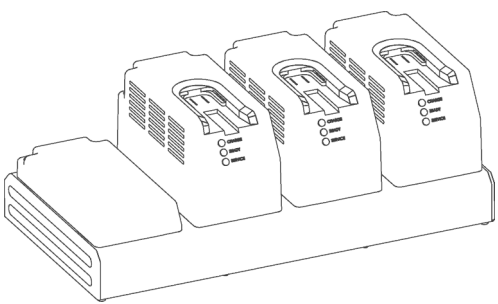
BUSA®
SURGICAL POWER & ACCESSORIES



BSP MAX™ II

FOUR STATION MODULAR BATTERY CHARGER

4-BAY POWER UNIT

PM-X00-520 (110V)

PM-X00-522 (230V)

Standard Battery Pack Charging Bay

PM-X00-731

Instructions for Use

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Introduction

Thank you for choosing BUSA® 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 4-Bay Power Units, PM-X00-520 and PM-X00-522 are units designed to accept up to four modular Standard Battery Pack Charging Bays, PM-X00-731. The modular standard battery pack charging bay is intended to charge BSPMAX™ II 9.6V Battery Pack, PM-X00-710 and 12V Battery Pack, PM-X00-715.

Warnings

- 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.
- DO NOT use if damage is apparent.
- Use of Eye protection is required while operating equipment.
- DANGER - Explosion Hazard. DO NOT use in atmospheres containing flammable gasses (anesthetics, etc) with concentrations within explosive limits. Not to be used in the OR.
- Clean 4-Bay Power Unit and Charging Bay before use.
- DO NOT modify the 4-Bay Power Unit or the Charging Bay.
- Always use the BUSA® charging bay when charging battery packs. Failure to comply may result in patient and/or medical staff injury.
- DO NOT operate the 4-Bay Power Unit with a damaged power cord or plug.
- DO NOT modify the ground of the 4-Bay Power Unit power cord.
- Install the power cord of the 4-Bay Power Unit directly into electrical outlet.
- DO NOT disassemble or service the 4-Bay Power Unit or Charging Bay. Return to Brasseler U.S.A. Medical, LLC, for service or repair. Failure to comply may result in electric shock or fire.
- Always disconnect the power cord from the 4-Bay Power Unit before performing cleaning to reduce the risk of electric shock.
- Install and place the 4-Bay Power Unit into service according to the EMC information in this manual. Portable and Mobile RF communications equipment can affect the function of the 4-Bay Power Unit.
- 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 sterilize the 4-Bay Power Unit or Charging Bays.
- DO NOT connect 4-Bay Power Units in series.
- REMOVE battery packs from Charging Bays when 4-Bay Power Unit is off to avoid battery discharge and/or irreparable damage to battery cells.

Explanation of Symbols

Authorized representative in the European community.

Catalog number.

Caution.

Conforms with the essential requirements of the European community directives with Brasseler USA Medical's notified body.

Date of manufacture.

Do not discard. Dispose of product or recycle in accordance with local laws and regulations.

Do not immerse.

Interference.

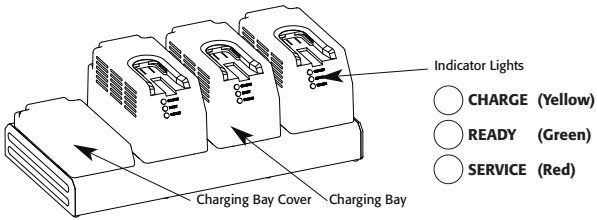
Manufacturer.

Serial Number.

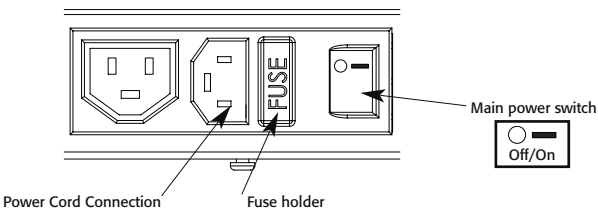
Shock hazard, type B.

Temperature limit.

Features



Power Connection



- Power Connection – Connects and disconnects Power Unit from facility power. Power connection contains:
  - *Fuse Holder*
  - *Main Power Switch*
  - *Power Cord Connection*
- Charging Bay – Modular battery charging bay for BSPMAX™ II battery packs. Power Unit will accept up to four (4) Charging Bays.
- Charging Bay Cover – Shields Power Unit's cooling fan and Charging Bay connector when not in use. Cover should only be removed when installing a Charging Bay.
- Indicator Lights – Provide battery status information when illuminated.
  Charge - Yellow – Battery Pack is charging.
  Ready - Green – Battery Pack is fully charged and ready for use.
  Service - Red – Charging cycle failed.

Charging Bay – PM-X00-731

The 4-Bay Power Unit can be configured with a combination of Charging Bay(s) and Bay Cover(s). The 4-Bay Power Units (PM-X00-520 and PM-X00-522), Standard Battery Pack Charging Bay (PM-X00-731) and Charging Bay Cover (PM-X00-521) are sold separately. The power unit charges up to four battery packs simultaneously.

Cautions:

- DO NOT over tighten screws.
- DO NOT connect power cord to the electrical connector inside the charging bay.

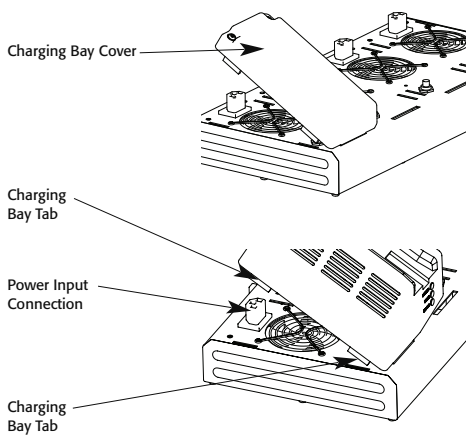
Tool Required:

- Standard Phillips #2 (medium size) Screwdriver.

Installation & Removal

Charging Bay Installation:

- Loosen screws and remove Charging Bay Cover.
- Align front Charging Bay tab with Power Unit slot.
- Lower the Charging Bay into the corresponding side slots and power input connection. Ensure Charging Bay tabs are aligned with Power Unit slots.
- Apply light force to seat fully.
- Tighten screws with screwdriver.
- Verify that the Charging Bay is flush with the top surface of the 4-Bay Power Unit and that the front tab is engaged into power slot.



Charging Bay Removal:

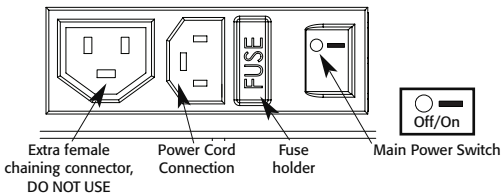
- Loosen Screws.
- Remove Charging Bay.
- Install Charging Bay Cover (PM-X00-521).

4-Bay Power Units – PM-X00-520 (110V) & PM-X00-522 (230V)

The 4-Bay Power Unit can be configured with a combination of Charging Bay(s) and Bay Cover(s). The 4-Bay Power Units (PM-X00-520 and PM-X00-522), Standard Battery Pack Charging Bay (PM-X00-731) and Charging Bay Cover (PM-X00-521) are sold separately. The power unit charges up to four battery packs simultaneously.

4-Bay Power Unit Fuse Replacement

1. Set the main power switch to OFF (O).
2. Disconnect the power cord.
3. Squeeze and pull out the fuse holder.
4. Replace with two (2) T6.3A (250V) fuses.
5. Replace fuse holder.
6. Connect the power cord.
7. Set the main power switch to ON (-).



4-Bay Power Unit Operation

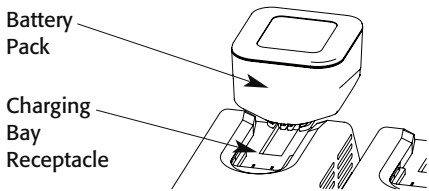
1. Set the main switch to the OFF position (O).
2. Connect the female end of the power cord to the power cord connection on the back of the power unit.
3. Connect the male end of the power cord to the wall outlet.
4. Activate 4-Bay Power Unit by depressing the main power switch to the ON position (-). Indicator lights will pulse when Power unit is activated. Indicator lights will illuminate when a Batter Pack is inserted.

Battery Pack Charging

1. Insert battery pack into a charging bay receptacle.

2. Follow warnings, cautions and notes in BSPMAX™ II PM-X00-710 (9.6V) & PM-X00-715 (12V) Battery Packs Instructions for Use.

3. A single light will illuminate to indicate battery pack status.



- All pulse - System is powered on.
- Yellow (pulsing) - Primary diagnostic test to determine voltage level.
- Yellow (solid) - Battery Pack is charging.
- Green (solid) - Battery Pack is charged and ready for use.
- Red (pulsing) - Secondary diagnostic test to determine charging capacity.
- Red (solid) - Charging cycle failed and battery pack should be disposed of properly (refer to Battery IFU for Product Disposal Information).

CHARGE (Yellow)
READY (Green)
SERVICE (Red)

Troubleshooting

Symptom	Potential Cause	Solution
Fans and indicator lights do not function.	Power cord not connected.	Connect power cord.
	Power unit is turned OFF (O).	Turn power switch On (-).
	Fuses are open/blown or missing.	Replace with appropriate rated fuses. See 4-Bay Power Unit fuse replacement.
	No power at electrical outlet.	Check circuit breaker.
Charging unit fan does not function.	Charging bay is not installed correctly.	See installation and removal.
Indicator lights do not function on charging bays.	Charging bay is not installed correctly.	See installation and removal.
	Power unit fuses are open/blown.	Replace with appropriate rated fuses. See 4-Bay Power Unit fuse replacement.
	Battery pack is not seated properly.	Fully seat battery onto charging bay.
	Charging contacts are dirty.	See cleaning recommendations.
	Battery pack malfunctions.	Replace battery pack.
After inserting battery pack into charging bay, red light illuminates.	Charging contacts are dirty.	See cleaning recommendations.
	Battery pack is at elevated temperature.	Allow to cool for 20 minutes, then reinsert into charging bay.
	End of life cycle for battery pack.	Replace battery pack.
	Battery pack is improperly sterilized.	Replace battery pack.

Troubleshooting (continued)

Symptom	Potential Cause	Solution
Charging bay will not fully connect onto power unit.	Misalignment of electrical plug.	Send power unit and charging bay to Brasseler U.S.A. Medical, LLC, for service.
	Electrical plug blades bent.	Send charging bay to Brasseler U.S.A. Medical, LLC, for service.
Indicator lights remain illuminated when battery pack is not installed.	Charging bay malfunctioned.	Send charging bay to Brasseler U.S.A. Medical, LLC, for service.
There is a recurring power unit open/blown fuses.	Charging board circuit failed.	Send power unit to Brasseler U.S.A. Medical, LLC, for service.
	Fuses have wrong rating.	Replace with appropriate rated fuses. See 4-bay power unit fuse replacement.
	A power surge occurred.	Install power surge suppressor.
Indicator light does not illuminate when battery pack is installed.	Charging bay malfunctioned.	Send charging bay to Brasseler U.S.A. Medical, LLC, for service.
	Fuses are open/blown or missing.	Replace with appropriate rated fuses. See 4-bay power unit fuse replacement.
	Power cord not connected.	Connect power cord.
	Power unit is turned off (o).	Turn power switch on (-).
	No power at electrical outlet.	Check circuit breaker.

Care & Maintenance

BUSA® Surgical Power & Accessories recommends that all BSPMAX™ II components (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 and a thorough inspection for damage. Routine preventive maintenance performed every twelve (12) months by the Brasseler U.S.A. Medical, LLC, Service Department can increase the reliability and extend the life span of your BSPMAX™ II Large Bone Power System.

Cleaning Recommendations

General Cleaning Precaution:

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

Warnings:

- DO NOT use if damage is apparent.
- DO NOT use 4-Bay Power Unit in the presence of explosive gases.
- DO NOT operate the 4-Bay Power Unit with a damaged power cord or plug.
- DO NOT disassemble or service the 4-Bay Power Unit. Return to Brasseler U.S.A. Medical, LLC, Service Department.

Cautions:

- DO NOT immerse the 4-Bay Power Unit or Charging Bays in liquid.
- DO NOT use solvents, lubricants, or other chemicals to clean the 4-Bay Power Unit or Charging Bays unless otherwise directed.
- DO NOT allow water to collect on the 4-Bay Power Unit or Charging Bays.
- DO NOT sterilize the 4-Bay Power Unit or Charging Bays.
- DO NOT clean the charging contacts with abrasives.
- Prior to changing fuses, set power unit main switch to OFF (O), then disconnect power cord.
- DO NOT use in operating rooms or locations with explosive gases.
- DO NOT connect 4-Bay Power Unit in series.
- Remove battery packs from charging bays when 4-Bay Power Unit is off to avoid battery discharge and/or irreparable damage to the battery cells.

Cleaning Recommendations (continued)

Cleaning Procedures:

1. Set the main power switch to OFF(O).
2. Remove all battery packs.
3. Disconnect the 4-Bay Power Unit power cord from the outlet.
4. Wipe the external surfaces of the 4-Bay Power Unit and Charging Bays with a clean lint-free soft cloth lightly dampened with a non-abrasive hospital disinfectant.
5. Dry immediately with a clean lint-free soft cloth.
6. Clean charging contacts using a cotton swab lightly with isopropyl alcohol. DO NOT clean the charging contacts with abrasives.
7. Ensure equipment is completely dry before reconnecting to power.
8. Inspect for damage or malfunctioning.
   Return damaged components to Brasseler U.S.A. Medical, LLC, Service Department.

Specifications

1. Performance

	PM-X00-520	PM-X00-522
Input Voltage	100VAC – 120VAC	220-240VAC
Max. Rated Current	10A	6A
Frequency	50 – 60 Hz	50 – 60 Hz
Output Voltage Max.	15VDC	15VDC
Classification	Protection Class 1	Protection Class 1
Class of Rating	Continuous operation	Continuous operation
Socket Outlet	5A 100 – 120V ~ 50/60 Hz	3A 220 – 240V ~ 50/60 Hz

2. Physical Characteristics

4-Bay Power Unit with 4 charging bays

Size	17″ x 8 5/8″ x 6 1/4″
Weight	16.75 lb

Charging Bay

Size	7 1/2″ x 3 1/2″ x 4″
Weight	1.8 lb

4-Bay Power Unit

Size	17″ x 8 5/8″ x 2 1/4″
Weight	9.55 lb

Specifications (continued)

3. Compliance Standards

EMC Compliance Standards: DN60601-1-2; IEC60601-1; CSA 60601.1
Safety Compliance: EN60950-1; IEC60950-1; CSA 60950-1; UL 60950-1

4. Environmental Requirements

Operating:

- Ambient temperature : 50°F to 70°F (10°C to 21°C)
- Relative Humidity 30% - 75%
- Atmospheric Pressure: 700hPa to 1060hPa

Transport :

- Ambient temperature : -4°F to 158°F (-20°C to 70°C)
- Relative Humidity 10% - 100%
- Atmospheric Pressure: 500hPa to 1060hPa

Specifications (continued)

5. Electromagnetic Compatibility Requirements

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The BSPMAX™ II battery charger is intended for use in the electromagnetic environment specified below. The user of the BSPMAX™ II battery charger should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BSPMAX™ II battery charger uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BSPMAX™ II battery charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80MHz to 2.5 GHz	3 V/m 150 MHz to 80 GHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the BSPMAX™ II Battery Charger, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.67\sqrt{P}$ $d=1.67\sqrt{P}$ 80 MHz to 800 MHz $d=2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80MHz and 800MHz the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The BSPMAX™ II Battery Charger is intended for use in the electromagnetic environment specified below. The user of the BSPMAX™ II Battery Charger should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 KV contact ±8 KV air	±2, 4, 6 KV contact ±2, 4, 8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 KV for power supply lines ±1 KV for input/output lines	±2 KV for power supply lines ±1 KV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	Main power quality should be that of a typical commercial or hospital environment.

Specifications (continued) 5. Electromagnetic Compatibility Requirements continued

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%U_T (>95% dip in U_T) For 0.5 cycle	100% Reduction (10 ms)	
	40%U_T (60% dip in U_T) For 5 cycles	60% Reduction (100 ms)	
	70%U_T (30% dip in U_T) For 25 cycles	30% Reduction (500 ms)	
	<5%U_T (>95% dip in U_T) For 5 sec	95% Reduction (5 sec)	
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m At 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1: U_T is the alternating current mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Recommended separation distances between portable and RF communications equipment and the BSPMAX™ II handpiece.			
The BSPMAX™ II Battery Charger is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the BSPMAX™ II Battery Charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BSPMAX™ II Battery Charger as recommended below, according to the maximum output power of the communications equipment.			
Related maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d=[\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Repair Service

Contact your distributor for details regarding repairs.

BUSA® Surgical Power & Accessories recommends that the BSPMAX™ II handpieces, attachments, accessories and Four Station Modular Battery Charger (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.

BUSA® 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 BUSA® 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 BUSA® 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.

Repair Service (continued)

Return to:
Brasseler U.S.A. Medical, LLC
4837 McGrath Street
Ventura, CA 93003

Warranty

Contact your distributor for details regarding warranty.

Return Goods Policy

Contact your distributor regarding returned goods policy.

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

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

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

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EC REP

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