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INDICATIONS FOR USE

The **2** Dermatome AN is a skin grafting instrument that is intended to provide variable graft thickness and width capabilities.

DESCRIPTION

The **2** Dermatome AN (see Figures 1, 2 and 3) is an air-powered surgical skin grafting instrument. The thickness control adjustment ranges from 0.004 in. (0.1 mm) to 0.024 in. (0.6 mm) in 0.002 in. (0.05 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 and 10.2 cm) are obtained with five width plates (see Figure 10). One stainless steel machine screw secures the plates to the underside of the instrument (see Figure 21). The plates are easily fastened and removed with the screwdriver provided (see Figure 22).

The dermatome has a self-cooling rotary-cup air motor. This motor is powered by water-pumped compressed dry nitrogen (99.97% pure) or by medical-grade compressed air and provides nearly vibration-free power.

SPECIFICATIONS

A. Physical Weight: Length: Width: Exhaust:	28 in. (714 g) 6.92 in. (22.68 cm) 5.15 in. (13.18 cm) Detachable hose with exhaust 10 feet (3.05 m) from surgical site
B. Operational No-load speed: Recommended Power Source: Operating Pressure: Consumption:	4,500-6,500 cycles/minute Water-pumped compressed dry nitrogen (99.97% pure) Where nitrogen is not available, medical-grade compressed air may be used. 100 PSI (680 kPa) running 8 CFM maximum

POWER SOURCE

Nitrogen (preferred) or medical-grade compressed air:

Compressed dry nitrogen is the preferred power source. Where nitrogen is not available, medical-grade compressed air can be used. These gases should meet the following specifications to ensure optimum safety for both patient and instrument:

Nitrogen:
 Oxygen content: 99.97% pure, dry nitrogen
 Quality assurance: To obtain the quality of gas needed, "water-pumped dry nitrogen or liquid nitrogen, pumped dry" should be specified.

Medical Grade compressed air:

Oxygen: 21% ± 0.5%
 Nitrogen and inert gases: Balance
 Moisture: 15.0 ppm (max)

Note: Use only compatible air hoses conforming to ISO 5452 for high pressure medical-grade compressed air.

The **2** Dermatome AN should be operated at 100 PSI (680 kPa) for maximum operating efficiency and should be monitored with the operating pressure gauge of the regulator. When using the recommended hose, pressure must be set out with the instrument running to avoid excessively low operating pressure.

WARNINGS AND PRECAUTIONS

To avoid serious injury to the patient and operating staff while the **2** Dermatome AN is in use, the user must be thoroughly familiar with its function, application and instructions for use.

Use only **2** Dermatome Blades (P07 86700070). The **2** Dermatome Blade has been specifically designed and engineered for use with the **2** Dermatome AN. Other blades may not fit properly in the dermatome and may cause serious injury. Use of non-**2** Dermatome Blades can cause the dermatome to take grafts deeper than what the user has selected.

Blade is sterile only if package is unopened and undamaged.

Blade is sharp. Handle with care.

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 making it, which may result in an uneven cut. To avoid blade damage, place the dermatome with blade side up when not in use.

The handle must lie in the SAFE (S) position before changing blades or hoses, 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 (S) position, the safety lock on the handle should be toward the blade end of the dermatome and only the SAFE (S) symbol should be visible.

Handle the **2** Dermatome AN carefully. Should it be inadvertently dropped or damaged, it should be returned for service. Do not use.

Do not use a worn or damaged hose. Under pressure, a severed or broken hose can whip out of control.

Be sure the hose is securely fastened to the instrument so that the hose will not fall against a hard surface and become damaged.

Never use standard compressed air with the **2** Dermatome AN. Standard compressed air directly from a compressor can contain impurities, oils, and moisture that can damage the dermatome.

The automatic shut-off valve in the end of the hose (see Figure 4) permits removal and reconnection of the hose under pressure. Use care to prevent oil or debris from entering the end of the handle when the hose/detachable hose is reconnected.

Never operate the **2** Dermatome AN above recommended pressures. Excessive pressure may cause internal damage and exert unusual stress on the hose.

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

Reuse of a single-use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

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 reworking.
- Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
- The **2** Dermatome AN should be returned every 12 months for inspection and preventive maintenance. Annual factory 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. Refer to **REPAIR AUTHORIZATION AND REPLACEMENT INFORMATION** section.

RECEIVING INSPECTION

After receiving the **2** Dermatome AN, examine the unit for external signs of damage. Return all received material and items to the supplier if any damage is observed. If the supplier has not been performed, if the device has been damaged, forward an immediate request to the delivering carrier to perform an inspection and prepare a "Confirmed Damage" report. The terms of all Surgical Supply agreements concerning this unit are in (C.B., Dover, Ohio, U.S.A.), and the responsibility of Zimmer Surgical ends with delivery to the final carrier. Therefore, the shipment becomes the property of the customer. Any claims for loss, damage, or non-delivery must be made against the delivering carrier within 10 days of shipment.

Your local Zimmer Biomet sales representative may assist you in determining the cost of replacement or repair so that a proper claim may be filed with the delivering carrier.

Note: Do not attempt to return damaged goods without first securing proper authorization from the delivering carrier.

SETUP INSTRUCTIONS

- Prior to initial usage, **2** Dermatome AN must be cleaned and sterilized per instructions (see **CLEANING PROCESS AND STERILIZATION PROCEDURE** instructions).
- Connect the handpiece to the hose by grasping both the lock on the end of the handpiece and the hose body. Push together and twist the hose to the right so that the pins are in the indentations (see Figure 4).
- When using a pressure tank, the tank should be thoroughly wiped off with disinfectant and placed prior to placement in the operating room. Always leave the tank securely fastened to the wall, a stable cart or some other stationary device to prevent falling, and keep it away from entrances of feet.
- Prior to setup in the operating room, open the tank valve very slowly and allow only enough gas to escape to blow out any debris that may have accumulated in the valve. Stay clear of the opening, behind the tank, during this procedure. Return the valve to the closed position. Install the regulator.
- Once the regulator is securely installed, be certain the regulator is in the full OFF position. The tank valve may then be opened slowly until it is fully open, which will allow the gas to pressurize the regulator.
- Never start a procedure if the pressure gauge indicates that there is less than 500 PSI (345 kPa) in the tank. Never allow the tank pressure to fall below 500 PSI (345 kPa), or correct output pressure will not be maintained.
- Insert the diffuser end of the hose into the quick-disconnect fitting on the regulator.
- Activate the dermatome by completely depressing the throttle lever with the safety lock in the (S) (S) position. Pressure is established by gradually turning the regulator control knob. Always maintain the designated pressure using the pressure gauge with the instrument running. Recommended pressure is 100 PSI (680 kPa) running, using a recommended hose. When using an extension hose, increase the pressure of the source 1 PSI per foot (22.5 kPa) of extension hose. For example, if a 10 foot (3.05 meter) extension hose is added to the standard hose, indicated pressure at the source should be 110 PSI (758 kPa) when the dermatome is running. Return the safety lock to the SAFE (S) position when the dermatome is not in use.
- During set-up procedure, carefully inspect the dermatome handpiece and hose for damage and/or wear. If damage or wear that may compromise the function of the instrument is noted, do not use.

Deral Tone Instruction Manual

A Gutmann



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