GLOBUS MEDICAL

DuraPro™

Oscillating System

USER MANUAL

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DuraPro™ USER MANUAL

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INTRODUCTION

System Overview

The DuraPro™ Oscillating System is an AC powered surgical instrument that features a motor and attachments to manipulate bone and soft tissue.

The system is comprised of a floor standing Foot Switch with an integrated foot pedal that provides ON/OFF control to the attached Handpiece. The Handpiece has a Power Cable that connects to the Foot Switch as well as an opening at the front to mate with the Attachments.

The DuraPro™ Oscillating System Attachments are available in an assortment of styles for various surgical applications.

User Manual Overview

This user manual describes important safety information regarding the use of the device and how to properly power on and off the system. This manual also describes how to set up the system and its components. This manual should be readily available at all times. Operators should review the procedures and safety precautions prior to use.

Intended Audience

This manual contains information that is intended for any operator responsible for setup or operation of the DuraPro™ Oscillating System. The operator of the system should either be a trained surgeon or qualified surgical assistant. This user manual, as well as all warnings, cautions, and labels, should be read before using the DuraPro™ Oscillating System.

Intended Use

The DuraPro™ Oscillating System is an AC powered surgical instrument that features a motor and attachments to manipulate bone and soft tissue. The system can be used in general, spinal, and orthopaedic surgical procedures.

Contraindications

Medical conditions that contraindicate the use of the DuraPro™ Oscillating System and its associated applications include any medical conditions that may contraindicate the surgical procedure itself.

Related Information

For specific instructions on the use of surgical instruments, including cleaning and sterilization, refer to the related sections contained within this User Manual, which are also available at www.globusmedical.com/eifu. Refer to the manufacturer's labeling for peripheral devices.

Conventions

This document employs the following conventions:

	**WARNING** **Warning messages indicate procedures or practices that, if not observed, could result in personal injury to the user or patient. Do not proceed beyond a WARNING message until all of the indicated conditions are fully understood and met.**
	**CAUTION** **Caution messages indicate procedures that, if not observed, could result in damage to the equipment. Do not proceed beyond a CAUTION message until indicated conditions are fully understood and met.**

Contact Information

Phone:	Customer Service	1-866-GLOBUS1 (or 1-866-456-2871)
Address:	Globus Medical, Inc. Valley Forge Business Center 2560 General Armistead Avenue Audubon, PA 19403 USA	
Internet:	www.globusmedical.com	

Ordering Disposables and Accessories

To order single use attachments or accessories, please contact Customer Service or your local Sales Representative.

SAFETY

Overview

Operators using the DuraPro™ Oscillating System should be aware of potential hazards and safety concerns that exist when operating the system. This section describes the relevant safety information related to the DuraPro™ Oscillating System and must be read carefully and understood by the operator prior to using the system.

The DuraPro™ Oscillating System should only be operated by qualified medical professionals with experience using surgical instrument systems with a similar purpose.

The DuraPro™ Oscillating System should only be used in a professional healthcare facility environment according to the operating conditions listed below.

Additional safety information is presented throughout this manual. If additional safety training is required, please seek assistance from qualified Globus personnel.

General Use

Ensure annual servicing is performed on schedule to confirm all electrical components and hardware are working properly. Preventative maintenance must only be performed by Globus Medical Service Technicians.

Safety Labeling

	**Instruction Manual**	**Refer to the User Manual for details before operating.**

Electrical Safety

Only plug the DuraPro™ Oscillating System into hospital grade outlets.

	**WARNING** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	**WARNING** The system power cord plug is the primary means of isolating the system from AC mains voltage; do not position the DuraPro™ Oscillating System in such a way that it would be difficult to access and remove the plug from the wall.
	**WARNING** To avoid electric shock, only trained service personnel are authorized to access internal system components via tool removable covers.
	**WARNING** Prior to cleaning, turn off power and remove plug from the wall to remove power to the system entirely.

Mechanical Safety

WARNING

Keep body parts away from moving components of the system to prevent unintentional laceration.

CAUTION

Ensure Attachments are securely affixed to the Handpiece before operating.

General Warnings

WARNINGS

- No modification of the DuraPro™ Oscillating System is allowed.
- The system and its associated applications should be used only by qualified medical professionals who are thoroughly trained on the use of the system.
- The system is not suitable for use in the presence of a flammable, anesthetic mixture with air, oxygen, or nitrous oxide.
- Inspect all components of the system prior to use. If visibly damaged or bent, do not use.
- The system may only be used in conjunction with system components provided by Globus Medical.
- Do not use the system in an MRI suite or any magnetic field.
- Electrical contacts must be dry before connecting.
- When not actively running the Handpiece, move foot away from the Foot Switch to reduce the risk of accidental operation.
- Do not exceed the duty cycle for the Handpiece.
- Keep the cutting tip away from fingers and loose clothing to prevent cross-contamination and laceration.
- Wear protective eyewear or a face shield when operating the system.
- This product may not be used at the same time as defibrilation.
- Take precautions while using cautery devices. Do not contact equipment attached to the Foot Switch with active cautery devices.
- The DuraPro™ Oscillating System complies with IEC 60601-1-2 safety standard for electromagnetic compatibility, requirements, and testing. However, if this equipment is operated in the presence of high levels of electromagnetic interference or highly sensitive equipment, interference may occur. The user should take whatever steps are necessary to eliminate or reduce the source of interference. Diminished performance may lengthen operating time for anesthetized patients.

General Precautions

	CAUTION
⚠	• Federal (U.S.) law restricts the sale, distribution, and use of this device to, or on the order of, a physician. • The system and its attachments contain no user-repairable parts. For repair or replacement of any part of the system or application, contact Globus Medical for technical support. • Verify that all relevant instruments and accessories have been properly cleaned and sterilized prior to surgery, in accordance with the corresponding instructions contained within this user manual. • Do not exceed the recommended electrical ratings for this system, as this could cause damage to the system. • System components are fragile. Use care when handling system components. • Do not actuate the Foot Switch while connecting the Handpiece to the Foot Switch. • Do not tug the cords of the system to unplug them. • Do not attach any third party devices to the system. The use of accessories other than those provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. • Do not sterilize the Foot Switch. • Do not wrap the cable tightly around a sharp edge. • Do not immerse the Foot Switch in any liquid. • Do not stand on the Foot Switch housing.

Compliance with Standards

NRTL LISTED MET US Electrical Safety E115709

This product conforms to the requirements of standards listed below when it bears the following NRTL Certification Compliance Mark, shown at right.

Electric and electromagnetic testing have been performed in accordance with the following applicable standards:

- ANSI/AAMI ES60601-1
- CISPR 11
- IEC 60601-1
- IEC 60601-1-2
- IEC 62304
- IEC 62366

High-Frequency (HF) Surgical Equipment

Based on safety testing performed, the system is compatible with the use of HF surgical equipment with no restrictions on the conditions of use.

EMC Compliance

In accordance with IEC 60601-1-2:2020 Edition 4, Medical Electrical Equipment needs special precautions regarding Electro Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables below. Portable and mobile RF communications equipment can adversely affect electrical medical equipment. The tables supply details about the level of compliance and provide information about potential interactions between devices. EMC Compliance tables from the 4th edition are shown below.

CAUTION

The DuraPro™ Oscillating System is intended for use in the electromagnetic environment specified below. The customer/user should ensure that it is used in such an environment.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the system including cables specified by the manufacturer. Otherwise, degradation in the performance of this equipment could occur.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSION

Emissions Test	Compliance Level	Electromagnetic Environment Guidance
Conducted and radiated RF Emissions CISPR 11	Group 1 Class A	The DuraPro™ Oscillating System uses RF energy only for its internal function (e.g., computer timing and internal communication). Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
Harmonic emissions IEC 61000-3-2	Class A	NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If the equipment is used in a residential environment (for which CISPR 11 class B is normally required), it might not offer adequate protection to RF communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY

The DuraPro™ Oscillating System is intended for use in the electromagnetic environment specified below. Users must ensure that it is used in this standard.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact	±8 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 5%.
	±15 kV air	±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines	±1 kV for input/output lines	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
	±2kV line(s) to earth	±2 kV line to earth	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT* (100% dip in UT) for 0.5 (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) and 1 cycle (at 0°) 70% UT (30% dip in UT) for 25 cycles	0% UT (100% dip in UT) for 0.5 (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) and 1 (at 0°) cycle 70% UT (30% dip in UT) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 5%.
	0% UT (100% dip in UT) for 5 sec	0% UT (100% dip in UT) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY (CONT'D)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the DuraPro™ Oscillating System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance (d) is calculated as follows: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 9 to 28 V/m 380 MHz to 5.8 GHz in set bands with various modulation	3 V/m 80 MHz to 2,7 GHz 9 to 28 V/m all frequency bands per standard	
Immunity to Proximity Magnetic Fields IEC 61000-4-39	65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz	65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz	Immunity to proximity magnetic fields in the frequency range 9k Hz to 13.56 MHz was evaluated

CAUTION

The DuraPro™ Oscillating System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/user of the DuraPro™ Oscillating System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DuraPro™ Oscillating System as recommended below, according to the maximum output power of the communications equipment.

RECOMMENDED SEPARATION DISTANCES

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1, 2\sqrt{P}$	$d = 1, 2\sqrt{P}$	$d = 2, 3\sqrt{P}$
0.01	0.3 *	0.3 *	0.3 *
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

***30 cm is the minimum recommended separation distance even though the calculation would yield a shorter distance.**

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

SYSTEM OVERVIEW

This User Manual is intended to provide an overview of the DuraPro™ Oscillating System and describe how the system can be used for bone removal, drilling of pilot holes, and soft tissue removal.

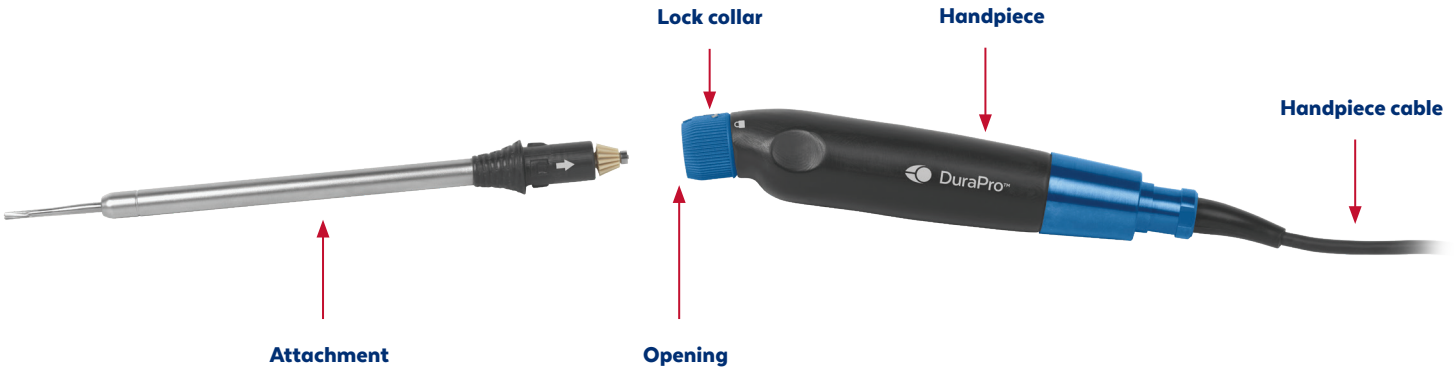
The DuraPro™ Oscillating System is comprised of a Handpiece, Foot Switch and Power Cord, Attachments, and Depth Stops.

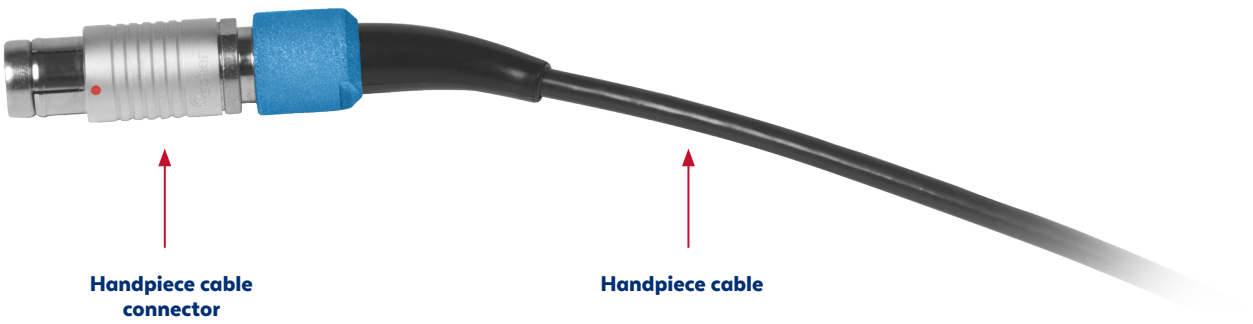
Attachment **Handpiece**

Foot Switch and Foot Switch Power Cord

Handpiece

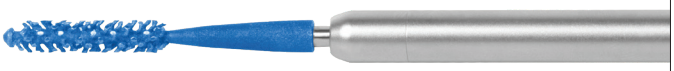
The DuraPro™ Oscillating System is an AC powered surgical instrument that features a motor and Attachments to remove bone and perform soft tissue cutting with a brush through an oscillating motion. The Handpiece has a cable that connects to the Foot Switch as well as an opening at the front for connection with the Attachments. The lock collar is designed to secure the Attachments to the Handpiece.





Attachments

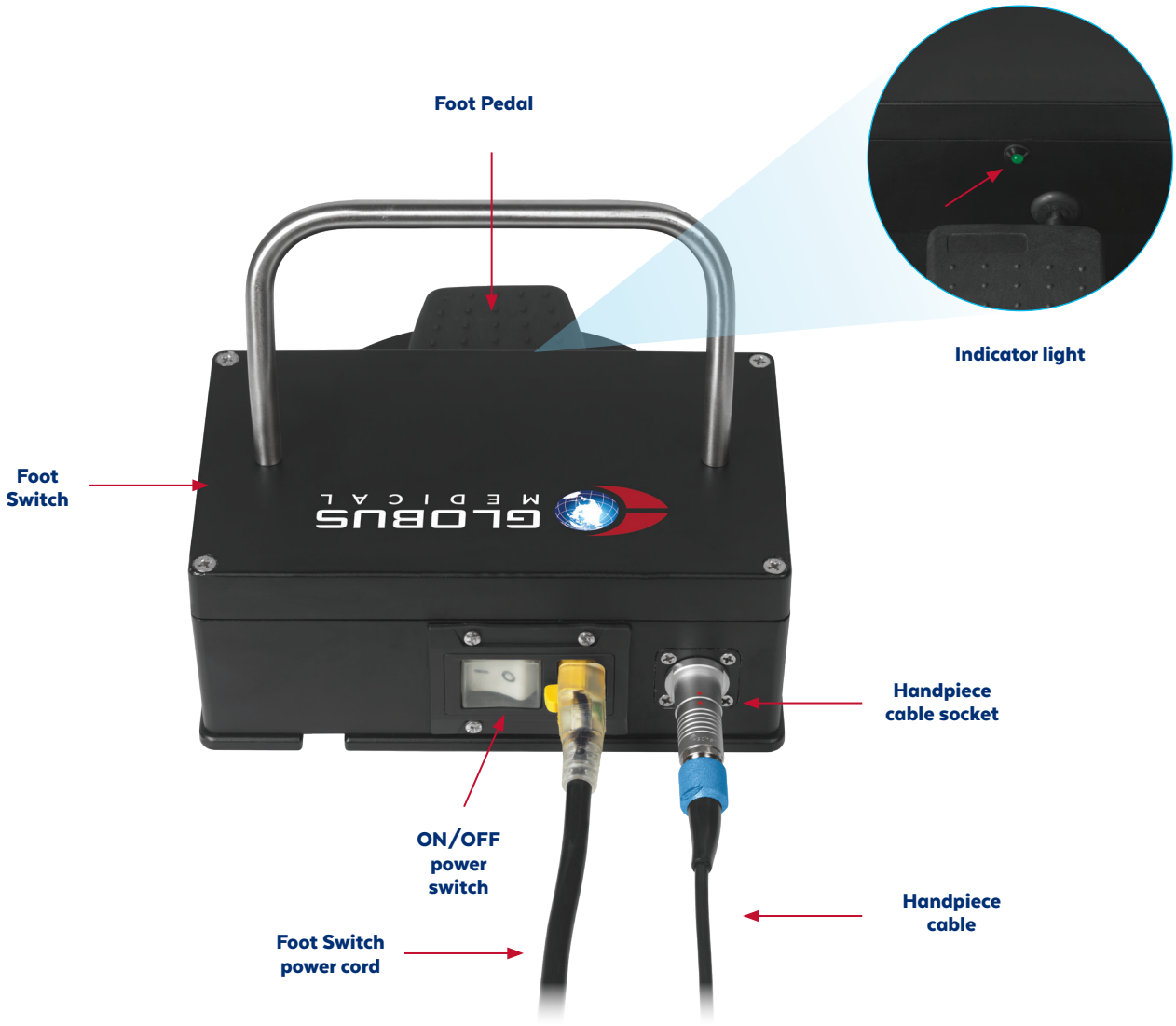
The Attachments are available in a wide range of styles for various surgical applications, including bone removal, soft tissue cutting with a brush, and pilot hole creation. The alignment rib on the attachment interfaces with an opening on the Handpiece and is secured with the lock collar. The gear on the back of the Attachment translates motion from the Handpiece to the cutting tip. The Attachments connect and disconnect from the Handpiece, allowing the user to switch between different styles within a single procedure. The Attachments are single use and are provided gamma sterilized.

Ball Attachments	
Barrel Attachments	
Brush Attachments	
Tapered Barrel Attachments	

Attachments

Foot Switch

The Foot Switch is the control unit that supplies power to the Handpiece. The Foot Switch is a floor standing power supply and has a power cord that allows for connection to hospital grade outlets. A socket at the back of the Foot Switch allows for connection of the Foot Switch power cord for power delivery. The Foot Switch provides powered ON/OFF control as well as regulating when the Handpiece starts and stops with an integrated Foot Pedal. There is also a handle to allow for movement and repositioning during operation. An indicator light at the front of the Foot Switch shows when the system is ready for use. The Foot Switch is reusable and not sterilizable.



Depth Stops

Depth Stops are available for use with specific Barrel Attachments to create a controlled pilot hole with a pre-determined depth in a single step.

The 2.4mm Depth Stops are compatible with the 2.4mm Barrel Attachments with pilot hole depth lengths ranging from 10mm to 18mm. The incremental depth lengths, controlled by the depth stop, correspond to commonly used lateral mass screw length sizes. The depth stops are assembled over the distal end of the corresponding Barrel Attachment. The Depth Stops are reusable and steam sterilizable.

Capital Equipment

Foot Switch 6262.0131

Foot Switch Power Cord-5M 6262.0134

Instruments

DuraPro™ Handpiece, Angled, 6262.1222

DuraPro™ Handpiece Cable 6262.1221

Single Use Attachments

BRUSH ATTACHMENTS

Part No.	Description	Profile	Head Diameter	Tip Length	Working Length
6262.4352S	DuraPro™ 5mm Brush Attachment, 15mm, 180mm		5mm	15mm	180mm
6262.4351S	DuraPro™ 5mm Brush Attachment, 25mm, 180mm			25mm	

BARREL ATTACHMENTS

Part No.	Description	Profile	Head Diameter	Tip Length	Working Length
6262.2122S	DuraPro™ 2.4mm Barrel Attachment, 28mm, 90mm		2.4mm	28mm	90mm
6262.2123S	DuraPro™ 2.4mm Barrel Attachment, 28mm, 140mm				140mm
6262.2133S	DuraPro™ 3mm Barrel Attachment, 22mm, 90mm		3mm	22mm	90mm
6262.2134S	DuraPro™ 3mm Barrel Attachment, 22mm, 140mm				140mm

Blue indicates Depth Stop compatibility.

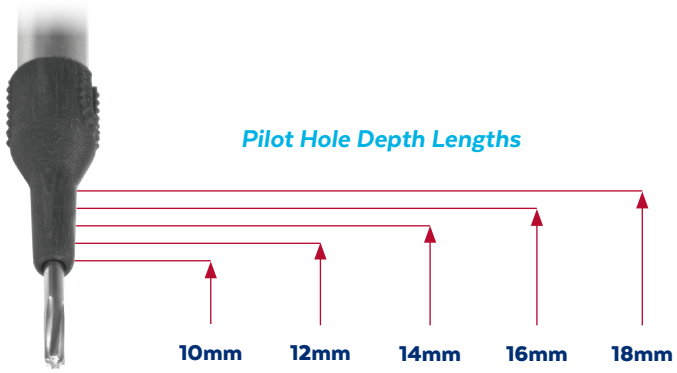
BALL ATTACHMENTS

Part No.	Description	Profile	Head Diameter	Tip Length	Working Length
6262.2352S	DuraPro™ 5mm Ball Attachment 22mm, 90mm		5mm	22mm	90mm
6262.2351S	DuraPro™ 5mm Ball Attachment 22mm, 140mm			22mm	140mm

TAPERED BARREL ATTACHMENTS

Part No.	Description	Profile	Head Diameter	Tip Length	Working Length
6262.3131S	DuraPro™ 3.5-4.5mm Tapered Barrel Attachment, 30mm, 260mm		3.5–4.5mm	30mm	260mm

DEPTH STOPS



Part No.	Description	Compatible Barrel Attachment Head Diameter	Color
6262.8210	DuraPro™ 2.4mm Depth Stop, 10mm (shown)	2.4mm	Black
6262.8212	DuraPro™ 2.4mm Depth Stop, 12mm	2.4mm	Gray
6262.8214	DuraPro™ 2.4mm Depth Stop, 14 mm	2.4mm	Purple
6262.8216	DuraPro™ 2.4mm Depth Stop, 16mm	2.4mm	Black
6262.8218	DuraPro™ 2.4mm Depth Stop, 18mm	2.4mm	Gray

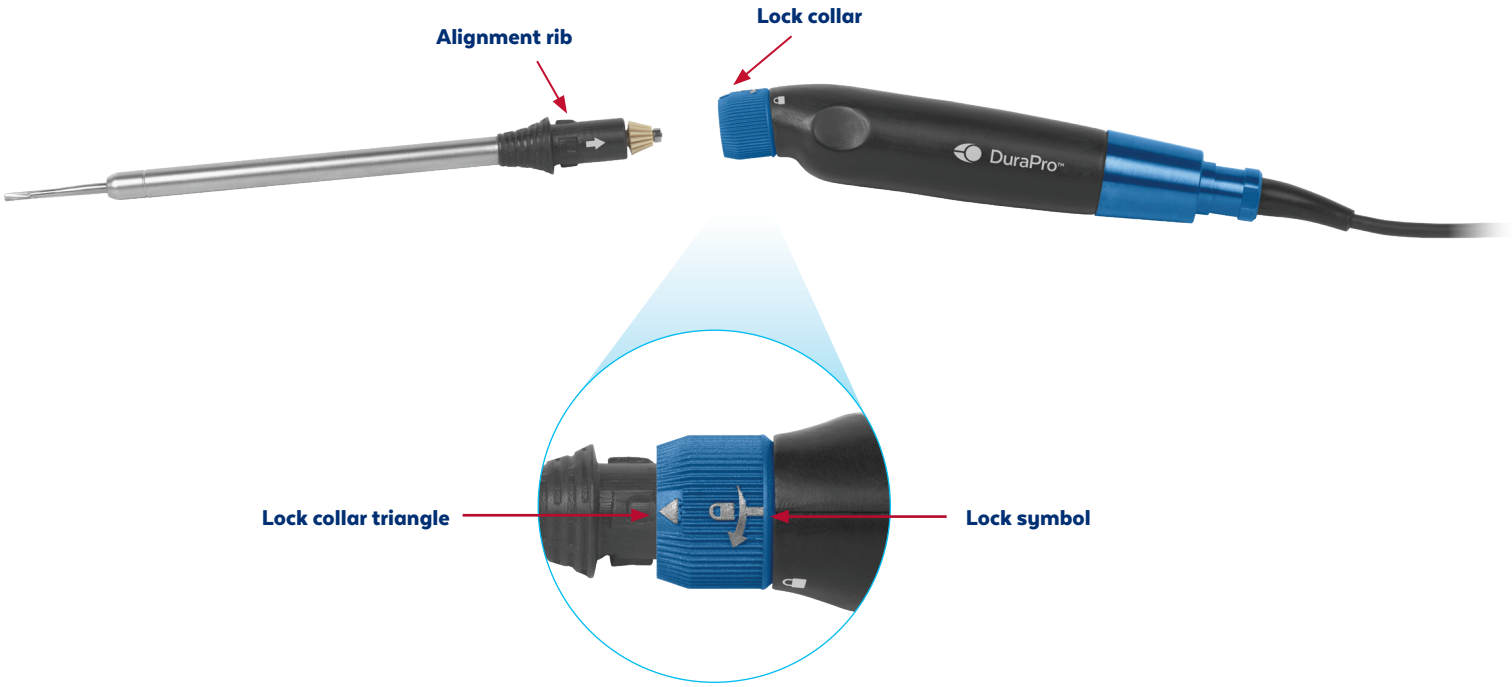
SETUP AND ASSEMBLY

Handpiece and Attachments

Determine the Attachment size and style to be used.

Assemble the selected Attachment to the Handpiece by aligning the arrow in front of any alignment rib on the Attachment with the triangle on the lock collar of the Handpiece and insert. Secure the Attachment by rotating the lock collar in the direction of the arrow next to the lock symbol to secure the Attachment. Ensure that the Attachment is fully seated by pulling gently and confirming it remains locked in position.

To remove the Attachment, rotate the lock collar in the opposite direction of the arrow next to the lock symbol, and pull the Attachment straight out.



Rotate lock collar in direction of lock symbol arrow to secure Attachment in place

Assembled Attachment and Handpiece

Optional: Assembling Depth Stops with Attachments

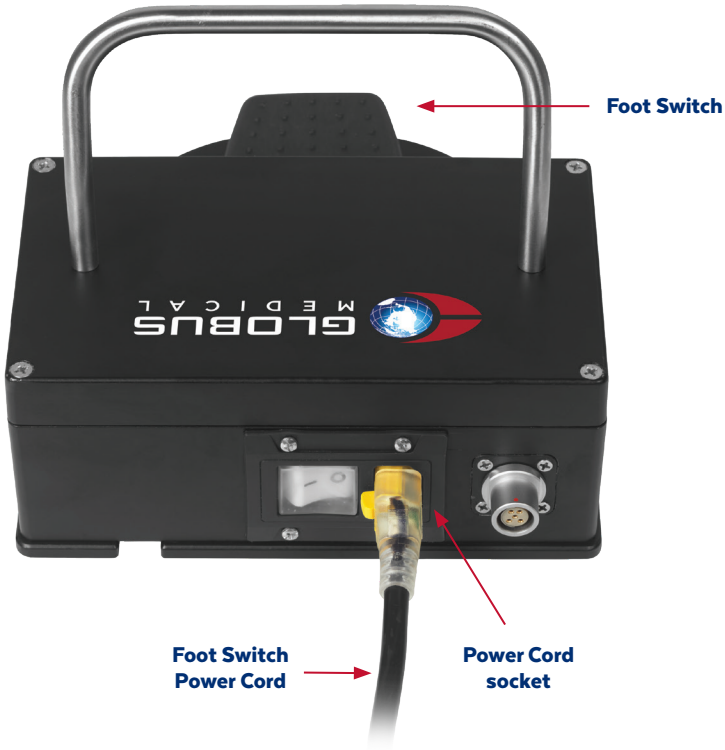
Select the appropriate Depth Stop size compatible with the desired Barrel Attachment and intended pilot hole depth. Insert the Depth Stop over the distal end of the Attachment until the Depth Stop is seated flush over the tip.

Depth Stop assembled to Attachment

Foot Switch Setup

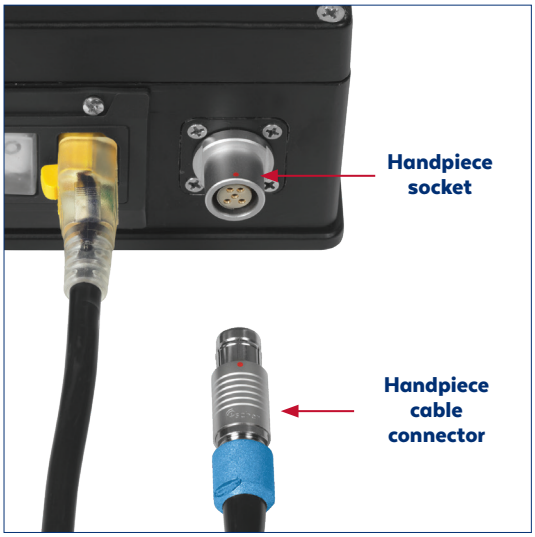
Connect the Power Cord to the power cord socket on the back of the Foot Switch. This cord should remain attached following initial setup. Place the Foot Switch on the floor and connect the Power Cord to the hospital grade wall outlet.

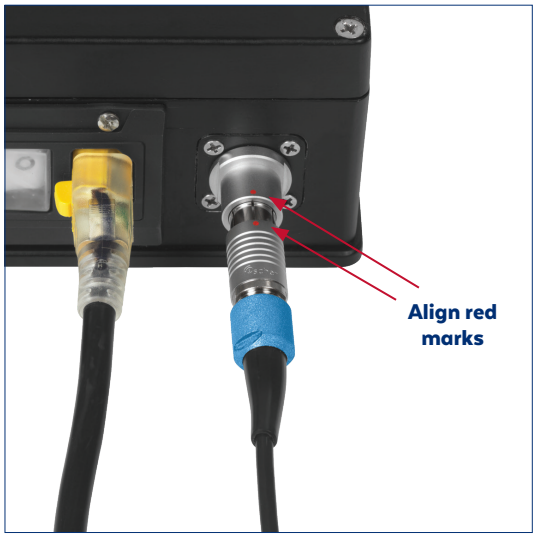
Power Cord



Connecting the Handpiece to the Foot Switch

Connect the Handpiece cable to the Handpiece socket on the back of the Foot Switch. Align the red marks on the cable end and socket, and press the cable in until fully seated and an audible click is heard. To disconnect the Handpiece, hold the Handpiece plug and pull straight out.





Connecting Handpiece to Foot Switch

Turn on the power using the switch located on the back of the Foot Switch. The green ready light will illuminate when the system is ready for use.

Important: Test the Handpiece operation by holding the Handpiece securely away from the patient and pressing the Foot Switch. Test essential performance by releasing the Foot Switch and ensuring the Handpiece turns off.

	CAUTION
	While testing and operating the Handpiece, listen and feel for conditions such as excessive vibration and inconsistent or rough sounds. If these conditions occur, discontinue use of the Handpiece.

The system is ready for use.

Procedural Use

The DuraPro™ Oscillating System can be used for bone removal, tissue cutting, and pilot hole drilling procedures. For general use, review the following procedures.

General Operation

Power on the Handpiece by engaging the Foot Switch. With the Handpiece running, remove bone by pressing the desired attachment tip into the tissue to be cut.

Note: The 2.4mm Barrel Attachments may be optionally used with compatible Depth Stops to create pilot holes.

To remove disc material during discectomy, advance the Brush Attachment tip fully into the disc space, and run the Handpiece by engaging the Foot Switch. Extra care should be taken to only run the Brush Attachments when the tip is completely contained in the disc space, or fully submerged in saline when removing tissue from the brush. Failure to follow these instructions may result in unintended removal of soft tissue.

Note: The Brush Attachment tip can be run while in contact with bone, but do not actively press it into bone. If significant vibration is felt while in contact with bone, reduce the force of the tip on the bone.

Be sure to stay within the allowed maximum limit of the Applied Part Duty Cycle. For each attachment:

i. The maximum allowable activation time is 30 seconds.

ii. It is important to let the system cool for a minimum of 30 seconds between cycles for a maximum of 4 cycles, followed by a 25-minute rest period before additional use.

	WARNING
	Be sure to stay within the allowed maximum limit of the Duty Cycle described in this manual. If these limits are exceeded, the user may experience unwanted heat production in the Handpiece.

Stop the Handpiece by releasing the Foot Switch.

Cool the Handpiece and Attachment tip by providing rest periods.

Brush Attachment Quick Clean

To quick clean the Brush Attachment tip of tissue debris during discectomy, remove the attachment from the disc space. Submerge the brush tip into a pre-prepared container filled with an appropriate liquid (i.e., saline). While the brush tip is fully submerged in the liquid, run the Handpiece by engaging the Foot Switch until tissue debris has loosened off the tip. Repeat as necessary throughout discectomy.

Disconnecting the DuraPro™ System

Turn off the Foot Switch using the power switch at the back of the device.

Disconnect the Handpiece from the socket on the back of the Foot Switch.

Disconnect the Attachment from the Handpiece, remove any Depth Stops, and dispose of the Attachment following facility guidelines.

Disconnect the Power Cord from the electrical outlet. Leave the Power Cord attached to the Foot Switch.

To keep the Power Cord with the Foot Switch, loosely wrap it around the handle. Store the Foot Switch and Power Cord in a safe, dry location.

CAUTION

Wrapping the cord tightly or around a sharp surface can cause permanent damage to the cord.

Parts List

CAPITAL EQUIPMENT

Part No.	Description
6262.0131	DuraPro™ Foot Switch
6262.0134	DuraPro™ Foot Switch Power Cord-5M

9262.9005 DURAPRO™ OSCILLATING SYSTEM INSTRUMENT SET

Part No.	Description	Qty
6262.1221	DuraPro™ Handpiece Cable	1
6262.1222	DuraPro™ Handpiece, Angled	1
6262.8210	DuraPro™ 2.4mm Depth Stop, 10mm	1
6262.8212	DuraPro™ 2.4mm Depth Stop, 12mm	1
6262.8214	DuraPro™ 2.4mm Depth Stop, 14mm	1
6262.8216	DuraPro™ 2.4mm Depth Stop, 16mm	1
6262.8218	DuraPro™ 2.4mm Depth Stop, 18mm	1
9262.9002	DuraPro™ Depth Stop Module	
9262.0002	DuraPro™ Oscillating System Graphic Case	

DISPOSABLES - SINGLE USE ATTACHMENTS

Part No.	Description
6262.2122S	DuraPro™ 2.4mm Barrel Attachment, 28mm, 90mm
6262.2123S	DuraPro™ 2.4mm Barrel Attachment, 28mm, 140mm
6262.2133S	DuraPro™ 3mm Barrel Attachment, 22mm, 90mm
6262.2134S	DuraPro™ 3mm Barrel Attachment, 22mm, 140mm
6262.2352S	DuraPro™ 5mm Ball Attachment 22mm, 90mm
6262.2351S	DuraPro™ 5mm Ball Attachment 22mm, 140mm
6262.3131S	DuraPro™ 3.5-4.5mm Tapered Barrel Attachment, 30mm, 260mm
6262.4351S	DuraPro™ 5mm Brush Attachment, 25mm, 180mm
6262.4352S	DuraPro™ 5mm Brush Attachment, 15mm, 180mm

CLEANING AND STERILIZATION

System Hardware

Clean the DuraPro™ Foot Switch in a location away from the patient environment, or immediately after use in its surgical location. To avoid exposure to blood-borne pathogens and chemicals, use personal protective equipment.

Read the labels on all approved cleaning agents, detergents, and solvents, and use only per the manufacturer's instructions. The approved cleaning materials include mild disinfectants, such as bleach or sodium hypochlorite-based solutions, ethanol (70%), or isopropyl alcohol at 70% to 90% concentration.

Clean outer surfaces with a lint-free cloth and approved mild disinfectant per the disinfectant manufacturer's instructions. Use caution not to drip or splash any liquid onto the interior of the equipment. Read the labels on all cleaning agents, solvents, and detergents to ensure that they will not cause damage or discolor the finishes of the outer surfaces.

Using a cloth and disinfectant, wipe all surfaces including cables. Replace cloth after cleaning surfaces that are heavily soiled to avoid cross-contamination.

Avoid the use of phenol-based, corrosive, or solvent disinfectant agents that may harm the surface material on equipment. If you are not sure of the properties of a disinfectant agent, do not use it.

WARNING

Do not use flammable or potentially explosive disinfectant sprays. The use of such sprays can create vapors that cause explosion and fire resulting in serious personal injury or death.

CAUTION

The system is not waterproof. If water or cleaning liquids enter the equipment, electrical short circuits can result once power is returned.

CAUTION

The use of sprays to disinfect medical equipment is not recommended. The vapor from the spray can enter the equipment and cause electrical short circuits and corrosion.

CAUTION

Failure to correctly clean and sterilize reusable components could result in patient infection.

Handpiece and Accessories

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using *neutral cleaners* before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, and bleach, and/or other alkaline cleaners, may damage some devices, particularly instruments, and should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per the manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard-to-reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard-to-reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per the manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in the lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat the cleaning process starting with step 3.

Sterilization

The DuraPro™ Oscillating System Instruments are provided non-sterile, except for the attachments, which are provided sterile only.

Sterile instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a medical grade HDPE protective tube inside a PETG container/Tyvek heat-sealed pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. They are single use and should be discarded properly after surgery; do not autoclave or re-use.

WARNING

Do not use sterile items if expired or packaging is damaged.

Non-sterile instruments have been validated to ensure an SAL of 10^{-6}, in accordance with ANSI/AAMI/ISO 17665-1. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed. If questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Sterilization Parameters

Method	Cycle Time	Temperature	Exposure Time	Drying Time
Steam	Pre-Vacuum	132°C (270°F)	4 Minutes	30 Minutes

Do not stack trays during sterilization. These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

LABELS AND TECHNICAL REFERENCE

Labels and Symbols

Requirement	Label Content	Location
Globus Logo		Product Label
Product Name	DuraPro™ Oscillating System	Product Label
Manufacturer Name and Address	Globus Medical Inc. 2560 General Armistead Ave Audubon, PA 19403	Product Label
Telephone Number	610-930-1800	Product Label
Manufacturer Symbol		Product Label
Date of Manufacture Symbol		Product Label
Date of Manufacture	YYYY-MM-DD	Product Label
Catalog Number		Product Label
Lot Number		Product Label
Serial Number		Product Label
Consult Instructions for Use Symbol		Product Label
Caution		Product Label
Single Use Only		Product Label

Requirement	Label Content	Location
Do Not Resterilize		Product Label
Medical Device		Product Label
Non-Sterile		Product Label
Use By (YYYY-MM-DD)		Product Label
Do Not Use If Package is Damaged		Product Label
Prescription Only		Product Label
Electrical Ratings	Voltage, Amperage, Power, Frequency	Product Label
Waste Electrical and Electronic Equipment (WEEE)		Product Label
Label Part of Number	Label P/N XXXX Rev X	Product Label
UDI Label	(01)XXXXXXXXXXXXX(11)MFG date[YYMMDD](21)Serial#	Product Label
Type B Applied Part		Cutting Tip
Temperature Limit		Shipping Containers

SYSTEM SPECIFICATIONS

Operating Conditions

- Temperature: 50°F (10°C) to 81°F (27°C)
- Operating Air Pressure: 70 to 110 kPa
- Humidity: 20% to 80% non-condensing

Duty Cycle

- For the operating environment described above, the system is rated for 4 cycles of 30 seconds ON followed by 30 seconds OFF.
- The system should rest for 25 minutes following the duty cycle above.

System Transport and Storage Conditions

- The system components can be shipped in temperatures ranging from:
    - -40°F (-40°C) to 150°F (65°C) and altitudes of up to 35,000 feet (air cargo)
- Dry heated storage is required for any extended period of storage, more than a few days, at temperatures ranging from:
    - 32°F (0°C) to 104°F (40°C)
- Air Pressure: 70 to 110 kPa
- Humidity: 5% to 85% non-condensing
- Vibration
    - Frequency: 10 to 200 Hz
    - G Value: Random 1.14 g RMS
    - Amplitude: 0 to 0.15mm
- Shock
    - G Value: 0 to 10g
    - Pulse duration: 6 to 10 ms

Power Requirements

- 100 VAC 50/60Hz, 3.1A
- 120 VAC 60Hz, 3.1A
- 220-240 VAC 50/60Hz, 1.3A

General Specifications

- IPX7 Rated Foot Switch

Handling

The DuraPro™ Oscillating System and all instruments should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to use in surgery.

System Disposal at End of Life

It is the responsibility of the equipment owner to dispose of the system in a manner that conforms to local and country regulations. This normally requires the equipment to be collected separately from the municipal waste as indicated by the symbol to the right.

The equipment may have resale value on the market or as parts. Your distributor or Globus Medical should be contacted before disposal for potential assistance and to determine if the parts can be recycled through these companies. In the event you choose to dispose of the system locally, to reduce risk to the environment and to the persons discarding the equipment, a service engineer trained on the maintenance of the DuraPro™ Oscillating System should be contacted to assist in the safe decommissioning of the system.

All components are RoHS compliant.

MAINTENANCE AND TROUBLESHOOTING

Problem	Possible Cause	Proposed Remedy
Attachment does not insert properly	Alignment Rib is not oriented correctly or is damaged	Remove Attachment and check alignment of collar and Attachment before re-inserting Replace with new Attachment
Handpiece does not stay locked	Alignment Rib is damaged Handpiece is damaged	Remove Attachment and check alignment of collar and Attachment before re-inserting Replace with new Attachment Replace with new Handpiece
Handpiece has excessive heat, noise, or vibration	Attachment is not properly aligned Attachment is damaged Handpiece is damaged	Remove Attachment and check alignment of collar and Attachment before re-inserting Replace with new Attachment Replace with new Handpiece
Attachment tip is getting hot	Attachment is damaged or bur may be dull	Replace with new Attachment
Foot Switch green LED does not come on	Foot Switch is not plugged in or turned on Foot Switch is damaged	Move ON/OFF switch to ON position Attach power cable to different outlet Replace with new Foot Switch
Foot pedal on Foot Switch does not turn Handpiece on	Foot Switch is not plugged in or turned on Handpiece is not plugged in Foot Switch is damaged Handpiece is damaged	Move ON/OFF switch to ON position Attach power cable to different outlet Remove and re-attach Handpiece cable to Foot Switch Replace with new Foot Switch
Attachment sounds like it is running, but no tissue is being removed	Lock collar may not be tightened (attachment not secured) Gears may be stripped	Replace with new Attachment Tighten lock collar to secure Attachment

NOTES

Globus Medical
Valley Forge Business Center
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Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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