Integra® Padgett®
Model SB
Slimline Dermatome
Introduction

The Integra® Padgett® Model SB Slimline Dermatome is intended for use in skin harvesting from cadavers or animals in registered tissue banks or testing laboratories.

This equipment is intended only for professional use in tissue banks and similar medical facilities, where it will be used under the supervision of trained personnel.

Features

• Available in 100 - 250V~, power supply will adapt to any input voltage.
• Power switch is controlled by the thumb and is located on the top of the hand piece.
• The complete dermatome is delivered to you in a sturdy carry case with the power supply, power supply cord, 13 ft (3.96 m) hand piece cord, guard, 2, 3 and 4 inch (5.08, 7.62 and 10.16 cm) width clips, screwdriver, calibration gauge, and dermatome wrench.
• The Model SB has multiple methods of sterilization including: Steam, Ethylene Oxide, Flash Autoclave and Sterrad® or Hydrogen Peroxide Gas Plasma.

Optional Features

• Integra Padgett Universal Dermatome Sterilizing Tray (part #3539-799). Contact your Integra Padgett representative to purchase the Sterilization Tray.
• A 25 ft (7.62 m) hand piece power cord (part # 3539-715-25) may also be purchased.

Warning: Read this manual thoroughly before using any parts of the Integra Padgett Model SB Slimline Dermatome.
Components—Model SB Slimline

The Model SB has no user serviceable parts! The complete unit must be returned to the authorized repair center to obtain repair or maintenance. Failure to do so voids the warranty.

For product ordering information please call 877-444-1122 or 609-275-0500.
Classifications

In accordance with: 60601-1/IEC 60601-1, Class I, Type BF
Continuous Operation with Short Term Loading
Explosion hazard. DO NOT use in the presence of flammable anesthetics.

Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Graft Width SB</td>
<td>4&quot; (10.16 cm)</td>
</tr>
<tr>
<td>Input Voltage</td>
<td>100-250Vac</td>
</tr>
<tr>
<td>Input Frequency</td>
<td>50 / 60Hz</td>
</tr>
<tr>
<td>Output Volts</td>
<td>48Vac</td>
</tr>
<tr>
<td>Output Current</td>
<td>1A</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>-20 to 50°C. Humidity 10% to 95% non-condensing</td>
</tr>
<tr>
<td>Storage</td>
<td>-40 to 55°C. Humidity 10% to 95% non-condensing</td>
</tr>
<tr>
<td>Assembled Weight</td>
<td>1 Lb 8oz. (.7 kg)</td>
</tr>
</tbody>
</table>
Warnings

⚠️ Danger: Explosion hazard. **DO NOT** use in the presence of oxygen, nitrous oxide, or other flammable anesthetics.

This equipment is intended only for professional use in hospital, physical therapy locations, and similar medical facilities where the patient will be under the supervision of trained personnel.

⚠️ To reduce the risk of electrical shock **DO NOT** remove power supply cover. Refer maintenance and servicing to the Integra Padgett Dermatome Repair Center.

The movement of the blade generates heat which may cause a heat related injury to the patient. Maintain forward movement while the dermatome is in contact with the patient.

The Model SB **DOES NOT** have an automatic turn off feature. This product may cause injury to the user if not operated in accordance with this manual. Handle the Model SB with care.

⚠️ **Do not reuse blades.** Blades are designed as single-use, disposable products and should not be re-sterilized. Re-sterilization and subsequent reuse will dull the blades and may result in cross-contamination or impaired function of the product. Sharpness of the blades is not guaranteed with repeated use. Any blade, once used, should be discarded according to hospital policy.

⚠️ Use **ONLY** with Integra Padgett Dermatome Blade part number 3539-252.

It is the sole responsibility of the end-user to validate alternate sterilization methods and cycles that do not comply with the validated sterilization methods and cycles specified within this manual. Failure to comply with the validated sterilization methods may result in ineffective sterilization and damage to the device.

The dermatome is supplied non-sterile and must be sterilized prior to use. Validated sterilization cycles are provided in the Sterilization section. The dermatome blades have been sterilized with a minimum dose of 2.5 Mrads (25 kGy) of gamma irradiation, sterility assurance level of $10^{-6}$. Prior to use inspect the blade packaging for damage which may compromise sterility. If damaged, or in any way compromised, the dermatome blade must be assumed to be non-sterile and must not be used.
Precautions

A thorough, manual cleaning process as detailed in the Cleaning and Decontamination section is recommended for the Dermatome Model SB. The Dermatome motor housing cannot be immersed in liquid cleaners, which would occur in an automated process. Automated cleaning methods may not be effective and may result in damage and reduced performance of the device.

**DO NOT** auto clave power supply or power supply cord which interconnects the power supply with the wall receptacle. Damage and reduced performance of the device may result.

**EMC Caution:** Care should be taken if the equipment is used adjacent to or stacked with other equipment. If adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

The Model SB incorporates sealing devices used to prevent moisture from entering the hand piece. One or more of these sealing devices can be damaged if disassembled and reassembled. Refer servicing to an authorized Integra Padgett Dermatome Repair Center.

Use Model SB hand piece with Model SB power supply and hand piece cord **ONLY**.

Prior to use visually inspect the dermatome hand piece and its cord for signs of physical damage or wear. Do not use the dermatome if damage is observed. The dermatome hand piece can only be serviced by the Integra Padgett Dermatome Repair Center (refer to Maintenance and Servicing Section, page 13). Dermatome hand piece cord damage may include cracks or discoloration of the cable jacket, exposed conductors, or distortion of the cord or connector. If cord damage is observed contact Integra Padgett Customer Service immediately to purchase a replacement power cord (part number 3539-715-13) and discard the damaged cord.

Used blades should always be disposed of in proper safety containers.

Unit disposal (if necessary) is to be in compliance with your facilities disposal protocols.

Avoid rough handling or dropping the dermatome hand piece and dermatome power supply. If rough handling is suspected or the unit is dropped, it is recommended to assess the condition of the dermatome system prior to use by the following method.
1. Visually inspect all dermatome components for signs of physical damage including loose parts, part distortion, rough edges, and areas of discoloration.
2. Check the oscillating pin calibration (see Calibration section).
3. Check fit of all dermatome cables. Connect dermatome hand piece cord between dermatome hand piece and power supply. Connect wall power cord to power supply. All cable connectors are to fit properly with their mating receptacles.
4. Connect power supply power cord to wall receptacle and turn power supply switch on. The indicator light on the power supply is to illuminate.
5. Depress thumb-switch on dermatome hand piece. Dermatome motor is to run and oscillating pin is to move rapidly from side to side. Note any unusual motor sounds.

If issues are experienced with any of these system checks, do not use the dermatome and return the unit to the Integra Padgett Dermatome Service Center for service (see Maintenance and Servicing section).
International Symbols

This symbol represents the international symbol for Type B Medical Equipment.

This symbol represents the international symbol for Protective Earth (ground).

This symbol represents the international symbol for Direct Current.

This symbol represents the international symbol for cutting.

This symbol represents the international symbol for “Caution, consult accompanying documents.”

This symbol represents the international symbol for Alternating Current.

This symbol represents the international symbol for Explosion Hazard.

This symbol represents the international symbol for Electrical Shock.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Serial number.
Calibration

A calibration guide is included with the dermatome and can be ordered as an accessory (part #3539-259). This guide is intended to determine if the oscillating pin, which moves the blade, is within specifications. If the oscillating pin is not within specifications, the blade may “chatter” or “skip,” yielding unsatisfactory results. **Prior to each use,** the dermatome should be checked using the calibration guide to determine if the particular instrument is within calibration specifications.

The calibration guide should be inserted between the oscillating pin and the base of the blade guide (as shown in the diagram). This can be done from the right. If the oscillating pin lies anywhere within the zone clearly marked on the calibration guide, the dermatome is properly calibrated. **If the pin lies on the edge or outside the zone, the dermatome should not be used, and should be sent to the Integra Padgett Dermatome Repair Center (IPDRC) for recalibration.** The calibration procedure is important because dropping the dermatome or inadvertently hitting the oscillating pin may knock the instrument out of calibration.

**Using the Calibration Guide (3539-259)**

1. Hold the Guide in your Right hand with the Integra logo facing up. Lower the LEFT side of the Guide Slot over the Oscillating Pin and against the top of the Blade Guides.

2. Gently slide the Calibration Guide to the LEFT until the Oscillating Pin touches the BOTTOM edge of the Guide Slot. If the Oscillating Pin lies anywhere between the two vertical lines the dermatome is properly calibrated.
The Power Supply

The green light on the power supply is a “ready” light, indicating that the dermatome is ready for use whenever the light is on. Please note there may be up to a two-second delay when the power switch is first activated before the green light illuminates.

DO NOT AUTOCLAVE THE POWER SUPPLY OR THE POWER SUPPLY WALL CORD.
How to Use the Model SB Slimline Dermatome

The **Model SB** Dermatome must be sterilized prior to use (refer to page 17 Sterilization Section for instructions). The Model SB Dermatome is equipped with a detachable cord. The detachable cord is color-coded. The silver end connects into the hand piece and the black end connects to the power supply. It is not possible to connect the cord to the wrong receptacles as they are keyed differently to accept the correct end of the cord. The design also includes a reverse pin configuration to avoid electric shock. The dots must be lined up for a connection. When you choose to disconnect the cord from the hand piece and power supply, you must grasp the silver cap.

**CAUTION:** Blades are single use **ONLY.** DO **NOT** reuse blades.

The on/off switch is on top of the hand piece and is operated with the thumb. Push the switch forward for continuous mode. Pull the switch back to return to the off position.

The blade should be given a very thin coat of sterile mineral oil on both sides before insertion. Hold the dermatome in both hands as shown in the picture. Place the blade such that the “This Side Up” marker is facing the operator. The blade grommet hole is to be placed over the dermatome's oscillating pin. Refer to illustration. Place both thumbs over the eccentric screws and push the blade down and forward. The blade will easily fall into place. The blade and dermatome blade bed should be free from lint or other foreign objects which may hinder free movement of the blade. The blade is removed by lifting up with both index fingers using the slots at each end of the blade.
Select the desired width clip. A one inch (2.54 cm) is available by special order. Fasten in place with the Integra Padgett supplied screwdriver as shown. Be sure there is no lint or other foreign object on the width clip that could restrict free movement of the blade. The screws should be sufficiently tightened to prevent screw loosening during dermatome operation. Excessively tightened screws may cause dermatome performance issues or permanent device damage. Only use the Integra Padgett supplied screwdriver to tighten the screws.

The desired thickness of the graft is predetermined by the operator and set by using the pointer on the thickness guide scale. The actual thickness of the harvested tissue is highly dependent upon the operator technique and the condition of the tissue being harvested. The thickness guide scale provides both inch and millimeter values.

Much of the weight of the motor should be carried by the hand that holds the dermatome to maintain a reasonably light pressure between the cutting edge and the patient’s body. The instrument should be held at a 25° - 45° angle. The cut graft automatically folds itself into the “pocket” of the dermatome head. To sever the graft, simply lift the dermatome up and away from the donor site. As per Association of Perioperative Registered Nurses (AORN®) recommended practice the dermatome’s hand piece cord should be secured to the sterile field with a non-perforating device.

Friction from the rapid back and forth movement of the blade generates heat which may result in an unsatisfactory graft. Once the dermatome is placed into contact with the skin surface you must maintain forward movement until the graft is taken.
Maintenance And Servicing

The Model SB Slimline Dermatome does not contain any user serviceable parts. All maintenance and servicing should be done at an approved Integra Padgett Dermatome Repair Center (IPDRC). **Failure to use authorized repair center voids the warranty.**

It is recommended that the dermatome system be sent to the repair center for **servicing annually**. Whether returning the dermatome for annual service or should repair service be required, it is very important to return the complete dermatome system, including the hand piece, all power cords, power supply, guard plate, all width blade clips, calibration guide, screwdriver, and dermatome wrench. A Return Material Authorization (RMA) number is required and may be obtained by contacting Integra Padgett Customer Service prior to returning product.

**The product is required to be properly cleaned and sterilized before it is returned to the repair center with documentation verifying sterilization. Failure to sterilize the product will result in a handling fee.**

For Domestic Returns

- Customer Service 800-654-2873 or 609-275-5363. Fax 609-275-5363
- Ship unit to: Integra Padgett Dermatome Repair Center (IPDRC)
  1109 Valley Ridge Drive
  Grain Valley, MO 64209 USA

For International Returns

- Customer Service +49 2102 5535 6150. Fax +49 2102 942 4872
- Ship unit to: Integra GmbH
  Technical Service and Repair
  Gewerbepark Ratingen
  Halskestrasse 9 D-40880
  Ratingen, Germany

Trade-In

Any dermatome, regardless of its working order or manufacturer, may be traded in for credit against the purchase of a new dermatome. Contact your Integra Padgett Representative for details. The trade-in program is based on a one-for-one trade. If you choose to dispose of your unit follow your facility’s disposal protocols.
Cleaning And Decontamination

A thorough, manual cleaning process is recommended for the Dermatome Model SB. The Dermatome motor housing cannot be immersed in liquid cleaners, which would occur in an automated process. Automated cleaning methods may not be effective and may result in damage and reduced performance of the device.

As with any decontamination procedure, personnel should follow accepted guidelines for hand washing, the use of protective attire, etc. as recommended by A.A.M.I. Standards and Recommended Practice ANSI/AAMI ST79:2010.

CAUTION: During this cleaning / decontamination process, the dermatome is to be partially disassembled by removal of the guard plate from the unit’s cutting head and removal of the cutting head from the hand piece. With these components removed, certain features of the dermatome that are critical to its proper operation are exposed. Therefore, extra care must be exercised when handling the dermatome components in this state to protect them from physical damage. The critical features of the dermatome components include the oscillating pin and drive shaft of the motor housing, the blade nest and leading edge of the cutting head, and the edge of the guide bar. Only remove the components as instructed below. Further disassembly of the instrument is likely to cause permanent damage. The dermatome contains no user serviceable parts and must be returned to an approved Integra Padgett Dermatome repair center for repair and maintenance.

Cutting Head Removal

CAUTION: The dermatome’s cutting head should only be removed to perform the cleaning and decontamination process. Use the dermatome wrench (3539-702) provided to disassemble the two hex nuts located on the motor housing’s flange. Tip the motor housing to create sufficient clearance between the motor shaft and the opening in the blade bed of the cutting head so that the motor housing freely slides out of the cutting head. Forcibly removing the motor housing from the cutting head may cause permanent damage.

A. Precleaning

Remove width clip and width clip screw fasteners. Carefully remove the single-use dermatome blade (CAUTION: Blade is sharp). Dispose of dermatome blade as per your institutions’ protocol regarding the handling and disposal of sharps. Remove any apparent debris from dermatome, width clip, and power cord with a lap sponge and sterile water to prevent drying of blood and body fluids.

B. Cleaning and Decontamination

To prevent the formation of biofilm, cleaning should occur as soon as possible after dermatome use.
1. **Maintain Moisture:** Immediately after the surgical procedure, place the dermatome hand piece, width clip, guard, and screw fasteners in an instrument container and apply a transport foam or gel product (e.g., Steris PRE-Klenz®) specifically intended to keep soil moist on surgical instruments. Also introduce some of the foam or gel product into the oscillating pin recess of the cutting head. Transport the tray containing the soiled dermatome in an impervious plastic bag or container to the decontamination environment. Keep the outside of the container clean.

2. **Enzymatic Soak:** Prepare an enzymatic detergent solution (e.g., ASP® ENZOL®) as per the manufacturer’s recommendation. Remove the two hex nuts fastening the dermatome’s cutting head to the motor housing. Immerse only the dermatome’s cutting head, width clips, guard, and screw fasteners in the enzymatic solution. Do not immerse the dermatome’s motor housing. Immersion of the motor housing can cause permanent damage to its electrical components.

   **CAUTION:** Removing the dermatome’s cutting head from the motor housing will result in exposing the oscillating pin and motor drive shaft. The contour of the oscillating pin is factory set to provide proper dermatome performance. Care must be taken in handling the motor housing in this state. Dropping the motor housing or hitting the oscillating pin can cause damage that will result in the instrument being out of calibration upon re-assembly.

3. **Rinse:** After the enzymatic detergent manufacturer’s recommended soak period, remove dermatome’s cutting head, width clips, and screw fasteners from the detergent solution and thoroughly rinse the items with tap water.

4. **Clean Instruments:** Prepare a cleaning solution appropriate for surgical instruments (e.g., ASP ENZOL) as per the manufacturer’s instructions. Using a small clean soft-bristled brush, remove soil from all surfaces of the dermatome’s cutting head, width clips, guard, and screw fasteners while they are submerged in the solution. Take particular care in removing soils from the dermatome’s cutting head features containing crevices and sharp inside corners. Clean the dermatome’s motor housing by wiping with a soft clean cloth moistened with the detergent solution. Pay special attention to removing soil from the area of the oscillating pin and drive shaft. Clean the power cord by wiping with a soft clean cloth moistened with the detergent solution.

5. **Rinse:** Thoroughly rinse all dermatome components under gently running tap water and wipe with a dry, soft, clean cloth. Do not immerse the dermatome components.
Cleaning And Decontamination (Continued)

6. **Final Rinse:** Rinse all dermatome components with softened or deionized water. Softened or deionized water should be used for the final rinse to better remove detergents and other residues from the rinse water. Excessively hard water can spot or stain instruments. Excess chlorine in the rinse water can result in pitting.

7. **Visual Inspection and Dermatome Assembly:** Visually inspect the dermatome components for cleanliness and ensure all components are in proper working order. Visually inspect the dermatome’s power cord for signs of damage that may include cracks or discoloration of the cable jacket, exposed conductors, or distortion of cord or connector. If damage is observed do not use the dermatome and return immediately to the Integra Padgett Dermatome Repair Center for service (refer to Maintenance and Servicing section).

8. **Assemble the unit** by aligning the holes in the motor housing flange with the threaded studs of the cutting head. Note that the thumbswitch on the motor housing is to be positioned on the top of the unit. Tip the motor housing to create sufficient clearance to carefully slide the motor housing drive shaft into the cutting head. Replace and tighten the two hex nuts using the dermatome wrench. Check the unit calibration (see page 9) after assembly.

9. **Wrap Dermatome for Sterilization:** The guard, width clips, and the width clip attachment screws are not to be assembled to the dermatome in preparation for sterilization. Prepare the dermatome hand piece assembly, guard, width clips, width clip screws, and handpiece power cord for sterilization using a wrapper that is appropriate for the method of sterilization to be used. The oscillating pin recess at the blade nest of the dermatome’s cutting head is to face downward to expedite drainage of potential condensate if a steam sterilization method is employed.

10. **Sterilization:** Utilize one of the validated methods of sterilization outlined in the sterilization section (page 17).
Sterilization

The Model SB Slimline Dermatome is provided NON-STERILE and must be sterilized prior to use. The sterilization cycle parameters outlined below have been validated for the Model SB Slimline Dermatome.

Steam Sterilization:

<table>
<thead>
<tr>
<th>Cycle Conditions</th>
<th>Exposure Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped Pre-Vacuum</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Wrapped Gravity</td>
<td>132°C (270°F)</td>
<td>15 minutes</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Unwrapped (Flash) Pre-Vacuum</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Unwrapped (Flash) Gravity</td>
<td>132°C (270°F)</td>
<td>15 minutes</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**NOTE:** Ensure sufficient cooling time after the sterilization process to allow the dermatome temperature to equilibrate to ambient room temperature. This is especially important when utilizing a flash sterilization cycle.

100% Ethylene Oxide Sterilization: Precondition the chamber to the specified exposure temperature and 55% relative humidity for a minimum of 1 hour. The 100% Ethylene Oxide gas concentration is 725 mg/L.

<table>
<thead>
<tr>
<th>Cycle Conditions</th>
<th>Exposure Temperature</th>
<th>Exposure Time</th>
<th>Aeration Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped</td>
<td>37°C (99°F)</td>
<td>8 hours</td>
<td>12 hrs. min at 51-59°C</td>
</tr>
<tr>
<td>Wrapped</td>
<td>55°C (131°F)</td>
<td>180 minutes</td>
<td>12 hrs. min at 51-59°C</td>
</tr>
</tbody>
</table>

Sterrad Sterilization: Dermatome to be processed on STERRAD® 100S unit (short cycle) which consists of the following steps:

- Vacuum
- 1st Injection Stage
- 1st Diffusion Stage
- 1st Gas Plasma Stage
- 2nd Injection Stage
- 2nd Diffusion Stage
- 2nd Gas Plasma Stage
- Vent
- Total cycle time = ~55 minutes

It is the user’s responsibility to validate any sterilization parameters that are not provided directly by the manufacturer.
Limited Warranty

INTEGRA LIFESCIENCES CORPORATION ("INTEGRA") warrants to its authorized distributors and the original purchaser only that each new INTEGRA product is free from manufacturing defects in material and workmanship under normal use and service for a period of one (1) year (except as otherwise expressly provided as to accessory items) from the date of delivery by INTEGRA to the first purchaser, but in no event beyond the expiration date stated on any product labeling.

- Surgical instruments are guaranteed to be free from defects in material and workmanship when maintained and cleaned properly and used normally for their intended purpose.
- Any covered product that is placed by INTEGRA under a lease, rental or installment purchase agreement and that requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement.

If any covered defect occurs during the warranty period or term of such placement agreement, the purchaser should communicate directly with INTEGRA's home office. If purchaser seeks to invoke the terms of this warranty, the product must be returned to INTEGRA at its home office. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to INTEGRA shall be at CUSTOMER's risk. INTEGRA's sole responsibility under this warranty shall be repair or replacement, at INTEGRA's sole discretion at INTEGRA's expense, subject to the terms of this warranty and applicable agreements.

IN NO EVENT SHALL INTEGRA BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and INTEGRA shall not be responsible for, any loss arising in connection with the purchase or use of any INTEGRA product that has been repaired by anyone other than an authorized INTEGRA service representative or altered in any way so as, in INTEGRA's judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA. THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON INTEGRA'S PART, AND INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA'S PRODUCTS.

INTEGRA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS. No warranty or guarantee may be created by any act or statement nor may this Standard Warranty be modified in any way, except as a result of a writing signed by an officer of INTEGRA. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

Integra Padgett dermatomes are intended for use in conjunction with Integra Padgett dermatome blades only. Accordingly, using another manufacturer’s blades in conjunction with an Integra Padgett dermatome will void the product warranty.