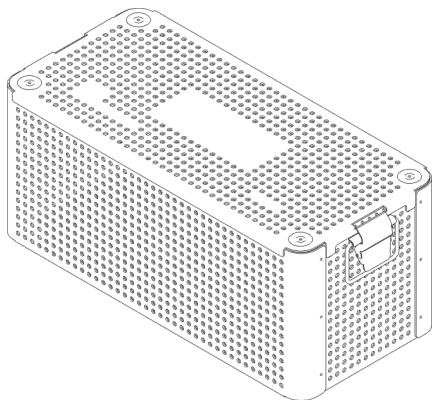




BRASSELER USA[®]
SURGICAL POWER & ACCESSORIES



BSP MAX[™] **II**

STERILIZATION CASE

PM-X00-770

3 Handpieces

Rx Only

Instructions for Use

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Introduction

Thank you for choosing Brasseler USA® Surgical Power & Accessories as supplier of your large bone power system.

The information and procedures described in this manual are intended to assist medical professionals in the safe and effective use, care, cleaning, sterilization and long-term maintenance of BSPMAX™ II Large Bone Power System.

Intended Use

The BSPMAX™ II Sterilization Case, 3-handpiece, PM-X00-770 is intended for use with the BSPMAX™ II Large Bone Power System. The case will accommodate a variety of handpiece and attachment combinations to include chuck keys.

Warning

- Only trained and experienced medical professionals should use this equipment. Failure to comply with the BSPMAX™ II Instructions for Use may result in patient and/or medical staff injury.
- Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. Consult WHO and local regulations for further information.

Cautions

- Do Not overload case with un-intended items. Only use placement locations provided in tray.
- Refer to individual product instructions for use for Sterilization Recommendations.

Notes

- Place handpieces, attachments and chuck keys into designated locations in the tray and place tray into sterilization case. The case insert is designed so steam will flow through cannulated handpieces and attachments when using a gravity displacement sterilizer.
- See the instructions for use provided with the handpieces, attachments, and battery packs for cleaning and sterilization recommendations.

Explanation of Symbols



Batch code.



Catalog number.



Caution.



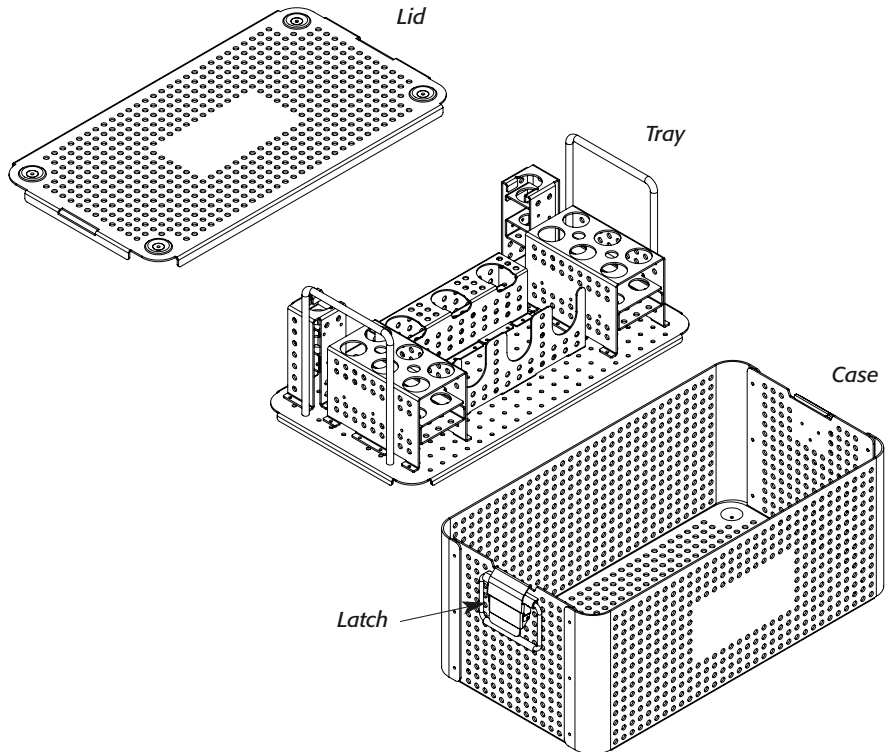
Date of manufacture.



Manufacturer.

Features

- **Case** – Location for tray.
- **Latch** – Secures lid to case.
- **Lid** – Cover that attaches to case.
- **Tray** – Placement location for handpieces, attachments and chuck keys.



Cleaning Recommendations

Warnings:

- Prior to cleaning and sterilization, remove all handpieces, attachments and chuck keys from tray and remove tray from the case.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.

Caution:

- Follow universal precautions and protective apparel when handling and cleaning contaminated instruments.

Cleaning Procedures:

1. Remove handpieces, attachments and chuck keys from tray and remove tray from the case.
2. Wash case, tray and lid with a clean lint-free soft cloth using a mild pH balance enzymatic cleaner. A brush with stiff, non-metallic bristles may also be used to remove debris. Manipulate moving parts of the handle and fasteners located on the case to ensure all debris is removed.
3. Rinse all external surfaces of the case, tray and lid under running tap water.
4. Visually inspect the case, tray and lid for any remaining debris; if any debris is present, repeat the cleaning and rinsing procedure.
5. Dry the case, tray and lid with a clean lint-free soft cloth.
6. Inspect case, tray and lid for damage and malfunctioning. Return damaged components to Brasseler U.S.A. Medical, LLC, Service Department.
7. Place handpieces, attachments and chuck keys into designated locations in the tray and place tray into sterilization case. Fasten sterilization case lid.
8. Sterilize as directed. See Sterilization Recommendations section.

Sterilization Recommendations

Steam sterilization has been found both safe and effective for the sterilization of BSPMAX™ II Large Bone Power System sterilization case. The case is capable of withstanding the recommended exposure times and temperatures of steam sterilization.

Warnings:

- The use of disinfecting solutions for an exterior instrument wipe will not sterilize equipment and is not recommended.

Caution:

- DO NOT sterilize cases with Ethylene Oxide (ETO).
- DO NOT sterilize cases in cold sterilization like CIDEX®.

Notes:

- These processes have been validated as being capable of cleaning and sterilizing the BSPMAX™ II handpieces, attachments and accessories in Sterilization Case, except battery packs and four station modular battery charger.
- The sterilizer manufacturer's written instruction for cycle parameters, load configuration and AAMI guidelines for steam sterilization should be followed.

Parameters for Sterilizing BSPMAX™ II in a Sterilization Case

Sterilization Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Pre Vacuum (Wrapped)	270° F (132° C)	4 Minutes	15-30 Minutes
Pre Vacuum (Wrapped)	273° F (134° C)	3 Minutes	15-30 Minutes
Gravity (Wrapped)	250° F (121° C)	100 Minutes	15-30 Minutes
Gravity (Wrapped)	270° F (132° C)	60 Minutes	15-30 Minutes

To Sterilize Battery Packs

See instructions for use provided with battery packs.

Specifications

Physical Characteristics	3-Handpieces PM-X00-770
Size (L x W x H)	18 x 10 x 7.5in (457 x 394 x 190 mm)
Weight (Empty Case)	10.8 lb (4.9kg)

Repair Service

Brasseler USA® Surgical Power & Accessories recommends that the BSPMAX™ II handpieces, attachments and accessories (excluding battery packs) be returned to Brasseler U.S.A. Medical, LLC, Service Department for routine preventive maintenance every twelve (12) months. Follow a regular care regimen that includes routine cleaning after each use, strict adherence to sterilization recommendations and a thorough inspection for damage of all devices after each use. Routine preventive maintenance performed by the Brasseler U.S.A. Medical, LLC, Service Department can increase the reliability and extend the life of your BSPMAX™ II Large Bone Power System.

Brasseler USA® Surgical Power & Accessories warrants any service or repair work performed will be free from defects in material or workmanship for the period of ninety (90) days from date of service or repair. This warranty applies to the actual work performed.

Products must be decontaminated and sterilized before returning.

Note: It is unlawful to ship contaminated non-sterilized products.

Contact a Customer Service Representative at Brasseler USA® Surgical Power & Accessories at 877-834-7133 to request repair, preventive maintenance, or a loaner instrument. If available, loaner instruments will be supplied in accordance with the Brasseler USA® Surgical Power & Accessories Loaner Program.

Please include the following information with the returned product(s):

- Indicate on the paperwork or the box the designated call ID number.
- When returning products from outside the U.S. please indicate on shipping documents per Customs requirements the following: "U.S. manufactured goods returned for factory service/repair".
- Catalog number, serial number and lot number (if applicable) of device.
- Customer name, address and account number.
- Itemized packing list.
- Brief statement describing reason for product repair or requesting preventive maintenance.

Return to:

***Brasseler U.S.A. Medical, LLC
4837 McGrath Street
Ventura, CA 93003***

Warranty

Brasseler USA® Surgical Power & Accessories warrants all BSPMAX™ II Handpieces, Attachments and Accessories excluding Battery Packs to be free from defects in material and workmanship for a period of one (1) year from the invoice date. Battery Packs are warranted to be free from defects in material and workmanship for a period of ninety (90) days from the invoice date. The warranty is limited to the repair of the product without charge. This warranty is nontransferable. In addition, this warranty is void in the event of any of the following: abuse, misuse, neglect or use in other than normal surgery environment, disassembly, alteration or unauthorized repair, or in the event that the product has not been used in reasonable manner and in compliance with the written instructions provided by Brasseler USA® Surgical Power & Accessories.

Return Goods Policy

If product needs to be returned, the following applies:

Consumable/Disposable Product:

Any unused consumable/disposable product may be returned for credit within ninety (90) days of invoice date if it qualifies for resale (unopened and unmarked package). Products may be subject to a restocking fee. Credit will not be issued for products that do not qualify for resale.

Capital Equipment:

Any unused capital equipment may be returned for credit within thirty (30) days of invoice date if it qualifies for resale (unopened and unmarked package). Products may be subject to a restocking fee. Credit will not be issued for products that do not qualify for resale.

Packaging and Shipping:

Returned items should be packaged in original packaging. Credit will not be issued for items damaged in return shipment due to packaging inadequacy.

Note: It is unlawful to ship contaminated non-sterilized products.

Contact a Customer Service Representative at Brasseler USA® Surgical Power & Accessories at 800-535-6638 to obtain a "Return Merchandise Authorization" (RMA) number.

Please include the following information with the returned product(s):

- Catalog number, serial number and lot number (if applicable) of device.
- Return Merchandise Authorization (RMA) number noted with the return.
- Original invoice number or copy of original invoice.
- Original invoice date.
- Customer name, address and account number.
- Itemized packing list.
- Brief statement describing reason for product return.

Return to:

***Brasseler U.S.A. Medical, LLC
4837 McGrath Street
Ventura, CA 93003***

Product Disposal

Dispose of product or recycle in accordance with local laws and regulations.

Product Ordering Information

HANDPIECES

PM-X08-700	MODULAR DRILL/REAMER
PM-X12-700	SAGITTAL/OSCILLATOR SAW
PM-X14-700	RECIPROCATOR/STERNUM SAW

ATTACHMENTS - DRIVERS

PM-X08-701	PIN DRIVER
PM-X08-702	WIRE DRIVER

ATTACHMENTS - DRILLS

PM-X08-905	TRINKLE/AO®
PM-X08-910	1/4 IN JACOBS® CHUCK W/ KEY
PM-X08-915	5/32 IN JACOBS® CHUCK W/ KEY
PM-X08-920	HUDSON®
PM-X08-925	ZIMMER®
PM-X08-930	1/4 IN KEYLESS CHUCK
PM-X08-935	3 MM KEYLESS CHUCK
PM-X08-940	ZHS - ZIMMER®/HUDSON®/STRYKER® UNIVERSAL

ATTACHMENTS - REAMERS

PM-X08-911	1/4 IN JACOBS® HI TORQUE W/ KEY - EXTENDED LENGTH
PM-X08-950	HUDSON® - EXTENDED LENGTH
PM-X08-955	ZIMMER® - EXTENDED LENGTH
PM-X08-960	AO® - EXTENDED LENGTH
PM-X08-965	ZHS - ZIMMER®/HUDSON®/STRYKER® UNIVERSAL - STANDARD LENGTH
PM-X08-970	1/4 IN JACOBS® HI TORQUE W/ KEY - STANDARD LENGTH

ATTACHMENT - STERNUM SAW GUARD

PM-X14-901	STERNUM SAW GUARD
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ACCESSORIES

PM-X00-520	4-BAY POWER UNIT 110V
PM-X00-521	CHARGING BAY COVER
PM-X00-522	4 BAY POWER UNIT 230V
PM-X00-710	9.6V BATTERY PACK
PM-X00-715	12V BATTERY PACK
PM-X00-731	STANDARD BATTERY PACK CHARGING BAY
PM-X00-770	STERILIZATION CASE – 3 HANDPIECES
PM-X08-000	1/4 IN JACOBS® CHUCK KEY
PM-X08-001	5/32 IN JACOBS® CHUCK KEY

BRASSELLER USA® SURGICAL POWER & ACCESSORIES OFFERS A COMPLETE LINE OF CUTTING ACCESSORIES (SAW BLADES/RASPS, BURS, K-WIRES, STEINMANN PINS, TWIST DRILLS AND ORTHOPAEDIC PIN PACKS).



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BrasselerUSAMedical.com

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