

# Meshgraft™ II Tissue Expansion System Instruction Manual

## INDICATIONS FOR USE

The Meshgraft II Tissue Expansion System (See Fig. 1–3) is intended to create perforations in a skin graft so it can be expanded to cover a recipient site that is larger than the donor site. Use of the Meshgraft II System also provides improved drainage, increased edge exposure, minimal contracture and conformance to irregular body surfaces.

## DESCRIPTION

The Meshgraft II Tissue Expansion System is a manually operated instrument used with a Dermacarrier™ II Skin Graft Carrier to obtain greater area coverage from a conventional sheet graft. It consists of a continuous feed roller, a cutter, a guidance plateau, a ratchet handle, and a curved stabilizing bar/carrying handle. The guidance plateau ensures proper alignment of the Dermacarrier II Skin Graft Carrier and the cutter. The ratchet handle facilitates proper advancement. The variable expansion ratios\* available (See ACCESSORIES) permit the user to adapt the expansion ratio to the specific surgical procedure. The degree of expansion selected is determined primarily by the contour of the recipient site. It is desirable to use minimal expansion on a sharply contoured area which will have a high degree of flexion after healing. \*To illustrate the meaning of expansion ratio, when 1 sq. in. (6 sq. cm) of donor skin is meshed in the Meshgraft II Tissue Expansion System using a specific expansion such as 6 to 1, that 1 sq. in. (6 sq. cm), when fully expanded will cover approximately 6 sq. in. (40 sq. cm) in the recipient area.

## DESCRIPTION OF RATCHET HANDLE (See Fig. 12)

The 00-2195-022-00 Ratchet Handle has been fabricated for use with the 00-2195-001-00 Meshgraft II Tissue Expansion System. The ratchet handle is easily disassembled for cleaning and is completely autoclavable.

## SPECIFICATIONS

Weight: 11.3 lbs. (5.1 kg) [Includes ratchet handle weight of .85 lbs. (.4 kg)]; Length: 9.875 in. (25.1 cm); Width: 4.5 in. (11.4 cm); Ratchet Handle Length: 8.75 in. (22.2 cm) ; Ratchet Handle Width: 1.25 in. (3.2 cm);  
Materials: Stainless Steel and Aluminum

## DESCRIPTION OF SKIN GRAFT CARRIER (See Fig. 4)

The Dermacarrier II Skin Graft Carrier is a disposable cellulose propionate board 3 in. (7.6 cm) wide. It is available in ratios of 1.5:1, 3:1, 6:1, and 9:1. Each carrier is sterile packaged in a film/Tyvek pouch, 20 carriers per box. The carriers are sterilized and ready to use once the packaging, which maintains their sterility, is removed.

## CONTRAINDICATIONS

Meshed grafts may not be suitable for patients known to form keloids, or in areas subject to constant trauma (e.g., popliteal fossa). Use in these areas has resulted in severe scar contractures.

## WARNINGS AND PRECAUTIONS

To avoid serious injury to the patient and operating staff while using the Meshgraft II Tissue Expansion System, the user must be thoroughly familiar with its function, application, and instructions for use. The user and operating staff must always pay close attention to the CLEANING PRECAUTIONS and MANUAL AND AUTOMATED CLEANING AND DISINFECTION PROCESS INSTRUCTIONS. Failure to follow these instructions may damage the Meshgraft II Tissue Expansion System. Use only Dermacarrier II Carriers with a 2195 catalog number with the Meshgraft II Tissue Expansion System (See ACCESSORIES). Use of any other

carrier will damage the skin graft and/or the device. The carriers are intended for single use only. Reuse may result in an unsatisfactory mesh pattern. The Dermacarrier II Carrier should be used grooved side up and the skin must be placed on this side of the carrier. If the skin is placed on the smooth side of the Dermacarrier II Skin Graft Carrier (upside down), the graft will be shredded into long strips and will be unusable.

The Dermacarrier II Skin Graft Carriers should be used at room temperature. Procedures such as placing them in warm solutions or allowing them to become heated causes softening of the plastic and results in incomplete and poor cutting of the skin. Do not place the Dermacarrier II Skin Graft Carrier in an autoclave because it will melt and may bond to the metal surface of the instrument.

## **IMPORTANCE OF THE NEED TO ADHERE TO A CARE REGIMEN**

The Meshgraft II Tissue Expansion System should be inspected prior to each use.

- Visually inspect for damage and/or wear.
- 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**

- Prior to initial usage, the Meshgraft II Tissue Expansion System must be cleaned and sterilized per instructions. (See MANUAL AND AUTOMATED CLEANING AND DISINFECTION PROCESS INSTRUCTIONS as well as the STERILIZATION RECOMMENDATIONS)
- Observe sterile field precautions per hospital protocol.
- The Meshgraft II Tissue Expansion System is placed on its side on the table with the extension of the knurled roller facing up. (See Fig. 7.)
- The ratchet handle is placed on the knurled roller extension so that the “THIS END OUT” note is facing out. (See Fig.8.)
- The ratchet handle is fully inserted when the end of the knurled roller extension is flush with opposite side of the ratchet. (See Fig. 9.) Do not force or pound ratchet onto the Meshgraft II Tissue Expansion System.
- If there is trouble with the insertion, verify that the correct ratchet handle is being used. If the correct ratchet handle is being used, then the roller extension end may be misaligned with the similarly shaped end of the ratchet handle. To facilitate alignment, grasp the knurled roller and keep it stationary, then turn the ratchet handle until the two shapes match and then push the ratchet on completely.
- To ensure that the ratchet handle will not come off when the Meshgraft II Tissue Expansion System is being used, take the set screw wrench (supplied with the ratchet handle), and turn the set screw down until it is tight against the knurled roller extension. (See Fig. 10.)
- Once the ratchet handle is attached, the Meshgraft II Tissue Expansion System is ready for 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.

## OPERATING INSTRUCTIONS

The Meshgraft II Tissue Expansion System has been preset to mesh skin grafts between .008 and .017 in. (0.2 and 0.4 mm). However, best results are obtained with grafts between .012 and .015 in. (0.3 and 0.38 mm) thick.

- Select the Dermacarrier II Skin Graft Carrier with the appropriate expansion ratio.
- The Dermacarrier II Skin Graft Carrier is aseptically removed from its sterile package and introduced onto the sterile field.
- The carrier is placed grooved side up on the table.
- Place the graft on the grooved side of the carrier. The grooved side of the carrier must be up and the smooth side down to ensure a proper mesh. (See Fig. 4.)
- Place the graft on the carrier epidermal side up. However, the graft may be placed dermal side up to facilitate direct transfer from the carrier to the transplant site.
- Smooth the graft out on the carrier. Sterile water may be poured over the graft to facilitate smoothing it out on the carrier.
- Place the carrier, with the skin side up, on the guidance plateau and push against the raised portion of the guidance plateau. The guidance plateau is used to ensure straight entry into the gap between the cutter and the knurled roller.
- The leading end of the Dermacarrier II Skin Graft Carrier is firmly introduced into the Meshgraft II Tissue Expansion System making sure the entry is straight. Apply firm pressure to the opposite end of the Dermacarrier II Skin Graft Carrier to assist the cutter in the initial engagement, as the ratchet handle is slowly turned clockwise. (See Fig. 5.)
  - After the Dermacarrier II Skin Graft Carrier has been turned through approximately 1/2 in. (1.25 cm), stop and check the cut portion of the skin graft. If the graft has not disengaged from the cutter, grasp the leading end of the graft with forceps, and disengage the entire meshed portion of the skin from the cutter. Avoid damaging the blades of the cutter during this action.
  - Check the uncut portion of the skin graft. The uncut portion must be kept taut at all times when turning the Dermacarrier II Skin Graft Carrier through the instrument.
  - Apply constant downward pressure on the leading end of the Dermacarrier II Skin Graft Carrier while turning it through the Meshgraft II Tissue Expansion System (See Fig. 2). This is done to ensure that the skin graft will not engage in the cutter. Rotate the ratchet handle back and forth from the 10 o'clock to the 2 o'clock position until the carrier exits the back of the mesher. Note: The ratchet mechanism operates only when there is a carrier in the unit.
- Once the graft covered carrier has been transferred to the operative site, remove the meshed skin from the carrier and expand it as desired. Apply the expanded skin to the prepared transplant site.
- If it is necessary to remove the carrier after it has been inserted, the ratchet handle should be removed and the back side of the handle attached to the knurled roller extension. Rotating the ratchet handle back and forth from the 10 o'clock to the 2 o'clock position will cause the carrier to reverse direction and exit from the front of the mesher.

## **CLEANING PRECAUTIONS**

All subsequent cleaning and sterilization steps are facilitated by not allowing blood, tissue debris, or disinfectants to dry on used instruments. 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. Never clean in an ultrasonic cleaner. Ultrasonic cleaning will dislodge oil from the bearings and may render the instrument inoperative. Ultrasonic cleaning may affect calibration of the Meshgraft II Tissue Expansion System. Steam sterilize the Meshgraft II Tissue Expansion System. Follow instructions in **STERILIZATION RECOMMENDATIONS**.

## **MANUAL AND AUTOMATED CLEANING AND DISINFECTION PROCESS INSTRUCTIONS**

- The following instructions and charts detail the cleaning and disinfection process for the Meshgraft II Tissue Expansion System.
- Safely dispose of all used carriers in accordance with hospital policy for contaminated waste.
- Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth. The damp cloth is utilized to assist in the prevention of the un-removed soil drying prior to cleaning and disinfection process. 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.
- Follow the Manual Cleaning Instructions (Chart 1) or the Automated Cleaning Instructions (Chart 2).
- Following the cleaning procedure, 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**.

**Chart 1. Validated Manual Cleaning and Disinfection Procedure**

	Step	Step Description	Step Instruction	Accessories	Duration
<b>Cleaning Steps</b>	1	Contamination Removal	Rinse product under Cold/ Room Temperature running tap water removing any visible organic material with assistance of a soft bristle brush	- Cold/Room Temperature Tap Water - Soft bristle brush (Do not utilize metal cleaning brushes)	Until all visible soil is removed
	2	Drying	Dry the device utilizing a dry non-shedding wipe. Medical quality filtered air may be utilized if available	- Non- shedding wipe - Medical quality filtered compressed air	Until product is visually dry
<b>Disinfection Steps</b>	3	Disinfection Application	Apply Neutral pH disinfectant to the device's surface area per manufacturer's recommendations	- Neutral pH disinfectant - Spray bottle or other manual applicator (Do not submerge the device)	Contact time will vary per product usage; minimum of one (1) minute is recommended
	4	Manual Disinfection	While Neutral pH disinfectant is on the device surface clean all contact surfaces, joints, mated areas utilizing a clean soft bristle brush	- Clean Soft bristle brush - Neutral pH disinfectant	Manual cleaning time duration is complete when the device's surface, joints, & crevices have been manually cleaned
	5	Final Rinse	Rinse product under Room Temperature Distilled/ Filtered Water	- Room Temperature Distilled/Filtered Water	Minimum of 30 seconds
	6	Final Drying	Dry the device utilizing a dry non-shedding wipe. Medical quality filtered air may be utilized if available	- Non- shedding wipe - Medical quality filtered compressed air	Until product is visually dry

**Chart 2 Validated Automated Cleaning and Disinfection Procedure**

	Step	Step Description	Step Instruction	Accessories	Duration
<b>Cleaning Steps</b>	1	<b>Gross Soil Contamination Removal</b>	Rinse product under Cold/Room Temperature running tap water removing any visible organic material with assistance of a soft bristle brush	- Cold/Room Temperature Tap Water - Soft bristle brush (Do not utilize metal cleaning brushes)	Until all visible soil is removed
	2	<b>Pre-soak (Optional)</b>	Place device with cutter and ratchet handle removed into Immersion Container containing water and liquid cleaner	- Tap water at manufacturer's recommended temperature - Neutral pH disinfectant/cleaner <sup>a</sup> - Appropriate Immersion Container	Contact time will vary per product usage; minimum of fifteen (15) minutes is recommended
	3	<b>Pre-soak Rinse</b>	Rinse product under Cold/Room Temperature running tap water with assistance of a soft bristle brush	- Cold/Room Temperature Tap Water - Neutral pH disinfectant/cleaner - Soft bristle brush	Minimum of 30 seconds
	4	<b>Drying</b>	Dry the device utilizing a dry non-shedding wipe. Medical quality filtered air may be utilized if available	- Non-shedding wipe - Medical quality filtered compressed air	Until product is visually dry
	5	<b>Automated Washer</b>	Place entire disassembled device with cutter and ratchet handle removed into the automated washer	- Automated Washer - Disassembled Device - Washer Cleaning Solution <sup>b</sup> - Washer Neutralizing Solution <sup>c</sup> (If Applicable)	Minimum total cycle time: 34 minutes when including all steps below
<b>Disinfection Steps</b>	<b>Recommended Automatic Washer Cycle</b>				
		<b>Step</b>	<b>Minimum Time</b>	<b>Recommended Temperature</b>	
		<b>Pre-Wash</b>	3:00minutes	Water Temperature 65°C	
		<b>Cleaning I-</b>	3:00minutes	Water Temperature 85°C	
		<b>Cleaning II <sup>c</sup>- Or Neutralizing</b>	1:00minutes	Water Temperature 10°C	
		<b>Rinse I</b>	1:00minutes	Water Temperature 10°C	
		<b>Rinse II(Final)</b>	1:00minutes	Water Temperature 80°C	
		<b>Thermal Disinfection &amp; Drying</b>	25:00minutes	Chamber Temperature 110°C	
<p>a: Pre-soak cleaner solution may be surfactant or protease/enzymatic based cleaning solution compatible with aluminum    b: Washer cleaning solution should be a neutral pH or solution compatible with aluminum  c: Neutralizing solution should be appropriate for the utilized cleaning solution, based upon the manufacturers' recommendation. Certain cleaning solutions do not require a neutralization post-application of the cleaner. If Neutralization is not required, initiate a second cleaning application.</p>					

## STERILIZATION RECOMMENDATIONS

Steam sterilization is safe and effective and is the only recommended method for the Meshgraft II Tissue Expansion System. There are no contraindications for sterilizing the Meshgraft II Tissue Expansion System. Do not autoclave Dermacarrier II Skin Graft Carriers.

- Place cleaned instrument in an instrument tray or fully perforated autoclave case. The Meshgraft II Autoclave Case (REF 00-2195-006-00) is recommended. An alternative sterilization case may be utilized when validated by the end user.
- If the Meshgraft II 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

Cycle Type	Minimum Temperature	Minimum Exposure Time <sup>6</sup>		Minimum Dry Time <sup>3,10</sup>
		Wrapped <sup>7,8</sup>	Unwrapped <sup>9</sup>	
Prevacuum/ Pulsating Vacuum <sup>1,3</sup>	134°C 273°F	3 min	3 min	8 minutes
Prevacuum/Pulsating Vacuum <sup>2,3</sup>	132°C 270°F	4 min	4 min	
Prevacuum/Pulsating Vacuum <sup>3,4</sup>	134°C 273°F	18 min	18 min	
Prevacuum/Pulsating Vacuum <sup>5</sup>	132°C 270°F	8 min	8 min	
Gravity/Gravity Displacement	Not recommended due to excessively long sterilization cycles which are not practical.			

1. Minimum validated steam sterilization time required to achieve a 10<sup>-6</sup> sterility assurance level (SAL). 2. Minimum validated steam sterilization temperature required to achieve a 10<sup>-6</sup> 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. AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable. 7. Medical grade steam sterilization compatible wrap equivalent to four thicknesses of 140-thread-count muslin. 8. Rigid sterilization container that complies with ANSI/AAMI ST46. 9. Flash (unwrapped) sterilization by exposure at 132°C/270°F should only be used as an emergency procedure. This device should be cleaned and disassembled. 10. 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 Meshgraft II Tissue Expansion System as this method may not provide sterility throughout the instrument.

## **MAINTENANCE**

The Meshgraft II Tissue Expansion System requires lubrication only if “oil” is stamped on sideplate. As needed, the ratchet handle should be lubricated by placing 1–2 drops of surgical instrument lubricant in the grooved section of the ratchet. Turn the ratchet sections a few times to spread the oil evenly before autoclaving the instrument.

## **DISASSEMBLY OF THE RATCHET HANDLE FOR FLASH STERILIZATION**

The ratchet handle is a three-piece assembly which can be disassembled to facilitate easy cleaning and maintenance.

- Grasp the handle at the knurled end with the slot in the shaft below the ratchet facing you. Take a blunt instrument and insert it in the indentation within the slot on the shaft (See Fig. 13) and pull downward toward the knurled handle. This will release the ratchet, and it should fall out of the assembly. This will expose the next place to disassemble. (See Fig. 14.)
- Reach into the exposed hole, grasp the pin, and pull it out of the assembly. This completes the disassembly. (See Fig. 15.)
- Reassemble the instrument by reversing the above procedure.

## **STORAGE CONDITIONS**

The system should be stored under normal warehouse conditions.

## **ACCESSORIES**

Description: Meshgraft II Tissue Expansion System Complete (includes 00-2195-001-00, 00-2195-00600, 00-2195-022-00)

REF: 00-2195-000-00

Description: Meshgraft II Tissue Expansion System Instrument

REF: 00-2195-001-00

Description: Meshgraft II Autoclave Case

REF: 00-2195-006-00

Description: Dermacarrier II Skin Graft Carriers (Sold Separately) REF: 00-2195-012-00 1.5:1 Expansion Ratio Box of 20 00-2195-013-00 3:1 Expansion Ratio Box of 20 00-2195-014-00 6:1 Expansion Ratio Box of 20 00-2195-015-00 9:1 Expansion Ratio Box of 20

Description: Meshgraft II Tissue Expansion System Ratchet Handle

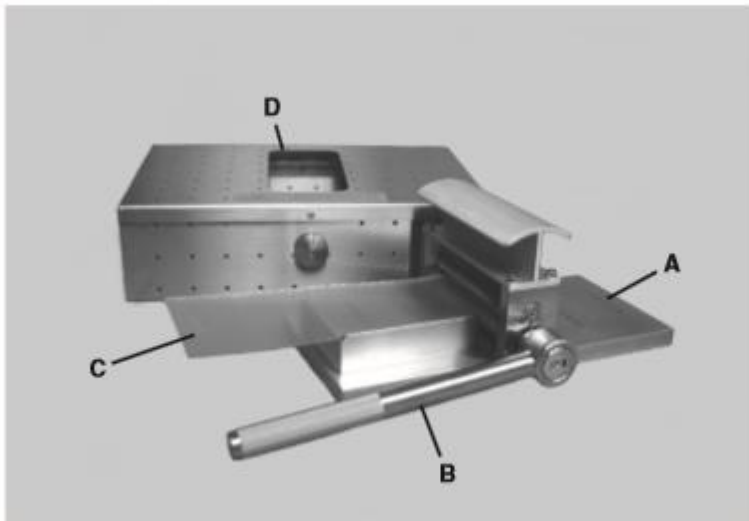
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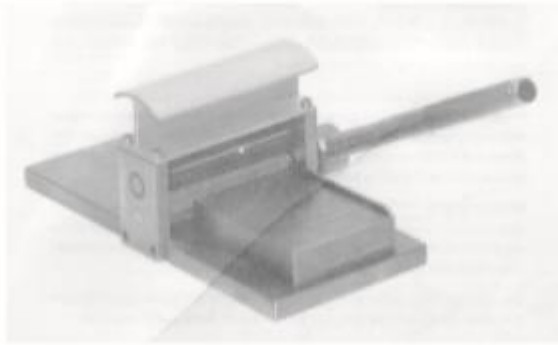
A. Meshgraft II

B. Ratchet Handle

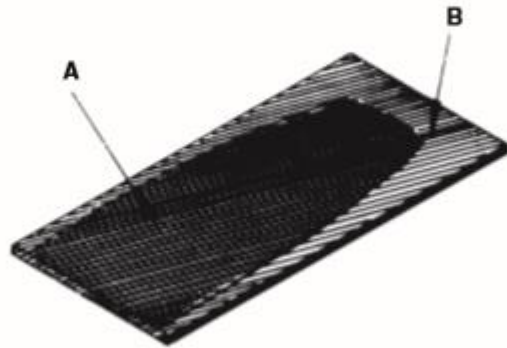
C. Dermacarrier (Sold Separately)

D. Autoclave Case

3



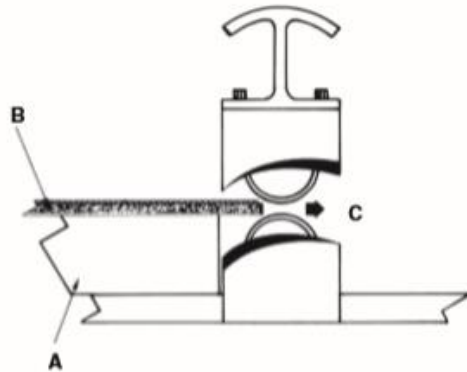
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A. Skin Graft

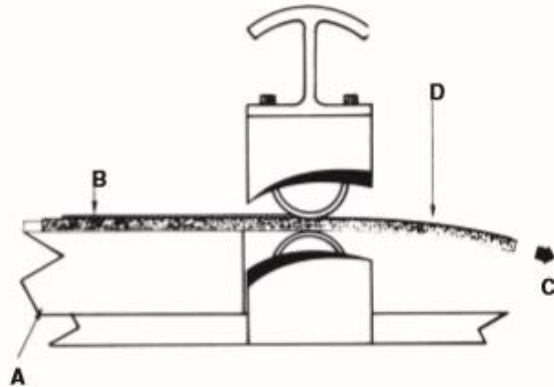
B. Dermacarrier Grooved Side Up

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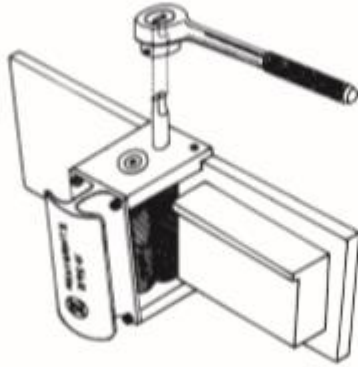
- A. Guide Rail
- B. Dermacarrier
- C. Direction of Pressure

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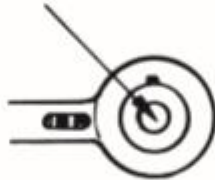


- A. Guide Rail
- B. Donor Skin
- C. Direction of Graft
- D. Keep downward pressure on this end of Dermacarrier

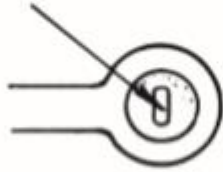
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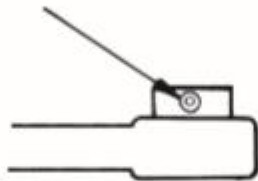
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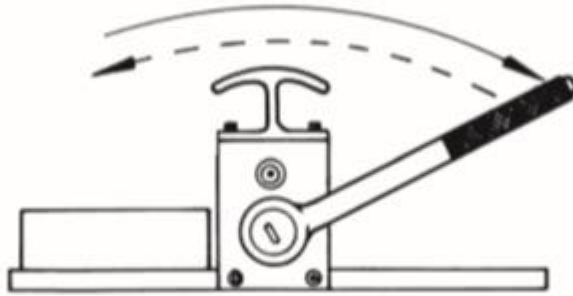
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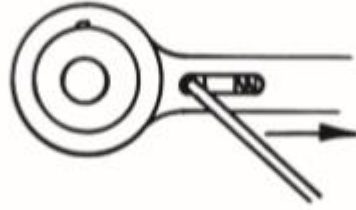
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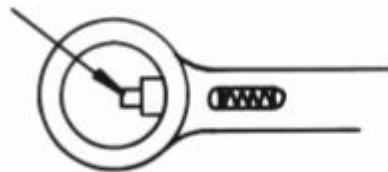
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