changes.	Check handpiece connection to power supply.
	Have unit serviced.

SERVICE INFORMATION

Annual calibration checks are strongly recommended to verify continued accuracy.



- A. Autoclave Case
- B. Power Supply
- C. Screwdriver
- D. Width Plates
- E. Handpiece





- A. Front
- B. Mains Switch
- C. Connector Receptacle
- D. Power Entry Module
- E. Back



- A. On/Off Safety Lock
- B. On/Off Lever
- C. Handpiece
- D. Connector Plug
- E. Thickness Control Lever



- A. Screwdriver
- B. Width Plate
- C. Blade
- D. Drive Pin Hole
- E. Drive Pin











METHOD I

- A. Handpiece
- B. Pocket



METHOD II

A. Handpiece

B. Forceps















