Operating Instructions and Maintenance Manual

- Power Control Console
- Modular Motor Units
- Footswitch Operations
- Handpiece Modules
- Maintenance
- Warranty

OSTEOMED
A Tradition of Quality and Innovation
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SYSTEM COMPONENTS
The OsteoPower™ System is comprised of hand-piece modules, Electric Drive Unit(s), and a Power Control Console (PCC) with or without irrigation, and Footswitches, as well as many other accessories.

DESCRIPTIONS
- **Power Control Console (PCC):** Electronic Control and Power Supply unit for Electric Drive Modules
- **Electric Drive Unit:** A high speed, high torque motor with a housing which is connected to the PC and converts power to the drills, saws, or drivers
- **Footswitch:** A foot control unit which is connected to the PCC to control the speed and direction of the Electric Drive
- **1:1 Straight Drill:** A high speed module which is attached to the Electric Drive for cutting, drilling, and deburring
- **1:1/20:1/80:1 Contra Angle Drills:** Angular drills with or without gear reduction for cutting, drilling, and tapping
- **Reciprocating Saw:** A module for cutting with reciprocating motion
- **Oscillating Saw:** A module for cutting with oscillating motion
- **VRO Saw:** A module for cutting with oscillating motion
- **Sagittal Saw:** A module for cutting with sagittal motion
- **Wire/Pin Driver:** A slow speed module to drive different sizes of wire or pins and for drilling

SPECIFICATIONS
(min⁻¹)

<table>
<thead>
<tr>
<th>Duty Cycle</th>
<th>Cycle ON</th>
<th>Cycle OFF</th>
<th>Total Number of Cycles</th>
<th>Minimum Break Time Between Cycles</th>
<th>Maximum Electric Drive Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:1 Straight Drill</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>70,000</td>
</tr>
<tr>
<td>4:1 Universal Drill</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>24,000</td>
</tr>
<tr>
<td>20:1 Contra Angle Drill</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>24,000</td>
</tr>
<tr>
<td>80:1 Contra Angle Drill</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>24,000</td>
</tr>
<tr>
<td>1:1 Contra Angle Drill</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>52,000</td>
</tr>
<tr>
<td>Wire/Pin Driver/Jacobs Chuck</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>24,000</td>
</tr>
<tr>
<td>AO Synthes Driver</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>24,000</td>
</tr>
<tr>
<td>Reciprocating Saw</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>20,000</td>
</tr>
<tr>
<td>Oscillating Saw</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>20,000</td>
</tr>
<tr>
<td>Sagittal Saw</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>20,000</td>
</tr>
<tr>
<td>VRO Saw</td>
<td>20 sec</td>
<td>30 sec</td>
<td>10</td>
<td>45 minutes</td>
<td>20,000</td>
</tr>
</tbody>
</table>

ELECTRICAL REQUIREMENTS
100-240 VAC, 1 Phase, 6.3 Amp, Hospital Grade

Classification: Type B Applied Part, Class 1

SYMBOL DESCRIPTIONS
- **ON:** Main Power On Switch
- **OFF:** Main Power Off Switch
- **Safety:** Motor Unit Control switch to temporarily disable the Electric Drive
- **Variable Speed Ranges (PCC):** Speed settings for Electric Drive=SAFETY, Di, 25, 50, 75, 100%
- **Variable Speed Range (FS):** Speed control for Electric Drive on Footswitch
- **Variable Speed (Motor Unit Sensor):** Electric Drive speed control
- **Fuse:** Current Limit safety mechanism
- **Disengage/Engage:** Direction to insert/extract module from Electric Drive
- **Electrical Warning:** Safety and Warning signs
- **Footswitch:** A foot-activated unit to control the speed and direction of the Electric Drive
- **Forward/Reverse:** Forward and Reverse motor control switch on Electric Drive
- **Forward:** Forward control switch on PCC
- **Reverse:** Reverse control switch on PCC
- **Irrigation (Pump Flow):** Speed setting in steps for irrigation: High, Medium, Low, OFF
  - **IN:** Direction of irrigation flow from irrigation bag
  - **OUT:** Direction of irrigation flow to the Electric Drive
  - **Di:** Dental Implant setting. Lower speed and specific torque settings: 12.5% (300RPM) speed range.
SYMBOLS

**DANGER** indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury and may result in property damage.

**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury and may result in property damage.

**CAUTION** indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury and may result in property damage.

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**DEFINITIONS**

**MOTOR UNIT** = Motor Unit  
**STALL** = Motor Unit stops due to extreme loading, torque, or jamming  
**EXCURSION** = The side-to-side travel of a saw blade  
**STROKE** = The forward and backward motion of a saw blade

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**ACRONYMS**

PCC = Power Control Console  
MU = Motor Unit  
LED = Light Emitting Diode  
F/R = Forward/Reverse  
FS = Foot Switch  
PCCi = PCC Irrigation

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**DISPOSAL**

Follow country, state/province and local regulations, standards, and guidelines for the disposal of used electrical devices.

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**STORAGE AND TRANSPORT CONDITIONS**

Relative Humidity Non-Condensing  
Range: 10% to 95%  
Range: 76kPa - 106kPa

Temperature Ambient  
Range: -10°C to +70°C  
Range: 49°C

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**OPERATIONAL CONDITIONS**

Relative Humidity Non-Condensing  
Range: 10% to 80%  
Range: 76kPa - 106kPa

Temperature Ambient  
Range: -10°C to +35°C  
Range: 55°C

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**EXPLOSION HAZARD**  
DO NOT operate the OsteoPower System in the presence of flammable gases, liquids, or anesthetics.
GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS

The OsteoPower/ECOS, Models 450-0005-XX and 450-0021-XX are intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoPower/ECOS, Models 450-0005-XX and 450-0021-XX should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions (EN 55011)</td>
<td>Group 1</td>
<td>The OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX use 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.</td>
</tr>
<tr>
<td>RF emissions (EN 55011)</td>
<td>Class B</td>
<td>The OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX are 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.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WARNING** The OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX should not be used adjacent to or stacked with other equipment without verifying proper operation of both the OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX with any such adjacent or stacked equipment.

The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.

GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY
(For all ME equipment and ME systems)

The OsteoPower/ECOS, Models 450-0005-XX and 450-0021-XX are intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoPower/ECOS, Models 450-0005-XX and 450-0021-XX should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6kV contact</td>
<td>±6kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>(EN 61000-4-2)</td>
<td>±8kV air</td>
<td>±8kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fasts transient/burst</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td></td>
</tr>
<tr>
<td>(EN 61000-4-4)</td>
<td>±1 kV for input/output lines</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Surge (EN 61000-4-5)</td>
<td>±2 kV differential mode</td>
<td>±2 kV differential mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines (EN 61000-4-11)</td>
<td>&lt;5% UT (&lt;95% dip in UT) for 0.5 cycle</td>
<td>&lt;12V (&gt;95% dip in 240V) for 0.5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td></td>
<td>40% UT (60% dip in UT) for 5 cycles</td>
<td>96V (60% dip in 240V) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% UT (30% dip in UT) for 25 cycles</td>
<td>168V (30% dip in 240V) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td>&lt;12V (&gt;95% dip in 240V) for 5 sec</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field (EN 61000-4)</td>
<td>3 A/m</td>
<td>Not Applicable</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**NOTES:** The OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX do not contain any magnetically sensitive devices.

UT is the AC mains voltage prior to application of the test level.

At 80 MHz and 800 MHz, the higher frequency range applies.

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 IMMUNITY
(For all ME equipment and ME systems that are not Life-Supporting)

The OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX, are intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX should assure that they are used in such an environment.

### Immunity Test

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>Test Level</th>
<th>Electromagnetic Environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF (EN 61000-4-6)</td>
<td>3 Vrms, 150 kHz to 80 MHz outside ISM bands(a)</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance.</td>
</tr>
</tbody>
</table>
| Radiated RF (EN 61000-4-3)    | 3 V/m 80 MHz to 2.5 GHz     | d=[3.5/V₁]√P 80 MHz to 800 MHz  
|                               |                             | d=[7/E₁]√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).  
|                               |                             | Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey,(a) should be less than the compliance level in each frequency range.(b)  
|                               |                             | Interference may occur in the vicinity of equipment marked with the following symbol: [![](https://example.com/symbol)](https://example.com/symbol) |

### NOTES:

(a)Field strengths from fixed transmitter, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AutoDriver is used exceeds the applicable RF compliance level above, the OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX should be observed to verify normal operation. If abnormal performance is observed, additional measured may be necessary, such as reorienting or relocating the OsteoPower Models 450-0005-XX and 450-0021-XX.

(b)Over the frequency range 150 kHz to 80 Mhz, field strengths should be less than 3V/m.

1 UT is the AC mains voltage prior to application of the test level.

2 At 80MHz and 800MHz, the higher frequency range applies.

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

Recommended separation distances between portable and mobile RF communications equipment and the OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX.

The OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX can help prevent electromagnetic interference by maintaining a Minimum distance between portable and mobile RF communications equipment (transmitters) and the OsteoPower/ECOS Models 450-0005-XX and 450-0021-XX as recommended below, according to the Maximum output power of the communications equipment.

### BIOCOMPATIBILITY

Note: The components and accessories intended to contact biological tissues, cells or body fluids have been evaluated and documented to ensure compliance with the requirements of ISO 10993-1.
The Power Control Console is the “brain” of the OsteoPower System. A number of features have been designed into the Power Control Console.

**FEATURES**

- LED speed range indicator scaled for SAFETY, DI (12.5%, 25%, 50%, 75% and 100% of maximum motor speed)
- Dental implant Setting for specified speed and torque limit
- Forward/Reverse directional controls
- 2 handpiece ports allow sequential dual handpiece operation
- Flashing “A” or “B” LED indicates “SAFETY” mode
- Positive-lock cord connectors ensure positive actuation and durability
- Repeating audible beep indicates Reverse operation
- Universal power supply provides over 260 watts of peak power
- Low profile enclosure to fit most office furniture spaces
OPERATION INSTRUCTIONS:

1. Plug the hospital grade AC power cord into the appliance inlet on the rear panel of the control console (Fig. 1). Plug the opposite end into a standard grounded wall outlet (100-240V, 50-60 Hz).

2. Activate the PCC by depressing the power switch adjacent to the appliance inlet to the “I” position (Fig. 2). All appropriate LED’s should light. Speed control will default to the “SAFETY A” mode.

3. The Motor Unit can be connected into either the “A” or “B” handpiece ports on the PCC. The Motor Unit connector plug is keyed. The red dot on the front motor unit connector plug should be aligned with the red dot on the PCC receptacle. (Care should be taken to avoid pushing the plug into the handpiece port when the red dot is out of alignment.) (Fig. 3)

   NOTE: The PCC has a redundant control circuitry to provide independent control for two Motor Units. Each Motor Unit activates when plugged into the PCC.

   NOTE: When one Motor Unit is operating independently, the controls of the second Motor Unit are temporarily disabled. All controls of the second Motor Unit reactivate when operation of the first Motor Unit is discontinued. The “A” or “B” indicator LED on the face of the PCC will illuminate and indicate which Motor Unit is active. See also footswitch operations.

4. Forward/Reverse operation can be controlled either on the front panel of the PCC, the top surface of the Motor Unit, or by utilizing a Bi-directional Footswitch. The bi-directional footswitch overrides the direction controls on the motor units and PCC.
The PCCi is equipped with an integrated automatic pump for internal and external irrigation systems.

**ACCESSORIES:**
- 450-0124 Contra Angle Irrigation Nozzle
- 450-0125-01 Single Silicone Tubing Set, 12 ft. (Clips Included)
- 450-0126-01 Dual Silicone Tubing Set, 12 ft. (Clips Included)
- 450-0525 Autoclavable Irrigation Bag Spike
- 450-0424 Series III Straight Drill Irrigation Nozzle
- 450-0422 Reciprocating Saw Irrigation Nozzle
- 450-0420-04 Bifurcated Contra Irrigation Tubing Internal/External
- 450-0128-12 Autoclavable Tubing Clips (12/bag)
- 450-0129 Irrigation Tubing (1 foot section)

**FEATURES:**
- Automatic start/stop and harmonics with handpiece operation.
- Multiple flow rate
- LED flow rate indicator: High, Medium, Low, OFF
- Integrated pump design with the PCC for simplicity
- Single step positive-locking pump feature

**OPERATING INSTRUCTIONS:**
1. Install irrigation pole to the back of the console with the hanger positioned directly above the PCCi (Fig. 4).
2. Attach selected tubing to the Motor Unit cord (Fig. 5).
3. Attach handpiece module irrigation clips to the Motor Unit and selected handpiece module. The needle end of the irrigation clips can be manipulated to optimize the direction of irrigation flow.
4. Attach irrigation tubing to Motor Unit cord using irrigation clips.
5. Pull and unlatch the lever of the irrigation cover to the direction labeled on the cover.
6. Locate the luer fitting of the tube to the input with the “IN” mark. Thread tubing around the rollers and exit through the slot marked “OUT.”
   **NOTE:** It is imperative that the luer connection (found two feet down from the bag spike) is placed just prior to the “IN” slot. Failure to do so may cause a pump stall condition (Fig. 6).
7. Place tubing into slot on the pump housing.
8. Rotate the lever in the direction indicated for locking and secure the cover.
9. Spike an irrigation bag and allow irrigation to fill tubing. It is recommended that the irrigation bag be spiked prior to handling. The irrigation bag should be elevated above the level of the handpiece using the IU pole provided with the PCCi.
10. Turn on the PCCi and set the flow rate by pressing the irrigation switch on the PCCI panel (Fig. 7).
11. Irrigation flow is activated automatically by pressing the variable speed sensor on the Motor Unit or by depressing the Footswitch (when using a Footswitch). Regardless of speed range setting.
**FEATURES COMMON TO ALL OSTEOPOWER MOTOR UNITS:**

- Proprietary brushless DC motor delivers exceptional, reliability and consistent speeds
- Ergonomic shape provides exceptional control
- Advanced electronic circuitry brakes motor instantaneously
- Operates in both high speed (0-70,000 RPM) and standard speed (0-24,000 RPM) modes
- Lightweight integrated power cord
- Internal module coupling mechanism allows the easy and quick insertion of a wide variety of handpiece modules
- All handpiece modules can be inserted in four different orientations at 90 degree intervals. This allows the operator to orient the handpiece module based on clinical assessment, visibility and comfort
- Insulating thermoplastic housing assures cool handpiece operation and extremely high durability
- Motor Unit and Cord are fully autoclavable

**HAND CONTROLLED MOTOR UNIT AND CORD - 450-0030 (Fig. 8)**

- The Hand Controlled Motor Unit allows for finger tip control of:
  - Variable speed
  - Maximum Speed Range
  - Forward/Reverse
  - "SAFETY" mode operation

**OPERATING INSTRUCTIONS - 450-0030:**

1. To activate the Motor Unit, depress the sensor to a setting other than "SAFETY" (Fig. 9)
   a. Maximum Speed Range selection choices are: SAFETY, 100%, 75%, 50%, 25% or Di (12.5%) of maximum speed capability
   b. Please refer to Speed Conversion Chart affixed to the top of the console to select handpiece module maximum speed
   c. At initial start up, the Motor Unit defaults to the SAFETY mode and the Forward direction
   d. Prior to inserting or removing handpiece modules, make sure the Motor Unit Speed Range Sensor is set to the SAFETY mode

2. After selecting the desired speed range setting, motor speed is controlled by depressing the variable speed control sensor pad. (Fig. 10) By varying the amount of finger pressure at any point along the length of the sensor, motor speed will vary. Greater pressure exerted on the surface sensor results in higher motor speed.

3. For handpiece modules designed to operate at 70,000 RPM, insert the handpiece module into the Motor Unit with the high speed dot in alignment with the speed control sensor on the Motor Unit. (Fig. 11)

4. To select a maximum speed of 24,000 RPM, insert the handpiece module into the Motor Unit in any other orientation.

5. Motor direction is controlled by the Forward/Reverse section of the sensor pad. (Fig. 12) By depressing this sensor, motor direction will be reversed. A repeating audible "beep" will occur when the motor is operating in reverse. The Reverse LED indicator on the Power Control Console will also illuminate when the motor is in the Reverse mode. Depression of the F/R sensor will change motor direction.
FEATURES:
The Lever Arm Motor Unit allows for finger control of:
- Variable speed
- Maximum Speed Range
- Forward/Reverse
- "SAFETY" mode operation
- Detachable Telescopic Lever Arm

OPERATING INSTRUCTIONS - 450-0034:
1. Before the Lever Arm Motor Unit (LAMU) can be activated, the safety wheel must be rotated backward to show green dot (Fig. 14)
   a. Maximum Speed Range selection choices are: SAFETY, 100%, 75%, 50%, 25% or Di (12.5%) of maximum speed capability (Fig. 15)
   b. Please refer to Speed Conversion Chart affixed to the top of the console to select handpiece module maximum speed
   c. At initial start up, the Motor Unit defaults to the “SAFETY” mode and Forward direction
   d. Prior to inserting or removing handpiece modules, make sure the Motor Unit “Safety Lever” is set to the SAFETY mode
2. To select a speed percentage setting, momentarily slide the speed control button backward. To change direction slide forward.
3. After selecting the desired speed range setting, motor speed is controlled by depressing the Lever Arm. By varying the amount of finger pressure at any point along the length of the Lever Arm, motor speed will vary. Greater pressure exerted on the Lever Arm results in higher motor speed. (Fig. 16)
4. Motor direction is controlled by the speed control button. By momentarily sliding the speed control button toward the handpiece module, motor direction will be reversed. A repeating audible “beep” will occur when the motor is operating in reverse. The Reverse LED indicator on the console will also illuminate when the motor is in the Reverse mode. (Fig. 17)
5. For handpiece modules designed to operate at 70,000 RPM, insert the handpiece module into the Motor Unit with the high speed dot in alignment with the laser marking on the distal tip of the LAMU. (Fig. 18)
6. To select a maximum speed of 24,000 RPM, insert the handpiece module into the Motor Unit in any other orientation.
7. When using the optional footswitch, the lever will be disabled. The lever may be removed by rotating the lever 180 degrees toward to motor unit cord and pull the lever arm out.

Fig. 13
Fig. 14
Fig. 15
Fig. 16
Fig. 17
Fig. 18
NOTE: The 450-0084 Motor Unit requires a Footswitch to operate.

MAXIMUM SPEED PERCENTAGE SELECTION
1. For handpiece modules designed to operate at 70,000 RPM, insert the handpiece into the Motor Unit with the high speed dot in alignment with the arrow located on the Motor Unit (Fig. 20)
2. To select a maximum speed of 24,000 RPM, insert the handpiece into the Motor Unit in any other orientation (Fig. 21)
3. Prior to inserting or removing the handpiece modules, make sure the Motor Unit Speed Range sensor is set to the “SAFETY” mode.

OPERATING INSTRUCTIONS
1. To activate the Motor Unit, set the speed range on the console to a setting other than “SAFETY”
2. Maximum Speed Range selection choices are: SAFETY, 100%, 75%, 50%, 25% or Di (12.5%) of maximum speed capability. (Fig. 22)
3. Please refer to the Speed Conversion Chart affixed to the top of the console to set module maximum speed.
4. During power up, the Motor Unit is automatically set to the “SAFETY” mode and the “Forward” direction.

CONTROL OF SPEED AND DIRECTION
1. After selecting the desired speed range setting on the console, motor speed is controlled by depressing the Footswitch sensor pad. By varying the amount of foot pressure at any point along the sensor, motor speed will vary. Greater pressure exerted on the surface sensor results in higher motor speed.
2. Motor direction is controlled by the Forward/Reverse section of the Footswitch pad (Bi-directional Footswitch, P/N 450-0390) . By depressing the “Yellow” side of the Footswitch sensor, motor direction will be reversed. A repeating audible “beep” will occur when the motor is operating in reverse. The Reverse LED indicator on the console will also illuminate when the motor is in the Reverse mode. Depression of the “F or R” sensor on the console will change motor direction. (Fig. 23)
Bi-directional Multi-Function Footswitch (BMF Footswitch) (Fig. 24)

**CAUTION** Do not drop Footswitch. Dropping the Footswitch may cause damage and void the warranty.

**BMF FOOTSWITCH OPERATION**

The Bi-directional Multi-Function Footswitch is designed for hands-free control of the “A” or “B” Motor Unit, Variable Speed and Forward/Reverse motor direction.

1. To activate the Bi-Directional Footswitch, insert its cord connector into the Footswitch receptacle on the back panel of the Power Control Console (Fig. 25). Once the Footswitch is plugged in, the hand control Motor Unit’s (450-0030) speed actuation and forward/reverse surface sensors are deactivated.

2. By varying the amount of foot pressure on either the Forward or Reverse sections of the Footswitch, the motor speed will vary. The greater the foot pressure, the higher the speed. Forward is controlled on the right (GREEN) side of the Footswitch, Reverse on the left (YELLOW) side (Fig. 26).

   **NOTE:** Maximum Speed Range setting and “SAFETY” continue to be controlled by the Motor Unit or the Power Control Console when utilizing a Footswitch.

3. By depressing the “A/B” button on the Footswitch, either the “A” or “B” Motor Unit can be selected for operation. Each Motor Unit can be operated sequentially; however, the proper “A/B” mode must be selected using the Footswitch in order to activate the desired Motor Unit (Fig. 27).

   **NOTE:** Unplugging the Footswitch enables the Motor Unit’s speed actuation and direction sensors. The maximum speed percentage sensor on the Motor Unit is always active with or without a Footswitch plugged in.

   **NOTE:** The footswitch may also be used to activate the irrigation pump, if equipped, when the PCCi is in safety mode.

**TANDEM FOOTSWITCH OPERATION**

The BMF Footswitch can be connected in tandem to allow single or dual Motor Units to be operated from two Footswitch locations (Fig. 28). This capability was designed to allow Footswitch placement on either side of an operating room table.

**SETUP**

1. Plug a BMF Footswitch into the receptacle located on the rear of the selected BMF Footswitch (Fig. 29).

2. Plug the selected BMF Footswitch cord connector into the female receptacle on the back panel of the Power Control Console.

3. Operate either Footswitch as described in “BMF Footswitch Operation.”

**TANDEM FOOTSWITCH OPERATION**

When using tandem Footswitches, either Footswitch can control a single Motor Unit. To activate a Motor Unit, depress the “A/B” button on either Footswitch until the LED on the Power Control Console is lit next to the connector port that the Motor Unit is plugged into.

When two Motor Units are plugged into the Power Control Console, either Footswitch can control either the “A” or “B” Motor Unit. The “A/B” button on either Footswitch must be depressed to switch from activating either the “A” or “B” Motor Unit. The “A” or “B” LED on the Power Control Console will illuminate to indicate which Motor Unit has been activated.

Operate either Footswitch as described in “BMF Footswitch Operation.”
**Part Number:** 450-0777 1:1 Straight Drill (Fig.30)  
**Part Number:** 450-0778 Lubrication Sleeves (Fig. 31)

The OsteoPower 1:1 Straight Drill is designed for both standard (0-24,000 RPM) and high speed (0-70,000 RPM) capability. This feature allows the operator to select an optimal speed range for the specific procedure.

**WARNING** Always select the “SAFETY” mode when the handpiece system is not in use or prior to inserting or removing burs and modules. Always visually check each bur prior to the procedure. Burs are intended as single-use disposable items. Never use a worn or bent bur. Never reuse a bur.

**BUR SELECTION**
OsteoMed offers a wide range of cutting accessories for the 1:1 Straight Drill. These accessories include: cross-cut fissure carbide burs, round carbide burs, twist drills and specialty burs. Each bur has been designed to produce quick, efficient cuts, with minimal heat buildup. Each OsteoMed Straight Drill should be operated at speeds appropriate for the cutting accessory being used. Appropriate speeds depend on the selected bur head size, length, and procedure performed. All OsteoPower burs feature a unique shank detail which is specific to the OsteoPower System (Fig. 32). This unique bur shank detail is intended to prevent the use of long or otherwise inappropriate burs in the 1:1 Straight Drill module. Because of the handpiece’s high speed capabilities, only OsteoPower burs can be safely used in the 1:1 Straight Drill.

**BUR INSERTION AND REMOVAL**

**WARNING** DO NOT operate the straight drill without ensuring that the locking collar is in the fully locked position. When no bur is inserted into the drill, when a bur is inserted and/or locked incorrectly, and/or when a bur with an incorrect latch is inserted into the drill, the handpiece system is designed to “stall” and may be damaged when activated.

**CAUTION** If a bur is inserted and the locking collar is in the unlocked position, the locking collar will automatically lock and the drill will run when the Motor Unit is activated.

To insert a bur, set the Motor Unit to the “SAFETY” mode and twist the locking collar into the unlocked position. This can be confirmed by having the green dot in alignment with the red oval (Fig. 33). Once open, insert the bur until it bottoms out. Return the locking collar to the locked position (green dot aligned with green dot) to secure the bur (Fig. 34).

To remove a bur, set the Motor Unit to the “SAFETY” mode, then twist the bur locking collar from the locked position to unlocked (Fig. 34 & Fig. 35). Remove the bur by extracting it out of the nose of the Drill.

**MOTOR UNIT OPERATING SPEED SELECTION**
For the 450-0030 and 450-0084 Motor Units, the maximum speed of 70,000 RPM is selected by inserting the handpiece into the Motor Unit with the high speed dot in alignment with the control buttons located on top of the Motor Unit (450-0030, Fig. 35) or the arrow (450-0084, Fig. 36). With the high speed dot in any other alignment, the maximum RPM is limited to 24,000 RPM. For the 450-0082, the Straight Drill module can be inserted into the Motor Unit in any orientation to achieve the 70,000 RPM high speed mode.

**WARNING** The 450-0082 Motor Unit cannot be operated in the standard speed mode (24,000 RPM mode). Care should be taken to use appropriate speeds for the module and cutting accessory being used and the procedure being performed.
The nose and bearing design of the straight drill minimizes but does not eliminate the chance for heat buildup, especially when side loads to the drill are applied.

**WARNING** Use of a drill with contaminated and/or worn bearings may rapidly generate heat and cause patient injury.

**WARNING** The straight drill must be thoroughly cleaned and lubricated (see instruction below) after each use to prevent bearing contamination and to prolong drill life. In addition, the drill must be well maintained, including periodically returning to OsteoMed for maintenance. Failure to properly clean, lubricate, and send in for periodic maintenance can lead to contaminated bearings that can fail and generate excessive heat. Increased use of a drill will reduce the life of the bearings, requiring maintenance on a more frequent basis.

Indications of Contaminated or Worn Bearings:

**CHECK FOR:**

1. Heat: OsteoMed Straight Drills are designed to operate within safe temperature ranges and without excessive heat if operated within specified duty cycles (refer to the Specification/Duty Cycle section of the OsteoPower Operating Instructions and Maintenance Manual for specified duty cycles). If a drill appears to generate heat, immediately stop using the drill and call OsteoMed Customer Service.

2. Unusual noise or vibration: If the straight drill creates unusual noise or vibration during use, immediately stop using the drill and call OsteoMed Customer Service.

3. Radial marks on the bur shaft: After the straight drill has been used, always inspect the shaft of the bur or drill bit before it is discarded. If the shaft of the bur or drill bit shows radial marks or grooves after use (Fig. 37), immediately stop using the drill and call OsteoMed Customer Service.

4. Failure of spin test (Fig 9): To conduct a spin test, insert a bur into the handpiece module. Hold the distal tip of the bur and spin the handpiece module (Fig 38). The module should spin freely. If the module does not spin freely, call OsteoMed Customer Service to return the module for service.
In order to properly lubricate the straight drill, the 450-0778 lubrication sleeve (Fig. 31 on page 11) must be used.

The lubrication sleeve is comprised of two parts. The top is labeled “Place over tip of drill” with an arrow facing down (Fig. 39) and the bottom has an arrow facing up.

1. To use the lubrication sleeve, hold the module as shown in Fig. 40, then slide the top component over the tip of the module with the arrow facing towards the magnet end of the module.

2. After locking the top component in place, slide the bottom component over the magnet end of the module with the arrow facing the distal end (Fig. 41).

3. Push the two components together tightly (Fig. 42).

4. Follow the lubrication instructions in the instruction manual (P/N 030-1179) (Fig. 43 & 44).

   **Note:** The 450-0778 lubrication sleeve should ONLY be used with the 450-0777 1:1 Straight Drill.
The OsteoGraft™ Bone Grafting Wheel is a circular saw and soft tissue guard attachment for OsteoMed 1:1 Straight Drill part number 450-0777. The OsteoGraft™ attachment is intended for the cutting of mandibular bone at precise depths.

There are two sterile-packed blades (Fig. 46) available for the OsteoGraft™ attachment. The blade choices are a .25mm thickness and .5mm thickness. Both blades have a cut depth of 4mm.

**NOTE:** An Allen wrench and a set screw are packaged with every blade (Fig. 47).

**WARNING**
Prior to inserting or removing blades, make sure the Motor Unit is set to the “SAFETY” mode.

**WARNING**
Running the OsteoGraft at a speed higher than 35,000 RPMs could cause the blade to strike the tissue guard.

**CAUTION**
Any blades not specifically designed for the OsteoPower OsteoGraft Bone Grafting Attachment will not secure properly and may damage the locking collar or handpiece.

**ATTACHING AND REMOVING THE SOFT TISSUE GUARD:**
1. To attach the soft tissue guard to the 450-0777 Straight Drill, slide the soft tissue guard onto the nose of the straight drill as shown (Fig. 48).
2. Once the soft tissue guard is fully seated onto the nose of the 450-0777 Straight Drill, use the Allen wrench provided with blade to tighten the hex nut in a clockwise direction (Fig. 49).
3. Tighten the hex nut until the soft tissue guard attachment is secure on the 450-0777 Straight Drill
4. To remove the soft tissue guard attachment, use the Allen wrench to loosen the locking hex nut in a counterclockwise direction. The soft tissue guard attachment can then be removed from the nose of the 450-0777 Straight Drill.

**BLADE INSERTION AND REMOVAL**
**WARNING** DO NOT operate the handpiece (Motor Unit) while the straight drill locking collar is in the unlocked position. When the locking collar is in the unlocked position and/or no blade is inserted into the drill, the Motor Unit will “stall” and may be damaged when the Motor Unit is activated. When using part number 450-0777, if a blade is inserted and the locking collar is in the unlocked position, the locking collar will automatically lock and the drill will run when the Motor Unit is activated.

1. Make sure the soft tissue guard attachment is properly secured to the 450-0777 Straight Drill before inserting and locking a blade into position.
2. To insert a blade, set the Motor Unit to the “SAFETY” mode and twist the locking collar clockwise into the unlocked position. This can be confirmed by having the green dot in alignment with the red oval (Fig. 50). Once open, insert the blade until it bottoms out. Twist the locking collar to the locked position (green dot aligned with green dot) to secure the blade (Fig. 51).
3. To remove a blade, set the Motor Unit to the “SAFETY” mode, then twist the locking collar from the locked position to unlocked. Remove the blade by extracting it out of the nose of the Drill.
Part Number: 450-0204 (Fig.52)

The OsteoPower 4:1 Universal Pilot Drill is designed for operation within 0-6,000 RPM.

**NOTE:** Always select the “SAFETY” mode when the handpiece system is not in use or prior to inserting or removing drill bits or modules. Always visually check each drill bit prior to the procedure. *Drill bits are intended as single-use disposable items.* Never use a worn or bent drill bit. Never reuse a drill bit.

**DRILL BIT SELECTION**

The Universal Pilot Drill accepts any bur/drill bit with either a straight shank or a J-latch shank, OsteoMed Shank and D-latch Shank in the Universal Straight Drill. The drill should be operated at speeds appropriate for the cutting accessory being used. Appropriate speeds depend on the selected bur head size, length, and procedure performed.

The 4:1 Universal Pilot Drill only accepts Straight Shank, J-Latch, OsteoMed or D-Latch drill bits with a 44.5mm, 51.0mm or 65.0 mm length shaft. Use of longer burs/pilot drills may cause whipping and/or damage to the drill.

**4:1 UNIVERSAL PILOT DRILL BUR GUARDS**

The following bur guards should be used with the drill bits shaft lengths noted:
- Short Bur Guard (450-0207) - 44.5mm length shaft (Comes standard with the drill)
- Medium Bur Guard (450-0208) - 51.0mm length shaft
- Long Bur Guard (450-0209) - 65.0mm length shaft

**DRILL BIT INSERTION AND REMOVAL**

**NOTE:** DO NOT operate the 4:1 Universal Pilot Drill without ensuring that the locking collar is in the fully locked position.

1. To insert a bur, set the Motor Unit to the “SAFETY” mode and twist the locking collar into the unlocked position. This can be confirmed by aligning the green mark with the red mark. Once open, insert the drill bit until it bottoms out. Return the locking collar to the locked position (re-align the two green marks) to secure the drill bit (Fig.53).

2. To remove a drill bit, set the Motor Unit to the “SAFETY” mode, then twist the bur locking collar from the locked position to unlocked (Fig.54). Remove the bur by extracting it out of the nose of the drill.

**BUR GUARD REPLACEMENT**

The bur guard design of the 4:1 Universal Pilot Drill minimizes but does not eliminate the chance for heat buildup especially when side loads to the drill are applied.

Use of a module with contaminated and/or worn bearings may rapidly generate heat and cause patient injury.

The 4:1 Universal Pilot Drill must be thoroughly cleaned and lubricated after each use to prevent bearing contamination and to prolong module life. In addition, the module must be well maintained including the periodic replacement of the bearings. Failure to properly clean, lubricate, and change the bearings on a periodic basis can lead to contaminated bearings that can fail and generate excessive heat. Increased use of a drill will reduce the life of the bearings, requiring that bearings be replaced on a more frequent basis.
INDICATIONS OF CONTAMINATED OR WORN BEARINGS:


2. Unusual noise or vibration: If the module creates unusual noise or vibration during use, immediately stop using the module and call OsteoMed Customer Service.

3. Radial marks on the bur shaft: After the module has been used, always inspect the shaft of the bur or drill bit before it is discarded. If the shaft of the bur or drill bit shows radial marks or grooves after use (Fig. 55), immediately stop using the drill and call OsteoMed Customer Service.

4. Failure of spin test (Fig. 56): Insert a drill bit into the module. Hold the distal tip of the drill bit and spin the module (Fig. 56). The module should spin freely. If the module does not spin freely, call OsteoMed Customer Service to return the drill for service.

Module may stall when under excessive load.

If the module begins to stall, set the console to reverse mode and back the drill bit/bur out of the site. If the drill stalls again, STOP THE MOTOR UNIT, REMOVE THE MODULE and complete the procedure using manual instruments.

LUBRICATION INSTRUCTIONS:

In order to properly lubricate the 4:1 Universal Pilot Drill, the 450-0206 lubrication sleeve must be used.

**NOTE:** The 450-0206 Lubrication Sleeve should ONLY be used with the 4:1 Universal Pilot Drill.

The lubrication sleeve is comprised of two parts. The top is labeled “Place over tip of drill” with an arrow facing down and the bottom has an arrow facing up.

Step 1. The use the lubrication sleeve, hold the module as shown in Step 1 then slide the top component over the tip of the module with the arrow facing toward the bottom of the module.

Step 2. After locking the top component in place, slide the bottom component over the magnet end of the module with the arrow facing the distal end.

Step 3. Push the two components together tightly.

Step 4. Follow the lubrication instructions on page 13 of this instruction manual.
Part Number: 450-0215 (Fig. 57)

The 1:1 Contra Angle Drill is intended for third molar removal procedures only. This module should not be used for low speed applications such as dental implant procedures.

NOTE: The 1:1 Contra Angle Drill has built-in external irrigation capability. This module does not require additional nozzles for irrigation applications.

1:1 CONTRA ANGLE OPERATION

1. Insert the drill into the Motor Unit. To obtain a maximum speed of 70,000 RPM, insert the handpiece into the Motor Unit with the dot symbol oriented as indicated in (Fig. 58). This insertion requires the drill to be inserted with the round dot in alignment with the control buttons located on top of the Motor Unit.

NOTE: Although the 1:1 Contra Angle Drill can operate in the 70,000 RPM mode, to ensure long life of the module, OsteoMed recommends operation be limited to a maximum of 75% or 52,500 RPM.

1:1 CONTRA ANGLE ACCESSORY INSERTION AND REMOVAL

A wide range of accessories are available for the 1:1 Contra Angle Drill (Fig. 59). Any standard type of dental latch bur, reamer, or drill can be used. OsteoMed offers cross-cut fissure carbide burs, round carbide burs, twist drills, and screwdrivers for this handpiece. Each bur has been designed to produce quick, efficient cuts, with minimal heat buildup.

1. To load an accessory, move the bur latch to the “OPEN” position and rotate the accessory during insertion (Fig. 60). Return the bur latch to the “LOCK” position, then pull on the accessory to ensure it is locked securely (Fig. 61).

2. To remove an accessory, push the latch forward with your thumb and pull it out of the head.

Prior to inserting or changing burs, make sure the Motor Unit is set to “SAFETY” mode. Use only accessories that insert easily and smoothly, securely latching into the Contra Head.

NOTE: The 1:1 Contra Angle Drill comes with a built-in external irrigation nozzle. The spray nozzle can be manually adjusted, as can the end where the silicone tubing is attached (Fig. 62).
18:1 CONTRA ANGLE DRILL/DRIVER
Part Number: 450-0222 (Built-In External Irrigation) (Fig. 63)

100:1 CONTRA ANGLE DRILL/DRIVER
Part Number: 450-0232 and 450-0234 (Built-In External Irrigation) (Fig. 64)

The 18:1 Contra Angle Drill is designed for medium speed (0-1,330 RPM) high torque contra angle drill applications, with or without internal or external irrigation.

The 100:1 Contra Angle Drill is designed for low speed (0-240 RPM) maximum torque contra angle drill applications, with or without internal or external irrigation.

A wide range of accessories are available for the 18:1 and 100:1 Contra Angle Drills (Fig. 65). Any standard type of dental latch bur, reamer, or drill can be used. OsteoMed offers cross-cut fissure carbide burs, round carbide burs, twist drills and screwdrivers for this handpiece. Each bur has been designed to produce quick efficient cuts with minimal heat buildup.

**WARNING** Prior to inserting or changing burs, make sure the Motor Unit is set to “SAFETY” mode.

18:1 and 100:1 CONTRA ANGLE ACCESSORY INSERTION AND REMOVAL

1. To load an accessory, push the spring-loaded latch forward with your thumb and rotate the accessory during insertion (Fig. 66). Release the latch mechanism, then pull on the accessory to ensure it is locked securely (Fig. 67).

2. To remove an accessory, push the latch forward with your thumb and pull it out of the head (Fig. 68).

**CAUTION** Use only accessories that insert easily and smoothly, securely latching into the Contra Head. During implant procedures, NEVER BOTTOM OUT A TAP. If the handpiece begins to stall, STOP THE MOTOR UNIT, REMOVE THE CONTRA ANGLE DRILL and complete the procedure using manual instruments. DO NOT TWIST the handpiece to assist the tap at any time. NEVER FULLY SEAT AN IMPLANT USING THE HANDPIECE. Seat the implant into the bone up to its collar and complete the placement manually.

**NOTE:** The Contra Angle Drills can be inserted into the Motor Unit in four orientations at 90 degree intervals (Fig. 69). This versatile feature allows the operator to orient the drill based on access, visibility, and the most comfortable handpiece holding position.
The Reciprocating Saw is designed for producing quick and accurate bone cuts. This module reciprocates blades at approx. 20,000 cycles per minute (see WARNING note below). In addition to its high speed, the stroke has been designed to not exceed 2.4mm. The combination of short stroke and high speed allows the handpiece to cut quickly, efficiently, and safely. The Reciprocating Saw operates with specifically designed saw blades to ensure secure and safe operation.

**WARNING** The Reciprocating Saw is designed to reciprocate at approx. 20,000 cycles per minute in the “Forward” mode. The Motor Unit must be set to 75% of the maximum speed setting when operating the Reciprocating Saw. Operation of the Reciprocating Saw at higher speeds may result in excessive vibration, loss of control at the osteotomy site, and/or damage to the saw module.

**WARNING** Use of any blades not specifically designed for the OsteoPower Reciprocating Saw will not secure properly and may cause injury to the user, patient, or operating personnel and/or damage the locking collar or handpiece.

A wide range of cutting accessories are available for the Reciprocating Saw (Fig. 72). The blade choices range from short to long cut lengths and straight, tapered and curved blade shapes. Rasps are also offered. Each blade has been specifically designed to produce quick, efficient cuts, with minimal heat buildup.

**SAW BLADE/ACCESSORY INSERTION AND REMOVAL WARNING:**
Prior to inserting the Reciprocating Saw into the Motor Unit, make sure the Motor Unit is set to the “Safety” mode.

1. To insert saw blades, loosen the Locking Collar (Fig. 73) and insert the desired blade. Rotate the blade shaft until the “flat” on the proximal end of the blade shaft seats fully in the blade Locking Collet. (Fig. 74) Blade seating is best accomplished by rotating the blade clockwise and counterclockwise during insertion.

2. Next, use the Reciprocating Saw Wrench Set (Fig. 75) to secure the blade. Begin by capturing the shaft of the saw using the wrench labeled “RECIP SAW SHAFT—STATIONARY” (Fig. 75). Next, use the wrench labeled “RECIP SAW COLLAR—TIGHTEN” (Fig. 75) to lock the blade in place.

**CAUTION** Do not over-tighten the blade Locking Collar. Over-tightening the blade Locking Collar may result in damage to Reciprocating Saw.

3. To remove saw blades, use the Reciprocating Saw Wrench Set to loosen the Locking Collar and remove the blade or accessory.

The Reciprocating Saw can be inserted into the Motor Unit in four orientations at 90 degree intervals. (Fig. 76). This versatile feature allows the operator to orient the blade’s cutting edge based on access, visibility, and the most comfortable handpiece holding position.
Part Number: 450-0241 (Fig. 77)

The Quick Connect Reciprocating Saw is designed for producing quick and accurate bone cuts. This module reciprocates blades at approx. 20,000 cycles per minute. In addition to its high speed, the stroke has been designed to not exceed 2.4mm. The combination of short stroke and high speed allows the handpiece to cut quickly, efficiently, and safely. The Reciprocating Saw operates with specifically designed saw blades to ensure secure and safe operation.

The Quick Connect Reciprocating Saw is designed to reciprocate at approx. 20,000 cycles per minute in the “Forward” mode. The power setting of the Motor Unit should not exceed 75% when operating the Quick Connect Reciprocating Saw. Operation of the Quick Connect Reciprocating Saw at higher speeds may result in excessive vibration, loss of control at the osteotomy site, and/or damage to the saw module.

**NOTE:** The 450-0241 (Quick Connect Reciprocating Saw) only works with OsteoPower Quick Connect accessories. (ie. 451-XXXX-SP)

**SAW BLADE/ACCESSORY INSERTION AND REMOVAL**

Prior to inserting the Quick Connect Reciprocating Saw into the Motor Unit, make sure the Motor Unit is set to the “Safety” mode.

**Inserting Blade/Accessory:**

1. To insert saw/rasp blades, align the flat on the proximal end of the blade shank with the flat depicted on the etching on the reciprocating saw (Fig. 78)

2. Retract the Quick Connect Reciprocating Saw collet (Fig. 79) and insert the blade. Keep the flat of the blade shank aligned with the flat of the laser mark (Fig. 80)

3. Release the saw collet to secure the blade. (Fig. 81)

**NOTE:** Pull on the blade to insure it is properly seated

**NOTE:** There is a black laser mark on the distal circumference of the blade/rasp shank. This laser mark will not be visible when the blade/rasp is completely seated.

**Removing Blade:**

1. To remove the blade from the Quick Connect Reciprocating Saw, retract the collet and pull the blade away from the saw
Part Number: 450-0255 (Fig. 82)

The Sagittal Saw is designed for producing quick and accurate bone cuts. At full speed, the Sagittal Saw blades oscillate at 24,000 cycles per minute. Blade stroke is limited to 3.5 degrees clockwise and 3.5 degrees counterclockwise. The combination of short stroke and high speed allows the Sagittal Saw to cut quickly, efficiently, and safely.

A wide range of cutting accessories are available for the Sagittal Saw (Fig. 83). The blade selection ranges from 5mm wide to 43mm long. Blade lengths and widths have been selected based on the cut depths and widths associated with the most common craniofacial and extremity osteotomies. Each blade has been designed to produce quick, efficient cuts, with minimal heat buildup.

The Sagittal Saw blades mount at an elevation to one side to allow for superior visibility of the surgical site and to simplify blade insertion and removal. The plane formed by the Blade Capture Hub can be used to improve visual orientation prior to making a bone cut. The Blade Capture Hub allows blades to be inserted in any of five different positions within a 160 degree range (Fig. 84).

NOTE: All Sagittal Saw blades are interchangeable with the Oscillating Saw blades.

WARNING Prior to inserting or removing the Sagittal Saw, make sure the Motor Unit is set to the “SAFETY” mode.

CAUTION It is recommended that the MU Maximum Speed Range Sensor be set to 75% or less to reduce the potential for blade vibration associated with the use of blades longer than 25mm.

SAW BLADE INSERTION AND REMOVAL
1. To insert a blade, depress the Blade Release Button and slide the selected blade between the elevated cap and the Blade Capture Hub. The Release Button is located on the underside of the Saw module (Fig. 85).

2. While continuing to depress the Blade Release Button, insert the desired blade over the Drive Pins in any of five different positions within a 160 degree range.

3. To remove a saw blade, depress the Blade Release Button, lift and remove the blade.

CAUTION To ensure proper blade retention upon insertion, care must be taken to orient holes in the blade with the pin locations on the Blade Capture Hub. The Blade Capture Cap should seat completely flush against the blade.

The Sagittal Saw can be inserted into the Motor Unit in four orientations at 90 degree intervals (Fig. 6). This versatile feature allows the operator to orient the blade’s cutting edge based on access, visibility, and the most comfortable handpiece holding position.
Part Number: 450-0261 (Fig. 87)

The Oscillating Saw is designed for producing quick and accurate bone cuts. At full speed, the Oscillating Saw blades oscillate at 24,000 cycles per minute. Blade stroke is limited to 7 degrees per full stroke. The combination of short stroke and high speed allows the Oscillating Saw to cut quickly, efficiently, and safely.

A wide range of cutting accessories are available for the Oscillating Saw (Fig. 88). The blade selection ranges from 5mm wide to 43mm long. Blade lengths and widths have been selected based on the cut depths and widths associated with the most common craniofacial and extremity osteotomies. Each blade has been designed to produce quick, efficient cuts, with minimal heat buildup.

**NOTE:** All Oscillating Saw blades are interchangeable with the Sagittal Saw blades.

**WARNING** Prior to inserting or removing blades, make sure the Motor Unit is set to the “SAFETY” mode.

**CAUTION** Use of any blades not specifically designed for the OsteoPower Oscillating Saw will not secure properly and may damage the Locking Collar or handpiece. It is recommended that the MU Maximum Speed Range Sensor be set to 75% or less to reduce the potential for blade vibration associated with the use of blades longer than 25mm.

**SAW BLADE INSERTION AND REMOVAL**

1. To insert saw blades, pull back on the Locking Collar and insert desired blade on to the mounting pins (Fig. 89). Make sure that the “slotted” section of the blade inserts fully into the blade drive shaft. Once the blade is fully seated, release the blade Locking Collar. The Locking Collar should close completely against the blade for secure retention (Fig. 90).

2. To remove saw blades, pull back on the Locking Collar, lower blade from pins and remove the blade.

**CAUTION** To ensure proper blade lock upon insertion, care must be taken to make sure the orientation holes in the blade align with the pin locations and the slotted end of the blade seats fully into the blade Lock Collar.

The Oscillating Saw can be inserted into the Motor Unit in four orientations at 90 degree intervals. This versatile feature allows the operator to orient the blade’s cutting edge based on access, visibility, and the most comfortable handpiece holding position.
The VRO Saw is designed for Vertical Ramus Osteotomy and other intra-oral posterior procedures. At full speed, the VRO Saw blades oscillate at 24,000 cycles per minute. The VRO Saw module extends approximately seven inches beyond the handpiece.

There are two blades available for the VRO Saw. The blade choices are a 7mm and 12mm length. Each blade has been designed to produce quick, efficient cuts, with minimal heat buildup.

**NOTE:** The Allen wrench is included sterile packed with every blade. (Fig. 93).

**WARNING** Prior to inserting or removing blades, make sure the Motor Unit is set to the “SAFETY” mode.

**CAUTION** Use of any blades not specifically designed for the OsteoPower VRO Saw will not secure properly and may damage the Locking Collar or handpiece.

**SAW BLADE INSERTION AND REMOVAL**

1. To attach a saw blade, insert the desired blade shaft into the locking collar. (Fig. 94).

2. Once the blade is fully seated, tighten the locking collar screws using the included Allen wrench. (Fig. 95).

   **NOTE:** The Allen wrench is included sterile packed with every blade (Fig. 93).

3. To remove saw blades, use the Allen wrench to loosen locking collar screws. The blade can then be removed from the locking collar and disposed.

The VRO Saw can be inserted into the Motor Unit in four orientations at 90 degree intervals (Fig. 96). This versatile feature allows the operator to orient the blade’s cutting edge based on access, visibility, and the most comfortable handpiece holding position.
Part Number: Wire/Pin Driver Body 450-0285 (Fig. 97)

NOTE: The 450-0285 Wire/Pin Driver Body is designed to ONLY work with the 450-0030 Hand Controlled Motor Unit and the 450-0084 Low Profile, Footswitch only Motor Unit.

The Wire/Pin (W/P) Driver Body is the connection between 2 OsteoPower Modular Motor Units and 3 Handpiece Modules with triggers. The 2 Modular Motor Units* that work with the 450-0285 are the Hand Controlled Motor Unit (450-0030) and the Low Profile Motor Unit-Footswitch Only (450-0084). The 3 handpiece modules are the Wire/Pin Driver Module (450-0286), High Torque Jacob’s Chuck (450-0287) and A.O. Chuck (450-0291). (Fig. 98)

* The Lever Am Motor Unit (LAMU) has its own LAMU W/P Driver Body (450-0300). Refer to page 25 of this manual.

The Wire/Pin Driver (W/P Driver) Body has a maximum speed of 3,645 RPM and produces 80 inch ounces of torque. However, it is recommended that the W/P Driver Body be operated at a maximum of 50% power (except when using the Jacobs Chuck attachment), resulting in 1,823 RPM.

INSERTION AND REMOVAL OF MOTOR UNITS:

1. To attach the 450-0030 Hand Controlled Motor Unit to the 450-0285 W/P Driver Body:
   a. Align the High Speed Dot on the motor unit connection of the W/P Driver Body with the surface controls of the Hand Controlled Motor Unit.
   b. Maintaining the dot to surface control alignment, insert the W/P Driver Body into the Motor Unit until fully seated.

2. To attach the 450-0084 Low Profile Motor Unit (Footswitch Only) to the 450-0285 W/P Driver Body:
   a. Align the High Speed Dot on the motor unit connection of the W/P Driver Body with the Dot on the top of the 450-0084 Low Profile Motor Unit (Footswitch Only).
   b. Maintaining the dot to dot alignment, insert the W/P Driver Body into the Motor Unit until fully seated.

   NOTE: The trigger mechanism will only function if the W/P Driver Body is inserted into the Motor Unit with the dot symbol oriented as indicated.

3. Remove either motor unit from the W/P Driver Body by:
   a. Taking hold of the W/P Driver Body and the body of the motor unit
   b. Pull until the two components separate

INSERTION AND REMOVAL OF W/P DRIVER BODY ATTACHMENTS:

1. Insertion of any of the 3 attachments is accomplished by carefully inserting the desired W/P Driver Body attachment into the W/P Driver Body until it is fully seated

2. Removal of the W/P Driver Body attachment is accomplished by releasing the attachment locking latch located on the top of the W/P Driver Body.
Part Number: Wire/Pin Driver Body Lever Arm Motor Unit (LAMU) 450-0300
(Fig. 102)

NOTE: The 450-0300 LAMU Wire/Pin Driver Body is designed to ONLY work with the 450-0034 Lever Arm Motor Unit.

The LAMU Wire/Pin (W/P) Driver Body is the connection between the 450-0034 Lever Arm Motor Unit and 3 Handpiece Modules with triggers. The 3 handpiece modules are the LAMU Wire/Pin Driver Module (450-0301), LAMU High Torque Jacob’s Chuck (450-0302) and LAMU A.O. Chuck (450-0303).

The LAMU Wire/Pin Driver (W/P Driver) Body has a maximum speed of 3,645 RPM and produces 80 inch ounces of torque. However, it is recommended that the LAMU W/P Driver Body be operated at a maximum of 50% power (except when using the LAMU Jacobs Chuck attachment), resulting in 1,823 RPM.

**INSERTION AND REMOVAL OF LAMU MOTOR UNIT:**

1. Remove the lever arm from the 450-0034 Lever Arm Motor Unit (LAMU) by rotating the lever 180 degrees toward the cord and pull the lever arm out.

2. To attach the 450-0034 Lever Arm Motor Unit (with the lever arm removed) to the 450-0300 W/P Driver Body:
   a. Align the front of the motor unit connection (the side facing the Handpiece Module Connection) of the LAMU W/P Driver Body with the surface controls of the Lever Arm Motor Unit.
   b. Maintaining the surface control alignment, insert the W/P Driver Body into the Motor Unit until fully seated.

   **NOTE:** The trigger mechanism will only function if the W/P Driver Body is inserted into the Motor Unit oriented as indicated.

3. Remove the LAMU from the W/P Driver Body by:
   a. Taking hold of the W/P Driver Body and the body of the LAMU
   b. Pull until the two components separate

**INSERTION AND REMOVAL OF LAMU W/P DRIVER BODY ATTACHMENTS:**

1. Insertion of any of the 3 attachments is accomplished by carefully inserting the desired W/P Driver Body attachment into the LAMU W/P Driver Body until it is fully seated

2. Removal of the W/P Driver Body attachment is accomplished by releasing the attachment locking latch located on the top of the W/P Driver Body.
**WIRE/PIN DRIVER HANDPIECE MODULE:**
Part Number: 450-0286 & 450-0296
Speed Range: 0-1,823 RPM @ 50%

**LAMU WIRE/PIN DRIVER HANDPIECE MODULE:**
Part Number: 450-0301 & 450-0306
Speed Range: 0-1,823 RPM @ 50%

The W/P Driver Handpiece Modules with trigger were designed to accommodate a wide range of wires, pins, and accessories. The W/P Driver Handpiece Modules accommodate wires as small as 0.028" and pins up to 0.125".

**INSERTION AND REMOVAL OF K-WIRES AND STEINMANN PINS**

1. To set the W/P Driver Handpiece Module to the desired wire/pin size, rotate the size selector in either direction until the desired wire/pin size is located within the window on the top of the housing. (Fig. 108).

   **NOTE:** The handpiece module lever arm should be in the relaxed position during the size selection.

   **NOTE:** If you are turning the size selector and it bottoms out, you should rotate in the opposite direction to get the desired size.

   **NOTE:** Never rotate the size selector when an accessory is inserted. Accessory may become lodged in the collet.

   **NOTE:** Prior to inserting or changing wires, pins, or accessories, make sure the Motor Unit is set to the “SAFETY” mode.

2. To insert a wire or pin, rotate the size selector collet to the appropriate size, then slide the wire or pin into the opening of the collet. The W/P Driver accepts “K”-wire and pin sizes: .028", .035", .045", .054", .062", .078", .094", .109" and .125".

3. To drive a wire or pin, depress the Locking Lever toward the Motor Unit while activating the trigger or Footswitch (Fig. 106 & 107).

4. To release a wire or pin, release the Locking Lever, then advance or retract the W/P Driver Handpiece Module along the wire or pin. Depressing the Locking Lever will then re-grip the wire or pin.
HIGH TORQUE JACOBS CHUCK HANDPIECE MODULE:
Part Number: 450-0287
Speed Range: 0-608 RPM @ 50%

LAMU HIGH TORQUE JACOBS CHUCK HANDPIECE MODULE:
Part Number: 450-0302
Speed Range: 0-608 RPM @ 50%

The Jacobs Chuck Handpiece Modules were designed to be used with accessories having a diameter up to 0.25".

The Jacobs Chuck Handpiece Modules have a maximum speed of 1,215 RPM and produces three times the torque of the 1:1 straight drill; however, it is recommended that the Jacobs Chuck Handpiece Modules be operated at a maximum of 50% power, resulting in 608 RPM.

NOTE: The Jacobs Chuck Handpiece Modules require the use of a key to open and lock its collet.

NOTE: Prior to inserting or changing wires, pins or accessories, make sure the Motor Unit is set to the “SAFETY” mode.

1. To load the Jacobs Chuck Handpiece Modules, the jaws must be open to a size larger than the diameter of the accessory to be used. The included chuck key (450-0287-90) is used to adjust the opening of the locking jaws.

2. Use the chuck key to tighten the locking jaws on the accessory until hand tight.

   NOTE: It is necessary to have the accessory centered between all three of the locking jaws. Failure to do so will cause the accessory to rotate eccentrically.

3. To drive an accessory, depress the trigger or footswitch.

4. To release an accessory, use the included chuck key to loosen the locking jaws until the accessory can be pulled out using hand force.
A.O. CHUCK HANDPIECE MODULE:
Part Number: 450-0291
Speed Range: 0-1,823 RPM @ 50%

LAMU A.O. CHUCK HANDPIECE MODULE:
Part Number: 450-0303
Speed Range: 0-1,823 RPM @ 50%

The A.O. Chuck Handpiece Modules were designed to be used with accessories having an A.O. shank.

**NOTE:** Prior to inserting or changing wires, pins or accessories, make sure the Motor Unit is set to the “SAFETY” mode.

1. Insert accessories into the A.O. Chuck by pulling back on the locking sleeve, inserting the accessory, then releasing the locking sleeve.

2. To drive an accessory, depress the trigger or footswitch.

3. To release an accessory, pull back on the locking sleeve and remove the accessory from the A.O. Chuck.

**NOTE:** The trigger mechanism will only function if the W/P Driver Body is inserted into the motor unit properly.
**MOTOR UNIT**

**CAUTION**
- **DO NOT** immerse Modular Motor Unit or connector cord.
- **DO NOT** use ultrasonic cleaning devices to clean handpiece modules.
- **DO NOT** allow water to run into or stand in electrical connectors.

**CAUTION**

**DO NOT** use solvents, lubricants, or other chemicals to clean the Motor Unit, unless otherwise specified. The use of such materials may cause the Motor Unit to malfunction or leak foreign materials during use, resulting in contamination of the surgical site.

1. Remove handpiece module from Motor Unit prior to cleaning.
2. Wipe Motor Unit clean with a lint-free cloth, mild detergent, soap, or surgical instrument cleaning solution and water. A soft brush may be used to remove debris from the E-Couple mechanism inside the Motor Unit.
3. Wipe away cleaning agent with a lint-free cloth and sterile water.
4. Dry with a lint-free towel. If available, forced air drying is preferred.
5. Refer to “STERILIZATION RECOMMENDATIONS” for sterilization details.
6. After sterilization, components may be cooled by wrapping in a sterilized damp sponge or cloth. **DO NOT** immerse any component of the OsteoPower System to cool.

**HANDPIECE MODULES**

**CAUTION**

**DO NOT** immerse handpiece modules.
**DO NOT** use ultrasonic cleaning devices to clean handpiece modules.

1. Remove cutting tool or accessory from handpiece module prior to cleaning.
2. Wipe clean with a lint-free cloth, mild detergent, Ivory soap, or surgical instrument cleaning solution and water. A soft brush may be used to remove debris (Fig. 3).
3. Wipe away cleaning agent with a lint-free cloth and sterile water.
4. Dry with a lint-free towel. If available, forced air drying is preferred. **DO NOT** direct forced air into the handpiece modules.
5. Refer to “STERILIZATION RECOMMENDATIONS” for sterilization details.
6. After sterilization, handpiece modules may be cooled by wrapping in a sterilized damp sponge or cloth. **DO NOT** immerse to cool.

**CONTROL CONSOLES/FOOT SWITCHES**

**WARNING**  *Unplug the control consoles prior to cleaning. Electrical shock hazard may exist.*

1. The control consoles and footswitches may be wiped clean with alcohol or a mild detergent such as soap and water.
2. Tubing, tips, clips, and assemblies should be flushed with water, then sterilized after every procedure.

**WIRE/PIN DRIVER MODULE, JACOBS MODULE & A.O. CHUCK MODULE LUBRICATION INSTRUCTIONS**

**Parts Required:**
- 450-0501 OsteoPower System Lubricant/Conditioner
- 450-0518 W/P Driver/Jacobs/AO Nozzle

1. Attach the 450-0518 (W/P Driver/Jacobs/AO Nozzle) to the 450-0501 (OsteoPower System Lubricant/Conditioner) by first pressing on the white nozzle, then threading it until it is hand tight.
2. After every four (4) surgeries, use the OsteoPower System Lubricant/Conditioner. Spray Lubricant/Conditioner into the open end of the handpiece module until the expressed cleaner is clear and contaminate free.
   **NOTE:** Make sure the 450-0518 W/P Driver/Jacobs/AO Nozzle is fully seated on the handpiece module.
3. Wipe the handpiece module clean using a cloth or disinfectant wipe to remove any excess spray.
4. Sterilize the handpiece module according to “STERILIZATION RECOMMENDATIONS”.
ALL OSTEOMED CUTTING ACCESSORIES ARE SINGLE USE ONLY.

Indications of a worn cutting accessory:
• Blunted flutes (cutting edges)
• Pitting and nicks
• Stains and metal discoloration (not harmful in themselves, but indicative of a cutting tool that has been used and autoclaved many times)

RECOMMENDED PERIODIC MAINTENANCE SCHEDULE

DO NOT use solvents, lubricants, or other chemicals to clean the Motor Unit. The use of such materials may cause the Motor Unit to malfunction or leak foreign materials during use, resulting in contamination of the surgical site.

1. Inspect the Motor Unit to assure it is in proper working order and there are no loose, damaged, or missing components.
2. Test handpiece by assembling system and running. Be aware of unusual sounds or vibrations and note operating speed. Be conscious of any overheating after 1 minute of running without cutting (surface temperature in excess of 120 degrees F, 49 degrees C or uncomfortable to touch). If overheating occurs, return the Motor Unit to OsteoMed for service.
3. “Contamination” is the number one cause of bearing failure. To ensure the longevity of the handpiece modules, OsteoMed recommends that each handpiece module be cleaned on a frequent and scheduled basis as follows: Straight Drills after every case; contra angles, saws and wire/pin drivers after every four cases.
4. Inspect each handpiece module to ensure it is in proper working order and that there are no loose, damaged, or missing components. Check all moving parts for free movement.
5. Thoroughly clean and condition each handpiece module on a regular schedule using the lubrication instructions:

LUBRICATION INSTRUCTIONS: (Fig. 114)

Parts Required: 450-0501 OsteoPower System Lubricant/Conditioner
450-0502 Cleaning Spray Aerosol Nozzle

1. Attach the 450-0502 (Cleaning Spray Aerosol Nozzle) to the 450-0501 (OsteoPower System Lubricant/Conditioner) by first pressing it on the white spray can nozzle, then threading it until it is hand tight (Fig. 115).
2. After each surgery, use the OsteoPower System Lubricant/Conditioner. Spray Lubricant/Conditioner into the open end of each handpiece module until expressed cleaner is clear and contaminant free.

   NOTE: Make sure that the module is fully seated on the aerosol nozzle (Fig. 116).
3. Operate the handpiece module in the forward direction for approximately 30 seconds or conduct a spin test (see 1:1 Straight Drill Operating Instructions).
4. Repeat the lubrication process detailed in step 2.
5. Wipe the handpiece module clean using a cloth or disinfectant wipe to remove any excess spray.
6. Sterilize the handpiece module according to “STERILIZATION RECOMMENDATIONS.”

The useful life of a cutting accessory is significantly reduced if it is allowed to come into contact with other cutting accessories and various objects in sterilizing pans and trays.
### Sterilization Recommendations

#### Manual Cleaning - Handpiece Modules, Modular Handpiece and Cord, Irrigation tubing and Cutting accessories

<table>
<thead>
<tr>
<th>Step</th>
<th>Duration Approximate</th>
<th>Manual cleaning instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 minutes</td>
<td>Rinse the article to be cleaned under running cool tap water to remove visible soil until visibly clean. Using a soft bristled brush, clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed. Use a syringe, pipette or water jet to clean the lumens, cannulas and other hard to reach areas. Irrigation tubing should be flushed with RO/DI (reverse osmosis/deionized water) or PURW (purified water) and then purged of liquid.</td>
</tr>
<tr>
<td>2</td>
<td>2 minutes</td>
<td>Prepare an enzymatic cleaner per manufacturer’s recommendations using lukewarm tap water. Soak a lint-free cloth until fully saturated with detergent and use to wipe soil away from device. Using a soft bristled brush, manually clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed.</td>
</tr>
<tr>
<td>3</td>
<td>Final Rinse</td>
<td>Rinse under running RO/DI or PURW water until all evidence of detergent is removed. A syringe, pipette or water jet may be used to aid in rinsing.</td>
</tr>
<tr>
<td>4</td>
<td>Drying</td>
<td>Dry using a clean, lint-free cloth. Pressured air at 450 psi may be used for drying if available. Flush irrigation tubing with RO/DI or PURW and then purge liquid from tubing using air filled or vacuum syringe.</td>
</tr>
<tr>
<td>5</td>
<td>Lubrication</td>
<td>Lubricate the Handpiece Modules to be located in the upper organizer tray using OsteoPower System Lubricant and Conditioner. Spray a short burst of Lubricant/Conditioner into the open end of each Handpiece Module until expressed cleaner is clean and contaminant free. Wipe the Handpiece Module using a lint-free cloth to remove any excess spray.</td>
</tr>
<tr>
<td>6</td>
<td>Visual Inspection</td>
<td>Visually examine each article for visible soil with unaided eye and adequate lighting. If visible soil or cleaning residue remains, repeat the cleaning procedures outline above.</td>
</tr>
<tr>
<td>7</td>
<td>Functional Test</td>
<td>Functionally Test each Handpiece Module by inserting each into the Motor Unit and running it for 1 minute. Be aware of unusual performance, sounds, vibrations or excessive heat build-up. Note: A test bur or drill is required to functionally test a straight drill handpiece module.</td>
</tr>
<tr>
<td>8</td>
<td>Sterilize prior to use</td>
<td>Follow sterilization method as shown in “Sterility” section.</td>
</tr>
</tbody>
</table>

#### Manual Cleaning – Irrigation Nozzles

<table>
<thead>
<tr>
<th>Step</th>
<th>Duration approximate</th>
<th>Manual cleaning instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 minutes</td>
<td>Rinse the article to be cleaned under running cool tap water to remove visible soil until visibly clean. Using a soft bristled brush, clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed. Fully immerse the articles in the prepared solution and sonicate the articles for a minimum of 10 minutes.</td>
</tr>
<tr>
<td>2</td>
<td>12 minutes</td>
<td>Prepare an enzymatic cleaner per manufacturer’s recommendations using lukewarm tap water. Using a soft bristled brush, manually clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed. Fully immerse the articles in the prepared solution and sonicate the articles for a minimum of 10 minutes.</td>
</tr>
<tr>
<td>3</td>
<td>Final Rinse</td>
<td>Rinse under running RO/DI or PURW water until all evidence of detergent is removed. A syringe, pipette or water jet may be used to aid in rinsing.</td>
</tr>
<tr>
<td>4</td>
<td>Drying</td>
<td>Dry using a clean, lint-free cloth. Pressured air at 450 psi may be used for drying if available.</td>
</tr>
<tr>
<td>5</td>
<td>Visual Inspection</td>
<td>Visually examine each article for visible soil with unaided eye and adequate lighting. If visible soil or cleaning residue remains, repeat the cleaning procedures outline above.</td>
</tr>
<tr>
<td>6</td>
<td>Sterilize prior to use</td>
<td>Follow sterilization method as shown in “Sterility” section.</td>
</tr>
</tbody>
</table>

#### OsteoMed

**OsteoPower™ Handpiece System**

**Product Information and Instructions for Use**

**Description**

The OsteoMed OsteoPower system is comprised of a power control console, a modular handpiece and cord, modular handpiece attachments and accessories.

**Material**

The modular handpiece and cord, handpiece modules, power control console, attachments and accessories are made from various grades of medical grade stainless steel, medical grade high temperature plastics, carbide steel, diamond coated steel, titanium and aluminum.

**Clinical Indications**

The OsteoMed OsteoPower System and Accessories are indicated for drilling or cutting bone or teeth and driving screws and/or pins and wires into bone, in conjunction with dental, craniofacial, orthognathic, mandibular, hand, foot, wrist and extremity reconstruction surgical procedures.

**Maintaining Device Effectiveness**

1. The operating instructions and maintenance manual should be read and understood prior to operating any component of the OsteoMed OsteoPower Handpiece system. The operating instructions and maintenance manual is enclosed with shipment of systems and can be obtained from customer service. Refer to part number 030-1179. Bulletins are provided with each module.
2. All OsteoMed implants and instrumentation may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
3. Carefully inspect the OsteoMed implants and instruments prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating conditions. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OsteoMed for disposition and repair.
4. OsteoMed recommends the use of OsteoMed products in a sterile environment.

**Cutting Accessories:**

OsteoMed cutting accessories, drills, burs, and blades are disposable and intended for single patient use only. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple uses, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient. Always review the instruction manual and caution/warning notices. The surgeon should be thoroughly familiar with the proper operations of the powered surgical instruments and accessories prior to use.

- Only use recommended accessories with OsteoPower equipment
- Check for any signs of damage to the cutting accessory before use
- Verify the cutting accessory is properly inserted and secured before activating the instrument
- Do not exceed the recommended cutting speed as detailed in the operating instructions and maintenance manual
- Eye protection should be worn when using cutting accessories
- Do not use any cutting accessories that exhibit excessive wobble or vibration
- Forceful side loading of the cutting accessories may cause the cutting accessories to break
- Monitor the temperature of the module and handpiece during use
- Autoclave no more than 24 hours prior to use
- Forceful side loading of the cutting accessories may cause the cutting accessories to break
- Irrigation at the surgical site during operation of the cutting accessory is recommended to reduce the possibility of thermal necrosis

**Storage**

Sterile packaged devices should be stored at controlled room temperature out of direct sunlight. Product package should be inspected prior to use for signs of damage or tampering. Sterile burs and blades have a limited shelf life. Refer to Use By date on package labeling for expiration.

**Cleaning**

- Products must be carefully cleaned prior to sterilization. Only properly trained personnel should perform cleaning, lubrication and functional inspection prior to sterilization.
- Compliance is required with the equipment manufacturer’s user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- Refer to the OsteoPower Operating Instructions and Maintenance Manual (030-1179) for specific OsteoPower Product Cleaning Instructions.
STERILIZATION RECOMMENDATIONS

Sterility
- Product is supplied NON-STERILE unless expressly labeled as STERILE.
- Steam sterilization is recommended for the Motor Unit/Cord, Handpiece modules, tubing sets, irrigation nozzles and clips, burs, blades, drills and accessories. DO NOT AUTOCLAVE THE POWER CONTROL CONSOLE OR FOOTSWITCH. DO NOT USE ETHYLENE OXIDE STERILIZATION FOR THE MOTOR HANDPIECE WITH CORD.
- Accessories such as drills, burs, and blades may be provided sterile packaged (Gamma Sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- Use of the sterilizer shall comply with the manufacturer’s user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Refer to the OsteoPower Operating Instructions and Maintenance Manual (030-1179) for specific OsteoPower Product Cleaning Instructions.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of OSTEOMED OsteoPower Products, the following parameters should be used:

**Recommended Sterilization Method**

1. Place devices to be sterilized in the designated location in aluminum organizer tray 450-0555. Place loaded organizer tray 450-0555 in a full DIN rigid sterilization container. Recommended sterilization container is Aesculap JN442/JK489 with filters US751.
2. Moist heat (steam) sterilize using the following sterilization parameters:
   - Sterilizer Type: Prevacuum
   - Preconditioning Pulses: 4
   - Minimum Temperature: 270°F (132°C)
   - Cycle time: 3 minutes
   - Minimum Dry: 3 minutes

**Alternative Sterilization Methods**

1. Place devices to be sterilized in the designated location in aluminum organizer tray 450-0555. Individually wrap organizer tray 450-0555 in two layers of 1-ply polypropylene wrap such as (Kimguard KO600 – 510(k) K082554) using sequential wrapping techniques.
2. Moist heat (steam) sterilize using one of the following sterilization methods:
   - **Method A**
     - Sterilizer Type: Gravity
     - Temperature: 250°F (121°C)
     - Time: 80 minutes
     - Dry Time: 45 minutes
     - Configuration: Wrapped Tray
   - **Method B**
     - Sterilizer Type: Gravity
     - Temperature: 270°F (132°C)
     - Time: 50 minutes
     - Dry Time: 45 minutes
     - Configuration: Wrapped Tray

Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

**“Immediate” Autoclave Sterilization:**

The following sterilization recommendation offers a reduced cycle time for a minimal amount of equipment including no more than one straight drill module and the irrigation accessories for each.

- Sterilizer Type: Prevacuum
- Preconditioning Pulses: 4
- Temperature: 270°F (132°C)
- Cycle time: 3 minutes
- Dry Time: 0 minutes

Do not exceed 275°F (135°C) to avoid compromising functions of polymeric instrumentation.

**Note:** Biological indicator of G. stearothermophilus was used in sterilization validation.

**Symbols and Definitions**

- Manufacturer / Date of Manufacture
- Date of Manufacture
- Serial Number
- Catalogue Number
- Batch Code (Lot Number)
- Use By (Date)
- Consult Instructions for Use
- Single Use Only
- Authorized Representative in the European Community
- Sterile, Method of Sterilization Using Irrigation
- Caution, Consult Accompanying Documents
- Do Not Use if Sterile Package is Damaged

**Medical Equipment**

- Underwriters Laboratories for Canada and United States with respect to electrical shock, fire and mechanical hazards only, in accordance with UL 2601-1 and CAN/CSA C22.2 No. 60601-1 (2008)

**Consult accompanying documents prior to use**

Caution
- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments. Inspect all components preoperatively to assure utility.
<table>
<thead>
<tr>
<th>Symptom</th>
<th>Probable Cause</th>
<th>Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>No lights or beeps from PCC</td>
<td>• Power cord not connected to PCC appliance inlet &lt;br&gt;• Blown fuse(s) on appliance inlet &lt;br&gt;• Power switch is off &lt;br&gt;• No power at AC power source &lt;br&gt;• Failed PCC</td>
<td>• Verify hospital grade power cord is connected between a hospital grade power source and the appliance inlet on the rear of the PCC.  &lt;br&gt;• Check each fuse adjacent to the appliance inlet. Replace as may be necessary.  &lt;br&gt;• Verify that switch is in the “I” position  &lt;br&gt;• Verify that voltage source provides 100-240Vac &lt;br&gt;• Contact Customer Service</td>
</tr>
<tr>
<td>Console continuously makes beeping sound</td>
<td>• Faulty motor unit &lt;br&gt;• Faulty PCC</td>
<td>• Disconnect all motor units and foot-switches to verify that the beeping stops. If so, contact customer service for repair of the faulty motor unit. &lt;br&gt;• Disconnect all motor units and foot-switches to verify that the beeping stops. If not, contact customer service for repair of the PCC.</td>
</tr>
<tr>
<td>Console remains in Safety Mode. Pressing speed range button causes beep but remains in safety mode</td>
<td>• Overheated PCC</td>
<td>• Continue to use other available motor unit port on PCC. Cool-down of overheated condition will reset the PCC to normal operating condition. Reference duty cycle for handpiece module being used.</td>
</tr>
<tr>
<td>No High Speed operation</td>
<td>• Module is not inserted with magnet facing high speed orientation. &lt;br&gt;• High speed feature not available on specific modules</td>
<td>• Remove module and re-insert aligning the ‘dot’ with the high speed indication on the motor unit. &lt;br&gt;• Identify module used with motor unit. Some modules are not equipped with high speed ‘dots’.</td>
</tr>
<tr>
<td>Motor unit with cord surface controls are inoperative</td>
<td>• Check footswitch controls &lt;br&gt;• Motor unit is not equipped with controls</td>
<td>• Motor unit controls are disabled when the footswitch is connected to the PCC. Remove footswitch to verify that the motor unit controls are available. &lt;br&gt;• Identify motor units used. 450-008X series motor units do not have hand controls.</td>
</tr>
<tr>
<td>Wire pin driver does not trigger motor unit operation</td>
<td>• Incompatible modules used with motor unit. &lt;br&gt;• Incompatible modules used with motor unit.</td>
<td>• Identify modules used with motor unit. The 450-030X series Wire Pin products are not compatible with the 450-0030 motor unit. Use 450-028X or 450-029X series Wire Pin products. &lt;br&gt;• Identify modules used with motor unit. The 450-028X or 450-029X series Wire Pin products are not compatible with the 450-0034 motor unit. Use 450-030X series Wire Pin products.</td>
</tr>
<tr>
<td>Symptom</td>
<td>Probable Cause</td>
<td>Check</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Motor unit stalls PCC                        | • Attached 450-0777 drill is running without a bur installed or bur or drill is not an OsteoPower reduced shank device.  
• Damaged motor unit. See Damaged PCC symptom also. Use of alternate motor unit or PCC should help determine which specific device is damaged.  
• Damaged PCC. See Damaged motor unit symptom also. Use of alternate motor unit port on PCC to determine if problem is associated with original motor unit port. | • Install correct bur or drill and operate drill to verify that the motor unit does not stall PCC.  
• Use alternate motor unit. Contact Repair Service Center.  
• Continue to use other available motor unit port on PCC. Contact Repair Service Center. |
| Drills, saw or driver modules are            | • Damaged expansion ring, o-ring or extremely worn output coupler on motor unit.  
• Damaged module interface                                                                   | Try using alternate motor unit. Inspect motor unit coupling on motor unit. Contact Repair Service Center if repair is needed.  
• Try using alternate module. Inspect module input interface and contact Repair Service Center if repair is needed. |
| difficult to insert or remove from Motor Unit |                                                                                                                                                                                                              |                                                                                                                                       |
| Motor Unit overheats                         | • Damaged or worn module  
• Attached 450-0777 drill is running without a bur installed or bur or drill is not an OsteoPower reduced shank device  
• Drill's collet is in the unlocked position                                                  | Operate motor unit without the module inserted and verify that the motor unit does not overheat.  
• Install correct bur or drill and operate drill to verify that the motor unit does not overheat.  
• Install bur or drill and ensure that the green indicator or laser mark on the drill's locking collet aligns with the locked indicator or laser marking on the drill's housing. |
| Motor Unit runs continuously without user    | • Damaged motor unit  
• Damaged PCC                                                                                                                                       | Use alternate motor unit. Contact Repair Service Center.  
• Try using alternate port on PCC. Unplug footswitch and use alternate motor unit to verify that motor unit does not run continuously. If problem persists contact Repair Service Center  
• Unplug footswitch to verify that motor unit stops. Contact Repair Service Center.       |
<p>| command                                      |                                                                                                                                                                                                              |                                                                                                                                       |</p>
<table>
<thead>
<tr>
<th>Symptom</th>
<th>Probable Cause</th>
<th>Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>Footswitches – No speed or</td>
<td>• Footswitch is a unidirectional model. Unidirectional devices are 450-0350, 450-0370.</td>
<td>• Use bi-directional footswitch if reverse is needed. Ref 450-0360, 450-0380 and 450-0390.</td>
</tr>
<tr>
<td>direction control</td>
<td>• Damaged footswitch</td>
<td>• Try alternate footswitch. Contact Repair Service Center if problem persists.</td>
</tr>
<tr>
<td></td>
<td>• Damaged PCC</td>
<td>• Try footswitch on alternate PCC. Contact Repair Service Center if problem persists.</td>
</tr>
<tr>
<td>Bur guard heats up</td>
<td>• Damaged, dirty or worn bur guard.</td>
<td>• Replace as required.</td>
</tr>
<tr>
<td>Bur does not seat</td>
<td>• Damaged, dirty or worn drill.</td>
<td>• Contact Repair Service Center</td>
</tr>
<tr>
<td></td>
<td>• Damaged bur</td>
<td>• Replace. Burs are single use only. Multiple indentations (&gt;3) on the proximal end of bur</td>
</tr>
<tr>
<td></td>
<td>• Incorrect bur</td>
<td>are indicative of the bur being removed and reseated multiple times.</td>
</tr>
<tr>
<td></td>
<td>• Drill’s locking collet is not in the ‘Locked’ position.</td>
<td>• OsteoPower burs can only be used with drill models 450-0210, 450-0212, 450-0214 and 450-</td>
</tr>
<tr>
<td></td>
<td>• Bur or drill is not fully seated in drill.</td>
<td>0777. Standard (non-reduce) shank burs may be used with drill models 450-0203 and 450-0204.</td>
</tr>
<tr>
<td>Module heats up</td>
<td>• Damaged, dirty or worn module.</td>
<td>• Rotate collet to the ‘Locked’ position.</td>
</tr>
<tr>
<td></td>
<td>• Drill - Damaged bur</td>
<td>• Unlock collet and reseat bur or drill in drill module.</td>
</tr>
<tr>
<td></td>
<td>• Drill - Incorrect bur</td>
<td>• Remove and reseat saw into motor unit. Inspect module and motor unit interfaces for</td>
</tr>
<tr>
<td></td>
<td>• Drill’s locking collet is not in the ‘Locked’ position.</td>
<td>excessive wear. Contact Repair Service Center is repair is needed.</td>
</tr>
<tr>
<td></td>
<td>• Drill - Bur or drill is not fully seated in drill.</td>
<td>• Reduce speed setting value at or below recommended maximum settings for module being used.</td>
</tr>
<tr>
<td></td>
<td>• Module is not fully seated in motor unit.</td>
<td>• Module is being operated above its maximum rated speed.</td>
</tr>
<tr>
<td>Symptom</td>
<td>Probable Cause</td>
<td>Check</td>
</tr>
<tr>
<td>---------</td>
<td>----------------</td>
<td>-------</td>
</tr>
</tbody>
</table>
| Module produces excessive noise | • Drills - Bur or drill is bent.  
• Damaged, dirty or worn drill.  
• Drill's locking collet is not in the ‘Locked’ position.  
• Saw - Saw blade is not fully seated.  
• Module is not fully seated in motor unit. | • Inspect bur or drill for straightness or run-out. Try using another bur or drill.  
• Contact Repair Service Center  
• Rotate collet to the ‘Locked’ position.  
• Remove and reseat blade. No gap should be visible around blade in capture cap.  
• Remove and reseat saw into motor unit. Inspect module and motor unit interfaces for excessive wear. Contact Repair Service Center is repair is needed. |

PCC stalls. Stall is defined as a startup command followed by an immediate or delayed reset to ‘Safety’ mode. | • Damaged, dirty or worn module.  
• Module is being operated above its maximum rated speed.  
• Damaged bur  
• Incorrect bur  
• Drill's locking collet is not in the ‘Locked’ position.  
• Bur or drill is not fully seated in drill.  
• Overheated PCC  
• Damaged motor unit. See Damaged PCC symptom also. Use of alternate motor unit or PCC should help determine which specific device is damaged.  
• Damaged PCC | • Contact Repair Service Center  
• Reduce speed setting value at or below recommended maximum settings for module being used.  
• Replace. Burs are single use only. Multiple indentations (>3) on the proximal end of bur are indicative of the bur being removed and reseated multiple times.  
• OsteoPower burs can only be used with drill models 450-0210, 450-0212, 450-0214 and 450-0777. Standard (non-reduce) shank burs may be used with drill models 450-0203 and 450-0204.  
• Rotate collet to the ‘Locked’ position.  
• Unlock collet and reseat bur or drill in drill module.  
• Continue to use other available motor unit port on PCC. Cool-down of over-heated condition will reset the PCC to normal operating condition. Reference duty cycles for handpiece module being used.  
• Use alternate motor unit. Contact Repair Service Center.  
• Try using other motor unit port. If problem is resolved using other port, contact Repair Service Center for PCC repair. |
<table>
<thead>
<tr>
<th>Symptom</th>
<th>Probable Cause</th>
<th>Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reciprocating saw blades will not insert</td>
<td>• Blade is improperly rotated in collet.</td>
<td>• 450-0240 - Loosen collet. Rotate blade 360 degrees until fully seated in collet. Retighten.</td>
</tr>
<tr>
<td></td>
<td>• Blade is improperly rotated in collet.</td>
<td>• 450-0241 – Pull back quick-change collet to release blade. Reinsert 451-XXXX-SP series blade and rotate it until the quick change collar clicks to its outward position.</td>
</tr>
<tr>
<td></td>
<td>• Blade collet is damaged or excessively worn.</td>
<td>• Contact Repair Service Center</td>
</tr>
<tr>
<td></td>
<td>• Incorrect non-quick change blade 450-XXXX-SP series being used on Quick-Change saw 450-0241.</td>
<td>• Use only ‘Quick-Change’ blades 451-XXXX-SP on the 450-0241 saw.</td>
</tr>
<tr>
<td>Sagittal/Oscillating saw blades will not insert</td>
<td>• Damaged blade capture mechanism. Damaged or missing capture cap pins.</td>
<td>• Verify correct blade capture using new blade. Contact Repair Service Center if problem persists with module.</td>
</tr>
<tr>
<td>Saw module disengages from motor unit during use</td>
<td>• Damaged expansion ring, o-ring or extremely worn output coupler on motor unit.</td>
<td>• Try using alternate motor unit. Inspect motor unit coupling on motor unit. Contact Repair Service Center if repair is needed.</td>
</tr>
<tr>
<td></td>
<td>• Damaged module interface</td>
<td>• Try using alternate module. Inspect module input interface and contact Repair Service Center if repair is needed.</td>
</tr>
<tr>
<td>Irrigation pump does not run</td>
<td>• Irrigation tubing is too tight through pump</td>
<td>• Verify that pump operates without tubing installed in pump. If pump runs, reinstall tubing with less tensile force around the pump rollers.</td>
</tr>
<tr>
<td></td>
<td>• Damaged PCCi</td>
<td>• Contact Repair Service Center.</td>
</tr>
<tr>
<td>Irrigation pump runs continuously</td>
<td>• Motor unit control is malfunctioning</td>
<td>• Disconnect enabled motor unit from PCCi. Contact Repair Service Center for motor unit if problem is resolved when disconnected from PCCi.</td>
</tr>
<tr>
<td></td>
<td>• Damaged PCCi</td>
<td>• Disconnect enabled motor unit and footswitch from PCCi. Contact Repair Service Center if PCCi continues to run.</td>
</tr>
</tbody>
</table>
## TROUBLESHOOT GUIDE (CONT.)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Probable Cause</th>
<th>Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irrigation fluid continues to flow or drip when the pump is not running</td>
<td>• Irrigation tubing is too tight through pump</td>
<td>• Open pump housing and re-attach irrigation tubing leaving a small gap around the peristaltic pinch rollers. Close pump housing lever.</td>
</tr>
<tr>
<td></td>
<td>• Irrigation Pump Lever is not secured to lock position.</td>
<td>• Fully open and lock irrigation pump lever until handle seats into the pump housing detent.</td>
</tr>
<tr>
<td></td>
<td>• Damaged PCC</td>
<td>• Contact Repair Service Center.</td>
</tr>
</tbody>
</table>
The OsteoPower System does not contain any bio-hazardous materials. No special disposal instruction is required. Contact OsteoMed Customer Service in the event any component of the OsteoMed OsteoPower System requires servicing or is found to malfunction. OsteoMed Customer Service can be reached at 800/456-7779. Outside the United States, contact your local OsteoMed distributor.

**INSTRUMENT REPAIR AND LOANER PROGRAM**

Most OsteoPower System components are not field repairable. Unauthorized repairs to any component will void the component’s warranty. In case of operating problems, the affected component(s) must be returned to OsteoMed for repair or maintenance. By request, OsteoMed will provide loaner component(s) while repairs or maintenance are being performed.

To have OSTEOPOWER components repaired or returned, or to request loaner components:

1. Call OsteoMed CUSTOMER SERVICE at 800/456-7779 to receive a service repair order (SRO) number and request a loaner component, if needed. A request for loaner components must be covered by a purchase order and service repair order (SRO) number. All loaner components will be invoiced at the time of shipping.

2. Return the component in need of maintenance or repair to:

   OSTEOMED L.P.
   ATTN: SERVICE DEPARTMENT
   3885 Arapaho Road
   Addison, Texas 75001

   • Make sure to include a purchase order number and SRO number
   • Include a brief description explaining the nature of the problem
   • Include your complete name, address, and shipping instructions

3. The repaired or replaced component(s) will be shipped to the indicated return address along with an invoice for any repair charges, if the component is out of warranty.

4. A memo billing invoice will be provided with the repaired component(s) along with a request for the return of any loaner components. An SRO number must be obtained to return loaner components.

**REPLACEMENT FUSES (PRIMARY)**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>450-0513</td>
<td>4amp, 5x20mmx 250V, 1500A, Break Fast - F4L250V</td>
</tr>
</tbody>
</table>
OsteoMed L.P. warrants that all new OsteoPower components are free from defects in materials and workmanship for a period of one (1) year after the date of shipment from OsteoMed. This warranty extends to all purchasers and is limited to the repair or replacement of the affected product, without charge, when returned to OsteoMed. Any defective parts replaced under this warranty shall become the property of OsteoMed. This shall be purchaser’s exclusive remedy and in no event shall OsteoMed L.P. be liable for any incidental or consequential damages.

OsteoMed warrants that any service or repair work performed by OsteoMed on components out of warranty will be free from defects in materials and workmanship for a period of 90 days after the date of shipment to the customer. This warranty only applies to work performed by OsteoMed. Any defective parts replaced under this warranty shall become the property of OsteoMed. OsteoMed warrants that all parts used in the repair or service of any OsteoPower component will meet new part functional specifications although some parts may be reconditioned.

THIS WARRANTY IS PURCHASER’S EXCLUSIVE REMEDY AND IS MADE IN LIEU OF ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, EXPRESSED OR IMPLIED. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THIS WARRANTY, AND THIS WARRANTY SPECIFICALLY EXCLUDES ALL OTHER EXPRESSED OR IMPLIED WARRANTIES FOR MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR OTHERWISE.

OsteoMed recommends that all OsteoPower handpiece components be examined every twelve (12) months for preventative maintenance. Contact your OsteoMed representative or OsteoMed Customer Service to schedule examinations.

EXCEPTIONS:

- All Contra Angle modules are warranted for a period of six (6) months from the date of shipment
- All irrigation tubing sets, connectors, clips and nozzles are warranted for a period of thirty (30) days from the date of shipment
- All burs, blades, and cutting accessories ARE NOT warranted

EXCLUSIONS:

This warranty does not apply in the event OsteoPower components have been tampered with, damaged, altered or misused. This warranty does not apply in the event OsteoPower components are used in a way contrary to the guidelines outlined in this OPERATING INSTRUCTIONS AND MAINTENANCE MANUAL.
GENERAL WARNINGS

Read and understand the information in this manual prior to assembly and operation of any component of the OsteoPower Modular Handpiece System. Familiarization with the OsteoPower System prior to use is very important. The OsteoPower System is designed to be used by persons familiar with surgical procedures. Misuse may cause damage to the system components and could injure the operator, patient, or operating room personnel. Refer all servicing of any operating component to OsteoMed service personnel.

Prior to use, each system component and accessory must be inspected for proper operation. DO NOT use if damage is apparent.

DO NOT operate any handpiece component without the use of proper eyewear protection. Eye injury or blindness can result from dislodged burs, blades, bone or tooth fragments during handpiece operation.

DO NOT attempt to change an accessory while running any handpiece module. Always select the “SAFETY” mode before changing burs, blades or system components. Accidental activation of the handpiece could injure the operator, patient, or operating room personnel.

Use only OsteoMed-approved burs, blades, or accessories. Use of burs, blades, or accessories not intended for use with the OsteoPower System may result in injury to the operator, patient, or operating room personnel. DO NOT modify any bur, blade, or accessory.

Always inspect burs and blades prior to insertion and use in any handpiece module. Bent or damaged burs or blades may whip severely and dislodge from handpiece modules with great force, causing injury to the patient or operating room personnel.

NOTE: DO NOT attempt to straighten a bent bur or blade.

WARNING Use of dull, worn, or overused burs or blades may cause heat buildup in bone and handpiece modules. Overheating may cause serious injury to operator, patient, and/or operating room personnel. All OsteoMed burs and blades are intended for single use only.

Excessive bending or prying pressure may cause burs, blades, or handpiece modules to break and cause harm to operator, patient, or operating room personnel.
Overheating of handpiece modules may occur if bearings are not kept clean, or if the handpiece module operates above the specified duty cycles (listed on page 4 under “Specifications”). It is recommended that all handpiece modules be regularly inspected for overheating and/or proper operation. Discontinue use of any handpiece modules that appear to be overheating. Overheating may cause serious injury to operator, patient, or operating room personnel.

DO NOT attempt to open or service the Power Control Console, Motor Unit, or Footswitches. An electrical shock hazard may exist. There are no user-serviceable parts and the user should refer to the manufacturer for repairs. If there is a malfunction, call OsteoMed Customer Service or your sales representative to have the system serviced.

DO NOT use the Motor Unit if the connector cord shows evidence of damage such as nicks, cuts, or exposed wires. An electrical shock hazard may exist.

Adequate ground can only be achieved when connected to an equivalent receptacle marked “Hospital Grade.” DO NOT modify the ground of the Power Control Console power cord. Electrical shock hazard may exist. The power cord is the main isolation device. Isolation from the AC main supply may only be obtained by disconnection of the power cord from the AC main supply receptacle. Use only properly rated AC power cord supplied by OsteoMed to match the voltage/frequency rating of the AC power source. Contact OsteoMed Customer Service for approved power cord.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected
- Contact OsteoMed Customer Service for help

GENERAL CAUTION

Should a bur bind in bone during a procedure, DO NOT leverage or twist the handpiece module to attempt to dislodge the bur. Slowly reverse the motor and back the bur out of the bone. If the reverse action will not free the bur, remove the handpiece module from the bur and dislodge the bur from the bone utilizing surgical pliers.

DO NOT continue to operate any handpiece module when in a “stall” condition (see page 4 under “Definitions”). Overloading the PCC will trigger an internal overload circuit, resetting the Power Control Console to “SAFETY” mode. Repeated attempts to restart a stalled handpiece may result in Power Control Console (PCC) failure.

NOTE: Each Power Control Console motor unit output is equipped with a thermal overload feature. If overheating occurs due to extensive motor unit loading, the Power Control Console will reset to “SAFETY” mode. If attempts to restart the motor unit fail resulting in a continuous “SAFETY” mode, use the other motor unit output until the overheated motor unit output has cooled (approximately 5 minutes). If the continuous “SAFETY” mode persists, call OsteoMed Customer Service or your representative to have the system serviced.
DO NOT autoclave the Power Control Console or the Footswitches.

The “CLEANING AND MAINTENANCE RECOMMENDATIONS” section in this manual must be followed to ensure proper operation and reliability of handpiece modules. DO NOT immerse any handpiece module in any solution. Partial or full immersion may damage handpiece components and may void warranty.

DO NOT lubricate the Motor Unit. See “CLEANING AND MAINTENANCE RECOMMENDATIONS” for proper cleaning and maintenance of the Motor Unit.

Confirm that the Power Control Console is used with the proper input voltage. Refer to the Power Control Console specifications for further information.

DO NOT use any fuse rated other than that indicated on the Power Control Console label. Use only OsteoMed approved fuses rated for this product.

DO NOT open or insert objects into the pump during operation. Use OsteoMed-approved irrigation tubes only. Only change tubes when the pump is in “OFF” mode.

PRECAUTIONS:

When operating the Footswitch and after changing Motor Unit settings, always confirm which handpiece is selected to be in use with the A/B switch on the Footswitch.

Use the voice feedback feature for supplemental information only. Always confirm the operating mode by referencing the display on the Power Control Console.

DO NOT pull the Motor Unit cable from the Power Control Console connector to unplug the connector. Always unplug the connector by first pulling back on the sleeve of the connector to release the mating connectors.

Refer to handpiece module specifications for recommended operating speeds and duty cycles.