



Medtronic

MIDAS REX[®] LEGEND[®] EHS[®]

Electric High-Speed System



Instruction Manual

Rx Only

GLOSSARY OF UNIVERSAL SYMBOLS

The following symbols may appear within this manual, on product labeling, or on the product itself:

	Attention, see <i>Instructions for Use</i> .	TUBE	Tube Control
Rx Only	United States federal law restricts this device to sale by or on the order of a physician.		AC Power
	Reference Number		Use with
	Lot Number	Multi-Use Disposable Attachment	Multi-Use Disposable Attachment
	Serial Number	Instrument Case	Instrument Case
	Quantity	Lubricant/Diffuser	Lubricant/Diffuser
	For single patient use only. Do not re-use, re-process, or re-sterilize this product. Re-use, re-processing or re-sterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.	Dissecting Tool	Dissecting Tool
\approx	Approximately equal to	Attachment	Attachment
	Non-Sterile	Control Unit	Control Unit
	Sterilized by Gamma Irradiation	Refurbished	Refurbished
	Use by date	Accessory	Accessory
	Date of manufacture	Regulator	Regulator
	Temperature Limitations	Bone Mill	Bone Mill
	Unlock	Motor	Motor
	Lock	Brush	Brush
	On	Adapter	Adapter
○	Off	! USA	USA Only
	Handpiece		Protective Earth
	Foot-Operated Control		High Voltage
	Compliant with European Council Directive MDD 93/42/EEC.		Irrigation
	Authorized Representative in the European Community		Type BF

	Manufacturer		Speed Increase
	Do not dispose to unsorted municipal waste.		Speed Decrease
TOOL	Tool Control		Equipotential Point
	Fuse		EMC Compliance Mark
	UL Mark UL classified with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 2FF7. UL classified for Canada with respect to electric shock, fire, mechanical and other hazards only in accordance with CAN/CUSA C22.2 UL 601-1. Medical Equipment Certified for Canada 2FF7		Forward (default) / Reverse Selector
	Consult Instructions for Use		

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The MIDAS REX® LEGEND EHS® – Electric High Speed System (“Legend EHS System”)

is intended for use in surgical procedures for the following medical applications:

- Neurosurgical
- Spine
- Orthopaedic Surgery
- General Surgery
- ENT
- Maxillofacial
- Craniofacial

Contraindication: None

The Legend EHS System is comprised of the following:

- Legend EHS Motor, Legend EHS Stylus Motor**
- Legend EHS Console**
- Legend EHS Foot Control**
- Legend EHS Cables**
- Legend Attachments**
- Legend Dissecting Tools – single use, disposable**

NOTE

The Legend EHS System is designed to be used with Legend Attachments and Dissecting Tools.

Read and understand this instruction manual before use of the LEGEND EHS SYSTEM.

The **Legend EHS Motors** are described in this Instruction Manual as the “Legend EHS Motor” or “EHS Motor”. The **Legend EHS Stylus Motor** is described as the “Stylus Motor.”

The **LEGEND EHS SYSTEM** is designed for use by medical professionals familiar with powered surgical instrumentation. The surgeon is responsible for learning the proper techniques in the use of this system, as inappropriate use may potentially be harmful.

It is strongly recommended that the surgeon and dedicated operating room personnel are knowledgeable with the use of this equipment, associated attachments, and dissecting tools, by being trained in Midas Rex® Institute Hands-On Workshops or by one of the local authorized representatives.

If Legend EHS components require servicing or refurbishing, contact Medtronic Powered Surgical Solutions Repair Services for a return authorization and instructions for returning the components.

Medtronic Powered Surgical Solutions provides quality assured service by factory-trained personnel who will utilize genuine MIDAS REX® LEGEND EHS® parts as required.

All Legend EHS motors, motor cables, and attachments returned for servicing or refurbishing should be properly cleaned and sterilized prior to shipping according to the directions provided in this Instruction Manual.

! USA **Rx only** Federal Law (USA) restricts this device to sale by or on the order of a physician.

For Questions or Problems, consult the Legend EHS Instruction Manual, or contact your Medtronic Neurologic Technologies sales representative, or call:

Medtronic Powered Surgical Solutions Technical Support:

8 a.m. to 6 p.m. (Central Standard Time)

Telephone: 800-643-2773 or 817-788-6400

Outside the U.S.A., contact your Medtronic Regional Distributor or Medtronic Neurological Sales Representative.

Environmental conditions for transport and storage: Ambient temperature of between -40°C and 70°C, Relative humidity between 30% and 75%, Atmospheric pressure between 500 hPa and 1060 hPa.

 This symbol is used to alert the reader to important safety and precautionary information. When displayed on the actual device or packaging, it refers the user to the instruction manual.

The words Warning, Caution and Note carry special meanings and should be carefully reviewed.

WARNING The personal safety of the patient, operator and/or operating room staff may be involved. Disregarding this information could result in injury to the patient, operator and/or operating room staff.

NOTE This provides special information to make maintenance easier or important operating instructions more clear.

CAUTION These instructions point out special service procedures or precautions that must be followed to avoid damaging the instrument. A damaged instrument could result in injury to the patient, operator, and/or operating room staff.

Read and understand warnings before use of the LEGEND EHS SYSTEM.

Important Safety Instructions:

NOTE The surgeon should become familiar with the operational characteristics of each tool and attachment combination at various speeds prior to use.

WARNING

General:

DO NOT use any other components except for Midas Rex Legend Attachments, Legend Dissecting Tools and Legend accessories in combination with a Legend EHS or Stylus Motor. Use of devices with other than Legend EHS Systems or associated parts or components may cause injury to the patient, operator and/or operating room staff. Use of devices with other than Legend EHS Systems or associated parts or components will damage the motor and attachments and will void manufacturer's limited warranty.

DO NOT interchange components of the Legend EHS System with components from the Midas Rex® Classic Motor System, the Midas Rex® III Motor System or the Mednext® Bone Dissecting System and their associated attachments and dissecting tools.

DO NOT operate the Legend EHS System in a Magnetic Resonance Imaging Suite.

DO NOT use Legend EHS Motors or Legend Attachments before following proper cleaning and sterilization protocols.

DO NOT dissect bone without adequate irrigation to prevent thermal necrosis.

DO NOT operate the Legend EHS Motors without protective eyewear.

DO NOT attempt to run the Legend EHS motors immediately after autoclaving. Allow an adequate "cool down" period (Typically 1 hour).

DO NOT use the Legend EHS System in the presence of flammable anesthetics.

DO NOT use Legend EHS System components if damage is apparent or if components do not run properly. The Legend EHS System must be inspected for damage prior to each use.

- Conduct a visual inspection of the cables for cracks, tears or corrosion.
- Check attachments for proper appearance. Install attachment and dissecting tool, then briefly run motor.
- Check motor for overheating.
- Check attachment for overheating.
- Check dissecting tool for flail.
- Check for bent or missing pins in cable connectors

DO NOT attempt to use an overheating motor or attachment.

Consult the Legend Bone Mill product insert before use with the Legend EHS System.

For metal transection, observe the following safety precautions:

- a. Protective eyewear is essential.
- b. Irrigate copiously to cool the cutting surfaces.
- c. Protect the wound site from metal debris.
- d. Use a clamp or grasping device to control loose fragments during transection of any metal component.

Legend EHS Motors or Legend Attachments which fail due to extended use may as a result of such failing allow a component to detach and fall from the motor or attachment and may cause patient injury.

Electrical contacts must be properly dried prior to use.

Legend EHS Motors:

Heavy side loads may cause overheating of the motor to the point where the motor is uncomfortable to hold.

- a. Never place an overheated motor or attachment on the patient or patient draping during surgery.
- b. Mitigate the overheating by discontinuing use and rest the motor by using intermittently, or wrap the motor / attachment, when not in use, with a moist sterile towel.
- c. If the motor is passed off, the receiver must grasp the motor by the proximal end close to the motor cable.

DO NOT attempt to change a dissecting tool or attachment while the motor is running, or when the motor or attachment is in an overheated state.

DO NOT use a Legend EHS System if the motor continues to run after releasing the foot pedal. If a Legend EHS System requires servicing or refurbishing, return system to Medtronic Powered Surgical Solutions.

DO NOT immerse the Legend EHS System Motor or Cables.

DO NOT place motor, attachment and dissecting tool on the patient or in an unsecured location during surgery.

DO NOT kink EHS motor cables.

Legend EHS Console:

DO NOT open or disassemble the console. There are no user serviceable parts inside. Refer all servicing to Medtronic Powered Surgical Solutions.

DO NOT immerse the console.

DO NOT sterilize.

DO NOT connect any cables or equipment to the console unless the cables and equipment are approved for use by Medtronic Powered Surgical Solutions as documented in the appropriate Instructions for Use and Classified by UL for use with this system.

Legend Attachments:

DO NOT use a dissecting tool without the appropriate attachment as injury may occur to the patient and/or operator.

DO NOT use excessive pressure, such as bending or prying, on attachments or dissecting tools. This may cause the tool to bend or break and cause injury to the patient, operator and/or operating room staff.

DO NOT use a Legend Attachment if any part of the attachment appears to be bent, loose, missing or damaged. If a Legend Attachment requires servicing or refurbishing, return attachment to Medtronic Powered Surgical Solutions.

DO NOT force or modify any attachment or dissecting tool to fit a Legend EHS or Stylus Motor.

Consult the Legend Bone Mill product insert before use with the Legend EHS System.

Heavy side loads and/or long operating periods may cause overheating of the attachment to the point where the attachment is uncomfortable to hold.

- a. Never place an overheated attachment on the patient or patient draping during surgery.
- b. Mitigate the overheating by discontinuing use and rest the attachment by using intermittently, or wrap the attachment interface with a moist sterile towel.
- c. If the attachment is passed off, the receiver of the attachment must handle the attachment cautiously.

Remove Legend Footed Attachments cautiously and slowly as per instructions to avoid injury to the operator.

Legend Dissecting Tools:

DO NOT use a dissecting tool without the appropriate attachment as injury may occur to patient, operator and/or operating room staff.

DO NOT re-use or re-process a dissecting tool that has already been used. Using a dissecting tool that has already been used may cause injury to the patient, operator and/or operating room staff. Using a dissecting tool that has already been used may affect motor performance and will void manufacturer's limited warranty.

DO NOT use excessive pressure, such as bending or prying, on attachments or dissecting tools. This may cause tool to bend or break and cause injury to patient, operator and/or operating room staff.

DO NOT use an attachment and dissecting tool combination if flail or vibration occurs.

DO NOT use metal cutting dissecting tools on bone.

DO NOT use a twist drill or contra-angle dissecting tool at an operating speed over 62,000 rpm.

DO NOT use a dissecting tool if the sterile packaging is damaged.

If a dissecting tool package is opened, but the tool is not used or contaminated, the tool can be re-sterilized. Remove tool from original packaging and place into an approved autoclave package. Steam sterilize as follows:

High Vacuum Steam	270°F (132°C) for 5 minutes
Gravity Displacement	270°F (132°C) for 15 minutes

The re-sterilized tool must be used promptly following re-sterilization. If rust or corrosion is encountered after re-sterilization, do not use the re-sterilized tool.

Dissecting tool flutes are sharp and can perforate surgical gloves. Always handle with care. Do not spin, twist, or pull a tool by grasping the flutes. Gently pull on dissecting tool shaft to ensure that it is fully seated and properly installed in motor.

Legend EHS Foot Control:

DO NOT use the Legend EHS foot control to operate any systems other than Legend EHS.

DO NOT open or disassemble the Foot Control. There are no user serviceable parts inside. Refer all servicing to Medtronic Powered Surgical Solutions.

DO NOT sterilize the Foot Control.

Legend EHS Foot Control Cables and Motor Cables:

DO NOT use cables with cracks, tears or corrosion.

DO NOT use cables with bent or missing connector pins.

DO NOT kink EHS cables.

Legend EHS Power Cable:

DO NOT use power cable with cracks, tears or corrosion.

DO NOT use power cable with bent or missing connector pins.

LEGEND EHS COMPONENTS

LEGEND EHS MOTOR

High speed, high torque, reversible electric motor used to dissect bone and biomaterials at selectable speeds from 10,000 to 75,000 rpm.



LEGEND STYLUS MOTOR

A smaller compact high speed, high torque, reversible electric motor used to dissect bone and biomaterials at selectable speeds from 3,000 to 75,000 rpm. The Stylus motor cable is integral with the Handpiece and is not removable from the motor.



NOTE

Legend EHS Motors and associated cables do not contain latex.

WARNING

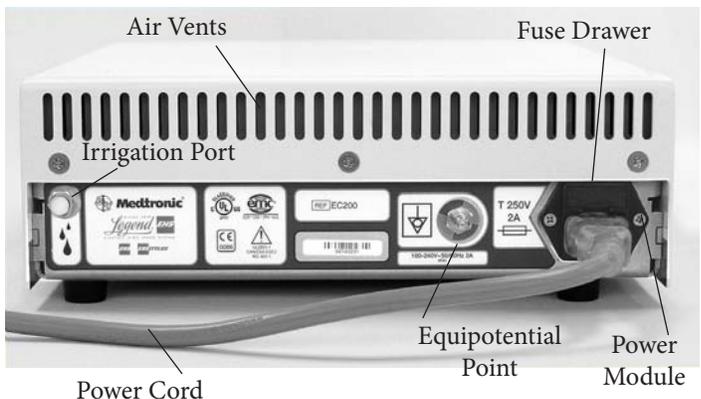
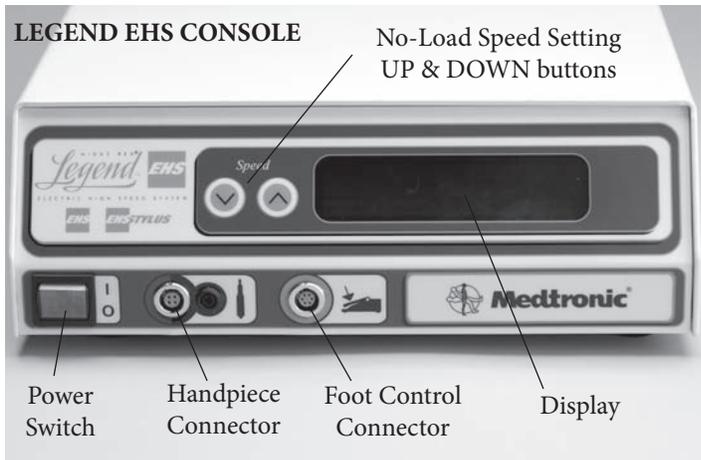
DO NOT use any other components except for Midas Rex® Legend® Attachments, Legend Dissecting Tools, and Legend accessories in combination with Legend EHS Motors. Use of devices other than Legend EHS System or associated parts or components may cause injury to the patient, operator and/or operating room staff. Use of devices other than Legend EHS System or associated parts or components will damage the motor and attachments and will void manufacturer's limited warranty.

NON-DISPOSABLE LEGEND ACCESSORIES:

Legend EHS Console

Controls the no-load speed of the Legend EHS Motors in a range of speed from 10,000 rpm for EHS motor and from 3,000 rpm for Stylus motor up to 75,000 rpm. The digital display indicates motor type, speed setting, and forward or reverse direction when the console is powered "on", but the motor is not operating.

When operating the motor, the motor speed is displayed.



NON-DISPOSABLE LEGEND ACCESSORIES *(continued)*

Legend EHS Cables

LEGEND EHS MOTOR CABLE

Connects the EHS motor / handpiece to the console. The cable is 4.57 meters (15 feet) in length and color-coded green with a 4-pin connection. EHS Motor cables are available with and without special console-end grounding connector (black boot).

STYLUS MOTOR/CABLE ASSEMBLY

Connects the Stylus motor / handpiece to the console and grounds the handpiece. The cable is 4.57 meters (15 feet) in length and color-coded black with a 4-pin connection. The Stylus Motor Cable is integral with the Handpiece and is not removable from the motor.

LEGEND EHS FOOT CONTROL CABLE

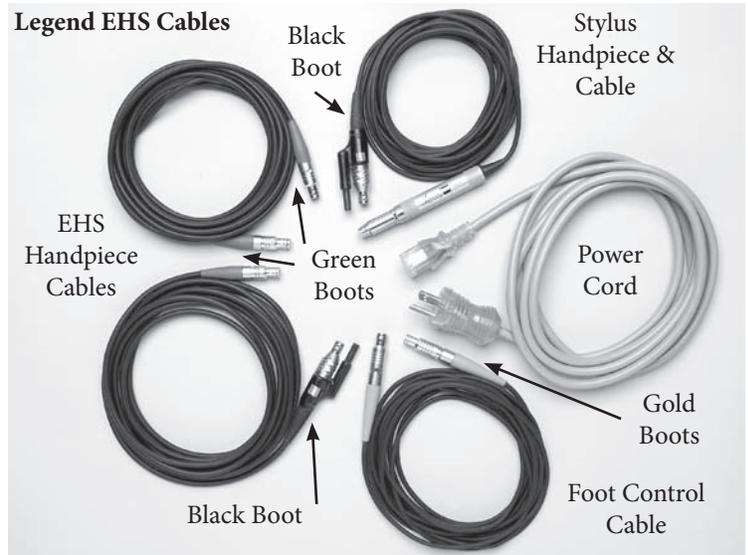
Connects foot control to the console. The cable is 4.57 meters (15 feet) in length and color-coded gold with a 6-pin connection.

LEGEND EHS CONSOLE POWER CABLE

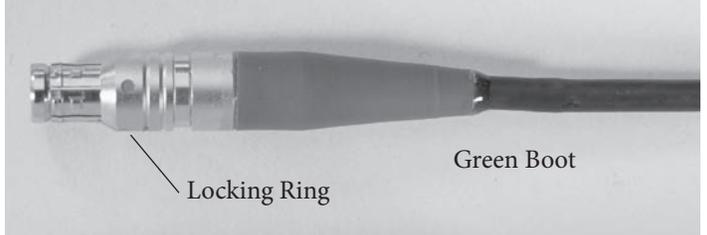
Connects console to the wall electrical source.

LEGEND INSTRUMENT CASE

Used to organize, customize, and contain Legend equipment. Available in a 3/4 DIN size with an individually labeled insert tray.



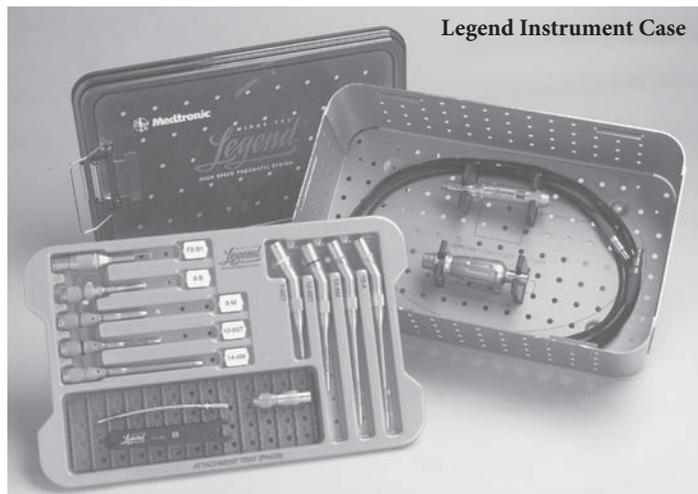
EHS Motor Cable without Ground (both ends)



EHS Motor Cable with Ground (console end)



Stylus Motor Cable (console end)



Legend Attachment Cleaning Nozzle

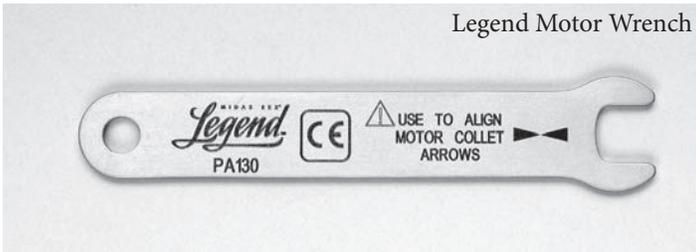


NON-DISPOSABLE LEGEND ACCESSORIES *(continued)*

LEGEND ATTACHMENT CLEANING NOZZLE

Allows recommended aerosol spray cleaner to be used in cleaning procedures.

Legend Motor Wrench



LEGEND MOTOR WRENCH

Used to align arrows on motor collet flats prior to installation of a Legend Attachment.

LEGEND EHS FOOT CONTROL



LEGEND EHS FOOT CONTROL

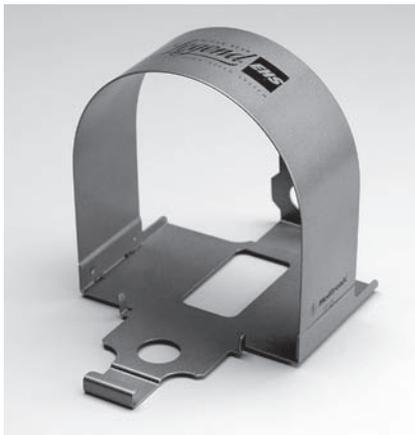
A variable position foot pedal with a reverse rotation button. Legend EHS Foot Control has an optional available hoop for ease of re-positioning the foot control on the floor.

CAUTION

- Use Legend EHS Foot Control to operate only the Legend EHS Motors.
- DO NOT autoclave Legend EHS Foot Control or Foot Control Cable.
- DO NOT carry Legend EHS Foot Control by the cable.

FOOT CONTROL COVER

Optional hoop for ease of repositioning the foot control on the floor.



NON-DISPOSABLE LEGEND ACCESSORIES (*continued*)

LEGEND ATTACHMENTS — Provides support and stability to the rotating dissecting tool.

Legend® motor attachments are available in various designs to facilitate a variety of surgical procedures. Attachments vary in length, diameter, and overall design. They are marked and color-coded to correspond with their associated dissecting tools. A few of the Legend® attachments available are listed in the table below.

Attachment	Example	Other Details/Options
Standard Straight Attachments	AS09	
Standard Angled Attachments	AA14	
Straight Variable Exposure Attachments	AVS07	
Angled Variable Exposure Attachments	AVA07	
Fixed Footed Attachments	AF01	
Rotating Footed Attachments	AF01R	
Telescoping Attachments	AT10 (base) TT12A (tube)	The telescoping attachment requires the use of the AT10 attachment base, as well as a telescoping tube. Tubes are available in straight, curved, or hooded form.
Contra-Angle Attachment	AC16	
Metal Cutting Attachment	ASMC	
Perforator Attachment	AD01	Available in 800 RPM or 1000 RPM form.
5/32" Jacobs Chuck Attachment	AD02	
Bone Mill Attachment	BM100	


WARNING

DO NOT use any other components except for Midas Rex® Legend® Attachments, Legend Dissecting Tools and Legend accessories in combination with a Legend EHS or Stylus Motor. Use of devices other than Legend EHS Systems or associated parts or components may cause injury to the patient, operator and/or operating room staff. Use of devices other than Legend EHS Systems or associated parts or components will damage the motor and attachments and will void manufacturer's limited warranty.

NOTE

Legend Attachments and Legend Dissecting Tools must be used with the Legend EHS System or with the Legend® Pneumatic High Speed System consisting of the Legend Gold, Gold Touch and Platinum Motors. Installation and removal of the attachments and dissecting tools are identical for all Legend Motors.

Angled and straight attachments with the same length, marking and color band share the same dissecting tools. Curved and straight telescoping tubes with the same length, marking and color band share the same dissecting tools. Example: The 14-AM straight and 14-AM angled attachments are 14 cm long, marked 14-AM and have a green color band. All dissecting tools with the prefix 14 (14MH30) may be used in either the 14-AM straight or 14-AM angled attachment.

Color band on attachment is for visual reference. Match the nomenclature on the attachment with the nomenclature on the dissecting tool packaging before matching the color band on the attachment with the dissecting tool packaging.

DISPOSABLE LEGEND ACCESSORIES

LEGEND DISSECTING TOOLS

Legend Dissecting Tools' intended use is for cutting bone and biomaterials.

Legend Dissecting Tools are provided as sterile.

Legend Dissecting Tools must only be used with the Legend EHS System, consisting of the EHS and Stylus motors, or with Legend Pneumatic High Speed System, consisting of the Legend Gold, Gold Touch, and Platinum motors.

NOTE

- The surgeon should become familiar with the operational characteristics of each tool and attachment combination at various speeds prior to use.
- Dissecting tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease speed on console. Change to a new dissecting tool.
- Dissecting tools with "L" identification are longer tools intended for light bone dissection. The increased dissecting tool head/stem configuration may affect dissection stability.
- Surgeons should familiarize themselves with the performance of the dissecting tools before use.

CAUTION

- **DO NOT** use any dissecting tools other than Legend Dissecting Tools with a Legend EHS or Stylus Motor.
- Match the nomenclature and color code on the Legend Dissecting Tool packaging to the same nomenclature and color code on the Legend Attachment.
- Legend Dissecting tools are single use devices.

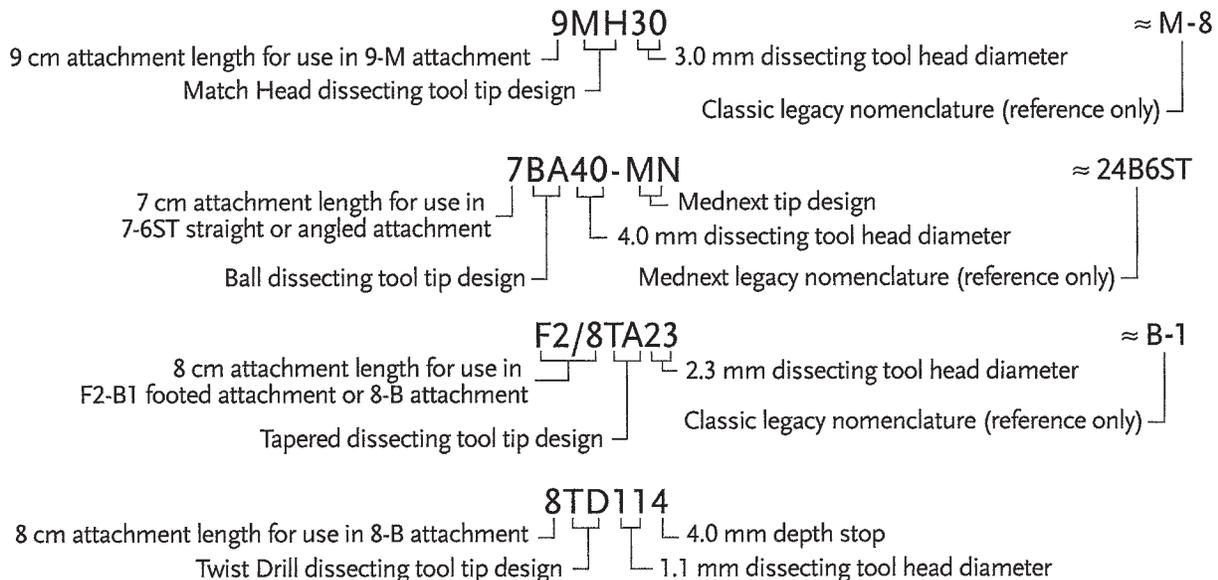
WARNING

- **DO NOT** re-use or re-process a dissecting tool that has already been used. Using a dissecting tool that has already been used may cause injury to the patient, operator and/or operating room staff. Using a dissecting tool that has already been used may affect motor performance and will void manufacturer's limited warranty.
- **DO NOT** use an attachment and dissecting tool combination if flail or vibration occurs.
- **DO NOT** use a twist drill or contra-angle dissecting tool at an operating speed over 62,000 rpm.

NOTE

- Match the nomenclature and color code on the Legend Dissecting Tool packaging to the same nomenclature and color code on the Legend Attachment.

LEGEND DISSECTING TOOL NOMENCLATURE:



DISPOSABLE LEGEND ACCESSORIES *(continued)*

Additional Dissecting Tool Identification following Dissecting Tool Head Diameter

DIAMOND COATED DISSECTING TOOLS:

Available in:

- D Diamond, e.g., 15MH30D
- DC Diamond, coarse, e.g., 10BA50DC
- DX Diamond, extra coarse, e.g., 15CY65DX

BALL DISSECTING TOOLS:

Available in:

- L Long ball — elongated tool stem, e.g., 7BA20L-MN
- F Fine ball — fine fluted head, e.g., 7BA40F-MN
- C Carbide ball, e.g., 7BA40C-MN

TAPERED DISSECTING TOOLS:

Available in:

- S Spiral cutting flute, e.g., F2/8TA23S

CYLINDER DISSECTING TOOLS:

Available in:

- L Long cylinder — elongated cylinder head design, e.g., 14CY50L
- B Ball tip cylinder — rounded tip design on cylinder shape, e.g., 14CY50B



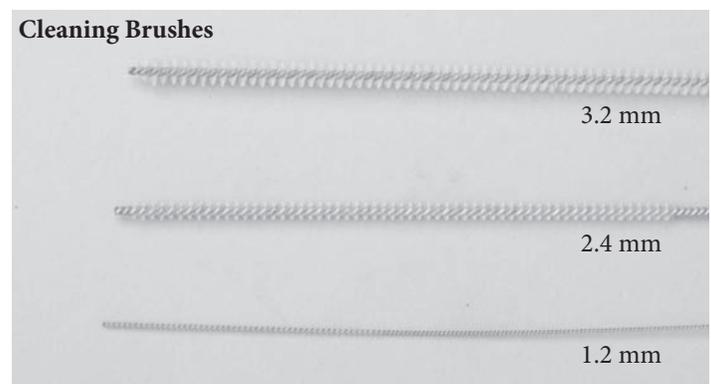
TELESCOPING TUBES

Provides support to the rotating dissecting tool. Telescoping tubes are disposable following multiple uses and should be discarded when heat, excessive vibration is noticed or insertion of the tool becomes difficult.



CLEANING BRUSHES

Used to clean debris from lumen of attachments and telescoping tubes. Sized for an internal bore diameter of 3.2 mm, 2.4 mm or 1.2 mm in Legend Attachments and Telescoping Tubes.



GENERAL GUIDELINES FOR ATTACHMENT AND DISSECTING TOOL APPLICATIONS

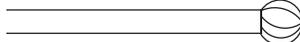
These are general guidelines for dissecting tool applications and are not an all-inclusive listing.

SURGERY

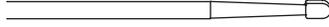
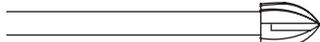
COMMONLY USED
LEGEND ATTACHMENTS

COMMONLY USED TYPES OF LEGEND DISSECTING TOOLS

SPINE

<p>8-B 9-M 14-AM straight or angled 15-A straight or angled</p>	<p>Match Head  Elongated spherical design allows controlled, delicate dissection. For laminotomy, foramenotomy, entry hole, nerve decompression, osteophyte removal...</p> <p>Ball  Helical cutting flutes dissect bone from a variety of approach angles. For debridement, decortication, corpectomy, osteophyte removal...</p> <p>Oval  Helical cutting flutes and curved design blend acorn and ball styles to vary dissection efficiency with approach angle. For decortication, laminotomy, entry hole, nerve decompression, osteophyte removal...</p> <p>Hole Maker/Saw  Matched sets of Hole Makers and Hole Saws are efficient and effective for interbody fusion...</p> <p>Cylinder  Effective bone sculpturing and planing. For graft shaping, debridement, corpectomy, decortication, interbody fusion, fusion takedown...</p> <p>Acorn  Curved designs varies dissection efficiency with varied approach angles. For entry hole, laminotomy, bone shaping, debridement, corpectomy, decortication, fusion takedown...</p>	
<p>Telescoping</p>	<p>Match Head  Elongated spherical design allows controlled, delicate dissection. For laminotomy, foramenotomy, entry hole, nerve decompression, osteophyte removal...</p>	
<p>Footed</p>	<p>Tapered  Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, laminectomy...</p>	

NEUROSURGICAL – CRANIAL

<p>7-6ST straight or angled 8-B 9-M 10-9ST straight or angled 14-AM straight or angled 15-A straight or angled</p>	<p>Match Head  Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, mastoidectomy, acoustic neuroma, skull base...</p> <p>Ball  Helical cutting flutes dissect bone from a variety of approach angles. For debridement, decortication, entry hole, nerve decompression, mastoidectomy, acoustic neuroma...</p> <p>Twist Drill  Helical design with stop produces a hole with a precise depth. Ideal for plating...</p> <p>Acorn  Curved design varies dissection efficiency with varied approach angles. For entry hole, bone shaping, debridement...</p>	
<p>Telescoping</p>	<p>Match Head  Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, mastoidectomy, acoustic neuroma, skull base...</p>	
<p>Footed</p>	<p>Tapered  Slender design for precise dissection with minimal bone loss. For craniotomy, transection, osteotomy...</p>	

GENERAL GUIDELINES FOR ATTACHMENT AND DISSECTING TOOL APPLICATIONS

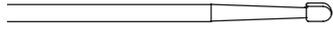
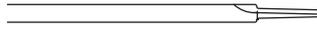
These are general guidelines for dissecting tool applications and are not an all-inclusive listing.

SURGERY

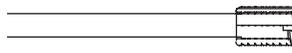
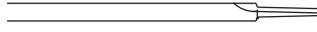
COMMONLY USED
LEGEND ATTACHMENTS

COMMONLY USED TYPES OF LEGEND DISSECTING TOOLS

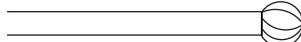
GENERAL SURGERY

<p>7-6ST straight or angled 8-B 9-M 10-9ST straight or angled 14-AM straight or angled</p>	<p>Match Head  Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal...</p> <p>Ball  Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication...</p> <p>Tapered  Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, entry hole, suture hole...</p> <p>Twist Drill  Helical design with stop produces a hole with a precise depth. Ideal for plating...</p>	
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ORTHOPAEDICS

<p>8-B 9-M 14-AM straight or angled 21-TU 26-R Footed Telescoping</p>	<p>Ball  Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, cement removal, acetabular revision...</p> <p>Tapered  Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, suture hole...</p> <p>Acorn  Curved design varies dissection efficiency with varied approach angles. For bone shaping, debridement, decortication, cement removal, acetabular revision...</p> <p>Cylinder  Effective bone sculpturing and planing. For graft shaping, debridement, decortication, cement removal, acetabular revision...</p>	
<p>Footed</p>	<p>Tapered  Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping...</p>	

ENT

<p>7-6ST straight or angled</p>	<p>Ball  Helical cutting flutes dissect bone effectively from a wide variety of approach angles. For mastoidectomy, acoustic neuroma, cochlear implant, labyrinthectomy...</p>	
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BIOMETALS/BIOCERAMICS/BIOMATERIALS

<p>MC</p>	<p>Metal Cutter  Cutting flutes or diamond wheel design remove metals, ceramics and other biomaterials effectively from a variety of approach angles. For cutting rods, pins, plates, implants, screws...</p>	
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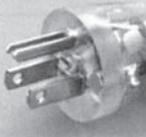
POWER SOURCE REQUIREMENTS

Electrical Power Requirements for Legend EHS System:

100-240 Vac, 50/60 Hz, 2 A

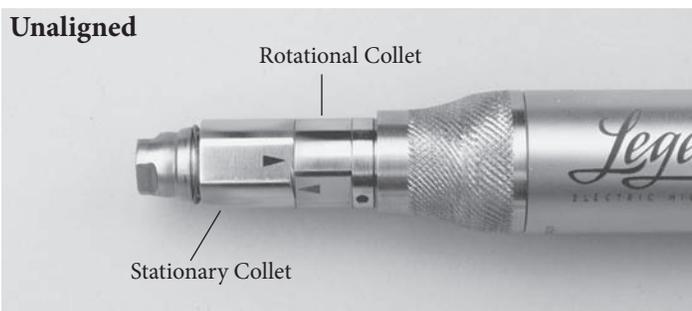
SYSTEM CONNECTIONS:

Console Power Cable styles available for various countries:

<p>North America: USA, Barbados, Belize, Bolivia, Canada, Columbia, Ecuador, Venezuela EA600</p>		<p>Japan EA603</p>		<p>Continental Europe: Austria, Belgium, Finland, France, Germany, Greece, Korea, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden EA602</p>	
<p>United Kingdom, Ireland, Hong Kong, Malaysia, Singapore EA606</p>		<p>Switzerland EA601</p>		<p>Australia, New Zealand EA605</p>	
<p>Israel EA609</p>		<p>Italy, Chile EA611</p>		<p>China EA604</p>	
<p>Denmark EA610</p>		<p>India, South Africa EA607</p>		<p>Argentina EA608</p>	

1. Check alignment of arrows on motor collet flats.

Prior to installation of a Legend Attachment and Dissecting Tool onto the Legend EHS or Stylus Motor, ensure that arrows on the motor collet flats are in proper alignment.



If the arrows are not aligned, use the Legend Motor Wrench to turn the rotational collet (closest to the motor case) until its arrow is aligned with the arrow on the stationary collet (farthest away from the motor case.)



NOTE

A Legend Attachment will not seat onto the Legend EHS or Stylus Motor if the arrows on the collet flats are not aligned.

DO NOT use any other components except for the Legend Motor Wrench to align arrows on motor collet.

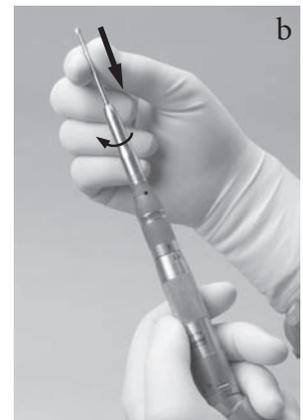
2. Install a Legend Attachment and Dissecting Tool.

Straight attachment installation is listed below. For more detailed information on all the various attachment and dissecting tool installation procedures, refer to the Attachment and Dissecting Tool Section.

- a. Slide straight attachment over motor collet aligning triangular arrows on the attachment and motor case. A tactile and audible click will be observed when the attachment is fully seated.



- b. Insert the dissecting tool into the attachment with a slight rotational motion. A tactile and audible click is observed indicating that the tool is fully seated.



CAUTION

Match the nomenclature and color code on the Legend Dissecting Tool packaging to the same nomenclature and color on the Legend Attachment.

Allow adequate “cool down” period following steam sterilization.

- c. Rotate attachment to the “” position on the motor case. Attempt to pull the tool out of the attachment to ensure that it is properly locked into place. If the tool does not rotate freely, unlock the attachment, re-seat the tool and lock the attachment.



NOTE

The Legend EHS and Stylus Motors attempts to maintain a known starting position for the dissecting tool. This may result in a small rotational movement of the tool, if it is rotated away from the starting position. This is normal operation and should not cause undue alarm nor does it indicate that the system is malfunctioning.

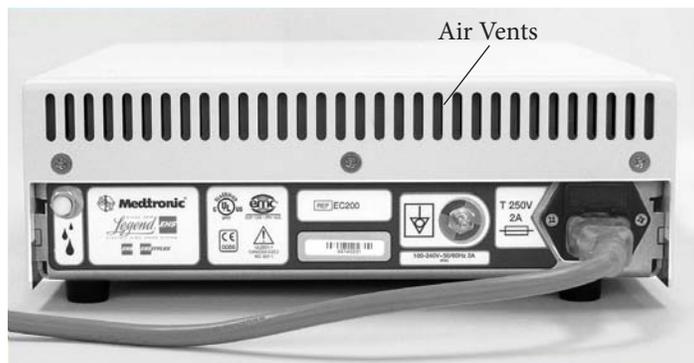
CAUTION

Legend EHS and Stylus Motors should only be operated when the attachment is in the “” position.

DO NOT use a twist drill or contra-angle dissecting tool at an operating speed over 62,000 rpm.

3. **Connect Legend EHS Console to electrical power source.**

Place Legend EHS Console on a flat, stable surface. **DO NOT** block air vents in back of console. Connect the Legend EHS Console Power Cable to the power receptacle on the back of the Legend EHS Console. Connect other end of Legend EHS Console Power Cable to a properly grounded electrical power source.



4. **Connect Legend EHS Foot Control Cable.**



The Legend EHS Foot Control Cable Boot and the console’s foot control receptacle are both color-coded gold. Connect either end of the Legend EHS Foot Control Cable, by aligning the red dots, to the Legend EHS Foot Control Unit.

Insert the other end of the cable into the foot control receptacle on the front of the console by aligning red dots.

CAUTION

DO NOT carry or drag the foot control by the cable.



5. Connect Legend EHS Motor Control Cable.

The Legend EHS Motor Control Cable Boot and the console's motor receptacle are both color-coded green. Connect the Legend EHS Motor Control Cable (EA200) to the Legend EHS Motor. Insert the other end of the cable into the motor receptacle on the front of the Legend EHS console by aligning red dots.

The Stylus Motor Control Cable is integral with the Handpiece and is not removable from the motor. Insert the console end (black boot) into the motor receptacle on the front of the Legend EHS Console.



6. Turn on the Legend EHS Console.

Turn the power switch on the Legend EHS Console to the "I" position. A green indicator light will come on inside the power switch. Listen for beeps at start-up of console. The console digital display will show the default no-load speed setting of 70,000 rpm for the EHS motor or 60,000 rpm for the Stylus motor, in the forward direction.

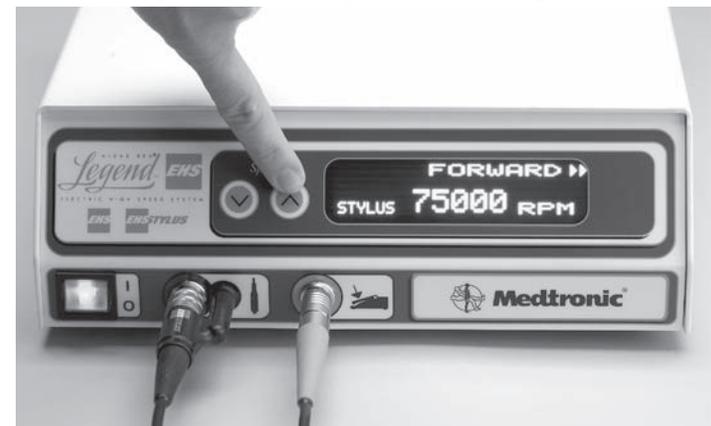


7. Operation of the Legend EHS Motors.

Activate the Legend EHS and Stylus Motors by depressing the foot pedal on the Legend EHS Foot Control.



To adjust the motor no-load speed setting, stop operation of the motor. Use the increase ^ or decrease v arrows on the Legend EHS Console to set desired speed. The no-load speed setting is the speed of the motor when it is operational, but not cutting bone. Once the cutting of bone begins, the speed will decrease depending on how aggressive a cut is being made.



NOTE The no-load speed setting of the motor may only be changed when the motor is not running and has come to a complete stop.

Duty Cycle (To avoid overheating): For continuous use in operating room temperatures up to 40°C (104°F), the **Legend EHS Motor** model **EM-100A** is rated for a cutting time of 3 minutes, model **EM100** is rated for 90 seconds, both at 70,000 rpm, and the **Stylus Motor** is rated for 3 minutes at 60,000 rpm, all followed by 25 minutes of rest.

For normal operating room temperatures (typically 20°C / 68°F) the **Legend EHS Motor** model **EM100-A** is rated for a continuous cutting time of 10 minutes and the model **EM100** is rated for 3 minutes, both followed by 25 minutes of rest. The **Legend Stylus Motor** is rated for continuous cutting indefinitely at 60,000 rpm.

The **Legend EHS Motor** model **EM100-A** is rated for intermittent use of 20 seconds ON / 20 seconds OFF, indefinitely at 70,000 rpm. The model **EM100** motor is rated 20 cycles of 20 seconds ON / 20 seconds OFF, followed by 25 minutes of rest.

NOTE

The surgeon should become familiar with the operational characteristics of each tool and attachment combination at various speeds prior to use.

WARNING

DO NOT use an attachment and dissecting tool combination if flail or vibration occurs.

8. Operation of Reverse Rotation.

To engage the reverse rotation feature of the Legend EHS and Stylus Motor, stop operation of the motor. Step one time on the reverse button located on the top of the foot control.



NOTE

Reverse rotation may only be selected when the motor is not running and has come to a complete stop.

In the reverse rotation mode, the Legend EHS Console's audible indicator will sound out three consecutive beeps to alert the operator each time the motor is operated in reverse. The "Forward" or "Reverse" direction will also be indicated on the console's digital display.



To return to forward rotation of the motor, stop the motor and step on the reverse button at the foot control. The console's digital display will indicate that forward rotation has been selected.

CAUTION

The motor must not be operating when changing speed or directional rotation of the motor.

Legend EHS Lock

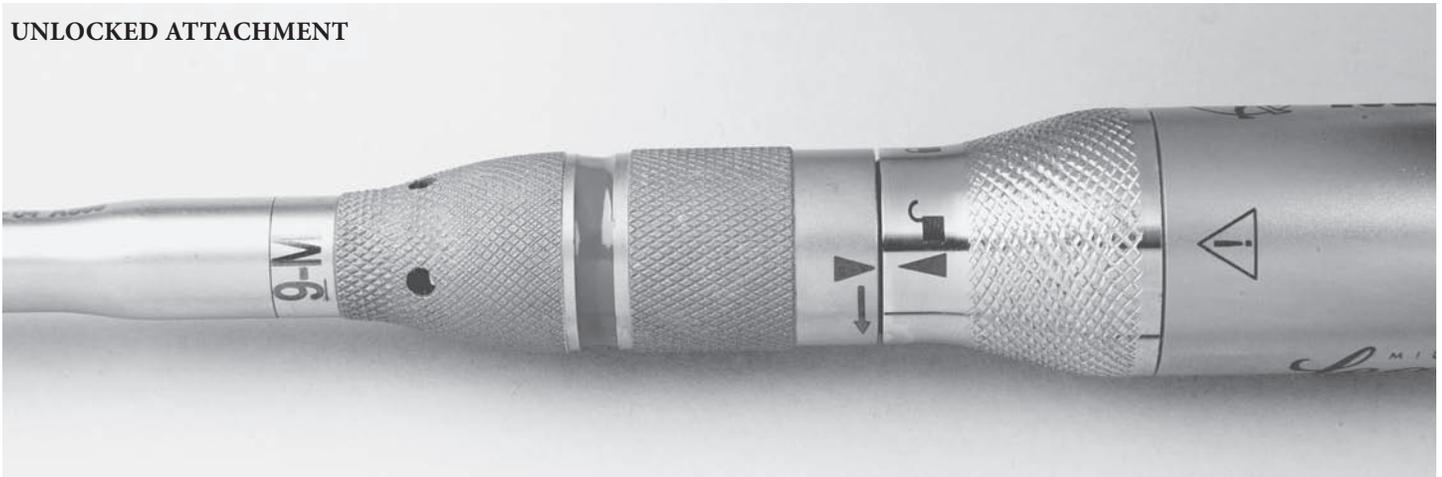
Legend EHS Motors should only be operated when the attachment is in the “” position on the motor.

LOCKED ATTACHMENT



Motor will operate.

UNLOCKED ATTACHMENT



Motor will not operate.

NOTE

- Verify that there is no accumulated bone debris inside the attachment before re-use during a surgery.
- Smoke may be generated if attachment is not in the “” position.

DISASSEMBLY OF EQUIPMENT

1. Turn off the power.

Turn power switch on the Legend EHS Console to the “O” position. Disconnect the Legend EHS Console Power Cord from the electrical source.

2. Disconnect Legend EHS Motor Cable from Legend EHS Console.

Push the cable sleeve towards the console, then grasp the motor cable connector by the locking ring and withdraw it from the console receptacle. Leave the cable connected to the EHS motor while cleaning. Before sterilization, the EHS motor should be disconnected from the cable.



3. Disconnect Legend EHS Foot Control Cable from the Legend EHS Console.

Push the cable sleeve towards the console, then grasp the foot control cable connector by the locking ring and withdraw it from the console receptacle. Leave the cable connected to the foot control while cleaning.



CAUTION

DO NOT attempt to disconnect cable from the Legend EHS Console, Foot Control or Motor by pulling on the cable. Always grasp the cable's connector at the locking ring.

DO NOT attempt to disconnect the cable from the Stylus motor.

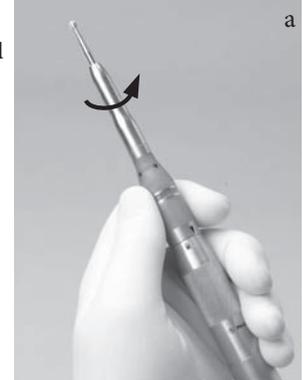
4. Removal of an Attachment and Dissecting Tool.

Straight attachment removal is listed below.

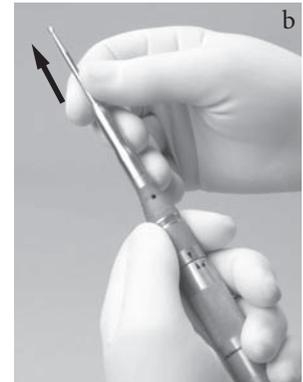
For more detailed information on the various attachment and dissecting tool removal procedures, refer to the Attachment and Dissecting Tool Section.

a. To remove a straight attachment, hold the motor in palm of hand.

Rotate attachment to the “” position.



b. Remove dissecting tool from the attachment and discard dissecting tool in an appropriate container.



c. Use thumb and index finger to lift attachment off motor.



WARNING

DO NOT re-use or re-process a dissecting tool that has already been used. Using a dissecting tool that has already been used may cause injury to the patient, operator and/or operating room staff. Using a dissecting tool that has already been used may affect motor performance and will void manufacturer's limited warranty.

STERILIZATION GUIDELINES

Legend EHS Motor

Warnings and Precautions	Do not soak/submerge Legend® devices. Do not use ultrasound to clean Legend® devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization.
Limitations	Verify functionality prior to re-use.

INSTRUCTIONS	
Point of Use	No particular requirements. Follow hospital procedures.
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.
Preparation for decontamination	No particular requirements. Follow hospital procedures.
Cleaning: Automated (Do NOT use ultrasonic washer)	Review the washer-disinfector warning above, before using this cleaning method. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. Recommended Washer/Disinfector Cycle Pre-Wash: 35°C, 5 min. Main Wash: 93°C, 30 min. Neutralize: 2 min. Final Rinse: 65°C, 10 min.
Cleaning: Manual	<ol style="list-style-type: none"> Wipe all external surfaces of the motor and cable with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0. Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent. Rinse motor thoroughly under running water, collet end pointed down. Dry collet and motor with lint free towel. Verify that devices are visually clean after manual cleaning. Rinse thoroughly with tap water.
Disinfection	No particular requirements. Follow hospital procedures.
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap

Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization:			
	Cycle:	Gravity	Pre-vac	Pre-vac*
	Temperature:	132°C	132°C	134°C
	Time:	25 min.	4 min.	3 min.
	Drying	15 minutes	15 minutes	10 minutes
*Items contaminated with TSE agents may be decontaminated using steam autoclave at a temperature of 134–137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles as referenced in NHS Estates HTM 2010 parts 4 & 6: Appendix 2, Items Contaminated With TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. Medtronic recommends that all products used on a patient suspected or confirmed with a TSE diagnosis be incinerated.				
STERRAD Sterilization: Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.				
100% EtO Sterilization Parameters: Preconditioning: 51-59°C, 70 ±5% relative humidity, 30 min. Temperature: 51-59°C Relative Humidity: 70 ±5% Ethylene oxide concentration: 725 ± 25mg/L Gas exposure time (full-cycle): 4 hours Aeration: 18 hours at 51-59°C				
Steris: Do not use liquid peracetic acid sterilization due to immersion procedure.				
Maintenance, Inspection and Testing	Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. Verify functionality prior to re-use.			
Storage	Store with other sterile devices.			

Legend Attachments / Tubes

Warnings and Precautions	<p>Do not soak/submerge Legend® devices. Do not use ultrasound to clean Legend® devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization. Do not steam or EO sterilize the Legend® attachment cleaning nozzle. Do not use Pana Spray on variable exposure attachments, as it may cause the attachment to overheat.</p>
Limitations	Verify functionality prior to re-use.

INSTRUCTIONS					
Point of Use	No particular requirements. Follow hospital procedures.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for decontamination	No particular requirements. Follow hospital procedures.				
Cleaning: Automated (Do NOT use ultrasonic washer)	<p>Review the washer-disinfector warning above, before using this cleaning method. Manually rinse devices under tap water, until no visible soil is noticed, before placing them into the automatic washer. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. After cleaning, lubricate attachments as in step 8 below.</p> <p>Recommended Washer Cycle</p> <p>Pre-Wash: Cold tap water, 2 min. Wash: 66°C, 5 min. using a neutral enzymatic detergent, pH 6.0-8.0 Rinse: Hot tap water, 1 min.</p>				
Cleaning: Manual	<ol style="list-style-type: none"> Wipe all attachments and telescoping tubes with a cloth, dampened with a surgical instrument cleaning solution. Immerse the head of Contra-Angle attachments in surgical instrument cleaning solution and run the motor for 1 minute. Other attachments and tubes may be mechanically agitated in cleaning solution, but not soaked or immersed. A nylon brush dampened with a surgical instrument cleaning solution may be used to clean the external surfaces and internal connecting surfaces of the attachments and tubes. Straight attachments, footed attachments and telescoping straight tubes have special cleaning brushes sized to the attachment's or telescoping tube's internal diameter. Push the brush wet with surgical instrument cleaning solution through the attachment or telescoping tube from rear to front to loosen and remove debris trapped inside. Move any moveable parts back and forth to allow solution to thoroughly clean attachment, e.g., sleeve on footed attachment, perforator attachment. Rinse thoroughly with tap water. Thoroughly dry attachments. An air gun may be used to blow moisture out from rear to front of attachment. Attach the Legend attachment cleaning nozzle to the recommended aerosol spray lubricant (Pana Spray®), and perform the following steps to lubricate attachments (except for variable exposure attachments): <ol style="list-style-type: none"> Attach the nozzle to the aerosol spray can and push the attachment onto the nozzle by aligning the arrows on the attachment and on the cleaning nozzle. Rotate the attachment slightly to ensure a tight fit. Cover the attachment with a paper towel. Spray in one 3-second squirt to remove debris and lubricate the attachment. Rotate the attachment back to the arrow on the nozzle and pull the attachment off of the nozzle. Clean the nozzle for re-use. 				
Disinfection	No particular requirements Follow hospital procedures.				
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization:				
	Cycle:	Gravity	Pre-vac	Pre-vac (FR/WHO)*	Pre-vac (UK)*
	Temperature:	132°C	132°C	134°C	134°C
	Time:	25 min.	4 min.	18 min.	3 min.
	Drying:	15 minutes	15 minutes	20 minutes	10 minutes
*Items contaminated with TSE agents may be decontaminated using steam autoclave at a temperature of 134–137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles as referenced in NHS Estates HTM 2010 parts 4 & 6: Appendix 2, Items Contaminated With TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. Medtronic recommends that all products used on a patient suspected or confirmed with a TSE diagnosis be incinerated.					

Sterilization (Temperatures are minimum required, times are minimum required)	STERRAD Sterilization: Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.
	100% EtO Sterilization Parameters: Preconditioning: 51-59°C, 70 ±5% relative humidity, 30 min. Temperature: 51-59°C Relative Humidity: 70 ±5% Ethylene oxide concentration: 725 ± 25mg/L Gas exposure time (full-cycle): 4 hours Aeration: 18 hours at 51-59°C
	Steris: Do not use liquid peracetic acid sterilization due to immersion procedure.
Maintenance, Inspection and Testing	Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. Verify functionality prior to re-use.
Storage	Store with other sterile devices.

NOTE

The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process.

Transmissible Spongiform Encephalopathies (TSE) Return Policy

Medtronic Powered Surgical Solutions (MPSS) will not authorize or accept the return of MPSS products that directly contact patients or is contaminated with a patient's body fluids who is suspected or confirmed with a Transmissible Spongiform Encephalopathies / Creutzfeldt-Jakob Disease (TSE/CJD) diagnosis. Furthermore, MPSS recommends that all Medtronic PSS products used on a patient confirmed with a TSE diagnosis be incinerated. Contact your Sales Representative for replacement of product incinerated under this policy or for temporary equipment while original equipment is quarantined. Contact MPSS Regulatory Affairs Department for additional information regarding TSE contamination. MPSS dissecting tools used on a patient suspected of a TSE/CJ diagnosis must be incinerated.

If TSE/CJD is excluded as a diagnosis, the quarantined reusable equipment may be returned for use after appropriate cleaning, decontamination and sterilization. Hospital personnel should contact their infection control personnel for current procedures and policy for reusable equipment processing when suspect of contamination with Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathies (TSE).

Reusable devices that have been used on patients with suspected Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathies (TSE) should be quarantined and not reused until diagnosis is confirmed or excluded. Reusable devices should be quarantined after having been cleaned, decontaminated, sterilized and packed in a ridged sealed container until final diagnosis.

NOTE Only Legend Attachments and Dissecting Tools should be used with the Legend EHS System. Installation and removal of attachments and tools is identical for all Legend Motors. The following instructions demonstrate Legend Attachment installation and removal on a Legend Gold Motor.

Straight Attachments

To Install:

1. Slide straight attachment over motor collet aligning triangular arrows on the attachment and motor case. A tactile and audible click will be observed when the attachment is fully seated.



NOTE

A Legend Attachment will not seat on a Legend EHS Motor if the arrows on the collet flats are not in alignment.

2. Insert a dissecting tool into the attachment with a slight rotational motion. A tactile and audible click is observed indicating that the tool is fully seated.



CAUTION

Match the nomenclature and color code on the Legend Dissecting Tool packaging to the same nomenclature and color code on the Legend Attachment.

3. Rotate attachment to the “” position on the motor case. Gently pull on dissecting tool shaft to ensure proper installation.

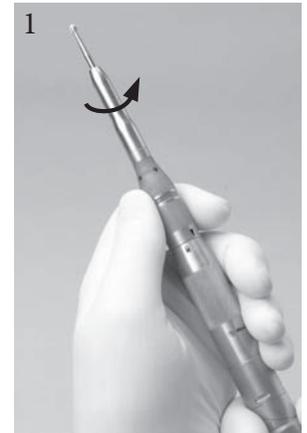


NOTE

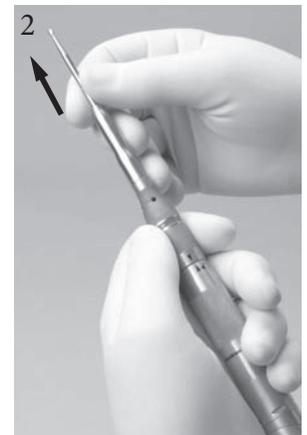
The Legend EHS Motors will not run properly unless the attachment is in the “” position. Smoke may be generated if attachment is not in the locked “” position.

To Remove:

1. Hold the motor in palm of hand. Rotate attachment to the “” position.



2. Remove dissecting tool from the attachment and discard dissecting tool.



3. Use thumb and index finger to lift attachment off of motor.



Angled Attachments

To Install:

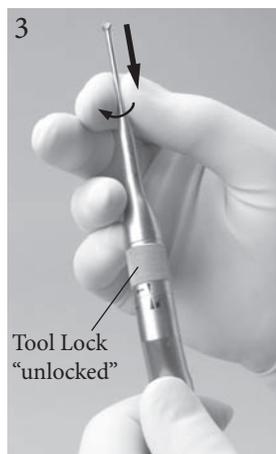
1. Slide the angled attachment over motor collet aligning triangular arrows on attachment and motor case. A tactile and audible click will be observed when attachment is fully seated.



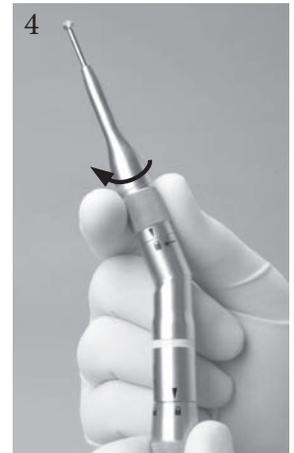
2. Rotate attachment to “” position on motor case.



3. With “Tool Lock” in the “” position, insert dissecting tool into angled attachment with a slight rotational motion. A tactile and audible click is observed indicating that the tool is fully seated.



4. Rotate Tool Lock to the “” position. Gently pull on dissecting tool shaft to ensure proper installation.



NOTE

A dissecting tool may be installed and locked in the attachment before the angled attachment is installed onto the motor.

Angled and straight attachments with the same length, marking and color band share the same dissecting tools.

The Legend EHS Motors will not run properly unless the attachment is in the “” position.

Smoke may be generated if attachment is not in the “” position.

To Remove:

Rotate the Tool Lock to the “” position to remove the dissecting tool from the attachment. Rotate the attachment to the “” position and lift attachment off of the motor.

CAUTION

When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece.

Variable Exposure Attachments

CAUTION

The Legend® Variable Exposure attachments can be distinguished from standard attachments by the dual color bands on the attachment. Match the color band on the attachment to the color code on the dissecting tool packaging.

WARNING

Surgeons should familiarize themselves with the performance of dissecting tools before use, and should explore the effect of various levels of tool exposure on dissection stability. If the tool exhibits excessive chatter, vibration, or movement, decrease the tool exposure.

Dissecting tool size and geometry may contribute to excessive vibration at certain speeds. Increase or decrease speed by adjusting the foot/finger control, or by changing the operating pressure or console speed setting. If necessary, use a different dissecting tool.

To Install:

1. Refer to the appropriate section of this manual on installing fixed or angled attachments.
2. After installation, use the TUBE adjustment ring to adjust the exposure of the dissecting tool. With the tool pointing away from you, turn the ring to the right to increase the length of the tube, thereby decreasing the exposure of the tool. Turn the ring to the left to decrease the length of the tube, thereby increasing the exposure of the tool.

WARNING

Do not use the Variable Exposure Attachment if the TUBE adjustment ring spins freely or fails to click into place with each adjustment, as the exposure may change without warning.

CAUTION

Make sure that the tool lock (angled attachments only) and the attachment lock are still in the  position after each adjustment of the tool exposure. Attempting to increase the exposure too far may result in the attachment becoming unlocked. Accidentally turning the tool lock may result in reduced speed and/or overheating of the attachment.

WARNING

Do not use the end of the tube as a depth gauge or depth stop.

To Remove:

1. Removal is the reverse of installation.
2. When cleaning, clean the attachment completely, first without adjusting the tube length, then with the tube fully extended, and with the tube fully retracted.



Rotating Footed Attachments

NOTE

Rotating and fixed footed attachments with the same length, marking, and color band share the same dissecting tools.

To Install:

1. Insert the dissecting tool into the motor collet with a slight rotational motion. You will feel and hear the tool click into place when it is fully seated.
2. Slide the attachment over the dissecting tool and onto the motor, aligning the triangular markers. You will feel and hear the attachment click into place when it is fully seated.
3. Turn the attachment to the  position.

NOTE

The footed end of the attachment now has 360° of unrestricted rotation.

To Remove:

Removal is the reverse of installation.



Footed Attachments

Footed Attachments:	USE ONLY the following Dissecting Tools:	Reference to Classic:
F1-B5	F1/8TA15 F1/8TA15S	B- 5 22S2CR (Mednext)
F2-B1	F2/8TA23 F2/8TA23S	B-1 B-1SP
F3-S	F3/9TA30	S-1

WARNING

DO NOT use a Legend Attachment if any part of the attachment appears to be bent, loose, missing or damaged. Excessive pressure or improper handling, such as bending or prying, with the attachment or dissecting tool may cause injury to patient, operator and/or operating room staff. If a Legend Attachment requires servicing or refurbishing, return attachment to Medtronic Powered Surgical Solutions.

To Install:

1. Insert a dissecting tool into the motor collet with a slight rotational motion. A tactile and audible click is observed indicating that the dissecting tool is fully seated.



2. Slide footed attachment over dissecting tool onto motor aligning triangular arrows on attachment and motor case.



3. Pull footed attachment towards motor and rotate attachment to the "lock" position on motor case.



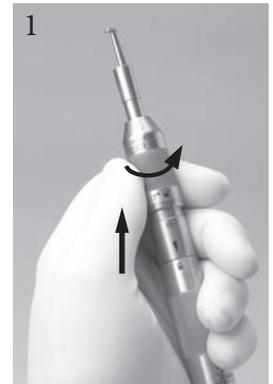
NOTE

Legend footed attachments have a unique feature of actuating a distal moving sleeve to remove the attachment. This will prevent accidental disengagement of attachment from motor during use.

The Legend EHS Motors will not run properly unless the attachment is in the "lock" position.

To Remove:

1. To remove Legend Footed Attachment, hold motor in palm of hand. Push sleeve on footed attachment distally while rotating attachment to the "unlock" position on the motor case. Release sleeve.



2. To avoid injury from the dissecting tool, use thumb and index finger to cautiously and slowly lift attachment off of motor and away from the dissecting tool.



3. Pull dissecting tool out of motor collet and discard tool.



WARNING

Remove Legend Footed Attachments cautiously and slowly to avoid injury to the operator.

Contra-Angle Attachment 16-MF Operating Speed: 62,000 rpm

CAUTION

DO NOT run the 16-MF attachment with operating speed above 62,000 rpm. This may cause over-heating and damage to internal gears of attachment.

To Install:

1. Adjust the no-load speed setting to 62,000 rpm using the speed control buttons on the Legend EHS console.



2. Slide Contra-Angle Attachment over motor collet aligning triangular arrows on attachment and motor case. A tactile and audible click will be observed when attachment is fully seated.



3. Rotate attachment to the “” position on the motor case.

4. Rotate attachment head's lever laterally to open position. Insert dissecting tool and return lever to closed position. Gently pull on dissecting tool shaft to ensure proper installation.



Lateral View



Lever Open



Lever Closed

NOTE

A dissecting tool may be installed and locked in the attachment before the Contra-Angle attachment is installed on the motor.

The Legend EHS Motors will not run properly unless the attachment is in the “” position.

To Remove:

Rotate lever on attachment head laterally to remove the dissecting tool. Discard dissecting tool. Rotate the 16-MF attachment to the “” position and lift attachment off of the motor.

Metal Cutting Attachment

The Metal Cutting Attachment uses the tungsten carbide or diamond wheel dissecting tools. All metal cutting dissecting tools have an “MC” attachment prefix in their nomenclature, e.g., MC254, MC30.

Metal cutting dissecting tools cannot be installed into any other Legend Attachment.

WARNING

DO NOT use metal cutting dissecting tools on bone.

For metal transection, observe the following Safety Precautions:

- Eyewear protection is essential.
- Irrigate copiously to cool the cutting surfaces.
- Protect the wound site from metal debris.
- Use clamp or grasping device to control loose fragments during transection of any metal component.

To Install:

1. Slide Metal Cutting Attachment over motor collet aligning triangular markers on attachment and motor case. A tactile and audible click will be observed when attachment is fully seated.

Rotate attachment to the “” position on the motor case.



2. With tool lock unscrewed several turns and holding the attachment UPRIGHT, insert dissecting tool into attachment. Rotate dissecting tool until it drops into position and is fully seated. A tactile click is observed indicating that the tool is fully seated.



3. Firmly and completely tighten the tool lock. Pull on the tool shaft to ensure that it is properly installed.



NOTE

The Legend EHS Motors will not run properly unless the attachment is in the “” position.

To Remove:

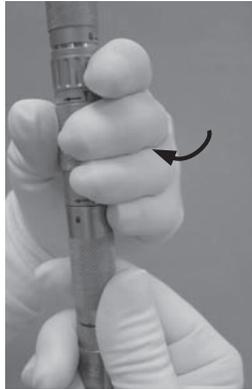
1. Unscrew the tool lock with several turns, then withdraw the dissecting tool.
2. Rotate attachment to the “” position on the motor case and lift attachment off of the motor.

Telescoping Attachment

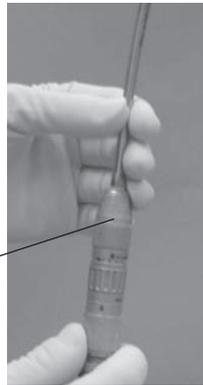
To Install:

1. Slide Telescoping Attachment over motor collet aligning triangular arrows on attachment and motor case. A tactile and audible click will be observed when attachment is fully seated.

Rotate attachment to the “” position on motor case.



2. Rotate TUBE Locking Ring towards “” by turning counterclockwise. Insert base end of selected telescoping tube into attachment. To lock tube in place, turn the TUBE Locking Ring clockwise until finger tight.



NOTE

DO NOT over tighten.

TUBE Locking Ring

3. Be sure that the TOOL Locking Ring is in the “” position. Insert the dissecting tool into the telescoping tube. Tactile feedback is felt when the dissecting tool is fully seated. Turn the TOOL Locking Ring to the “” position. Verify that the tool is in place by gently pulling on the tool.



TOOL Locking Ring

4. If tube position needs to be changed, rotate TUBE Locking Ring towards “”; re-position tube, then rotate TUBE Locking Ring towards “”. Gently pull on dissecting tool, then the tube, to ensure proper installation.



NOTE

A dissecting tool may be installed and locked in the attachment before the telescoping attachment is installed on the motor.

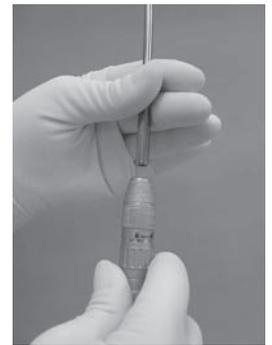
Curved and straight telescoping tubes with the same length, marking and color band share the same dissecting tools.

Telescoping tubes are disposable following multiple uses and should be discarded when heat, excessive vibration is noticed, or when insertion of the tool becomes difficult.

The Legend EHS Motors will not run properly unless the attachment is in the “” position.

To Remove:

1. Rotate the TUBE Locking Ring towards “”.
2. Rotate the TOOL Locking Ring to the “” position.
3. Pull telescoping tube out of attachment.
4. Rotate the attachment to the “” position on the motor case and lift attachment off of motor.



 **WARNING**

Dissecting tool flutes are sharp and may perforate surgical gloves. Dissecting tools for the Telescoping Attachment may be grasped with a hemostat to aid in installation and removal.

Perforator Attachments (AD01 & AD03)

The Perforator Attachment has a Hudson chuck to drive any device with a Hudson shank, i.e., cranial perforator device.

Maximum Speed		
EHS Console Setting	AD01 Output Speed (max)	AD03 Output Speed (max)
60,000 rpm	645 rpm	830 rpm
70,000 rpm	745 rpm	965 rpm
72,000 rpm	770 rpm	995 rpm
74,000 rpm	790 rpm	1020 rpm
75,000 rpm	805 rpm	1035 rpm

To Install:

- Slide Perforator Attachment over motor collet aligning triangular arrows on attachment and motor case. A tactile and audible click will be observed when Perforator Attachment is fully seated.



- Rotate Perforator Attachment to the “” position on the motor case.



- To install a cranial perforator device with a Hudson shank, pull back proximally on the collar of the Perforator Attachment. Insert device and release collar to its original position.



NOTE

Cranial perforator device may be installed in the attachment before the perforator attachment is installed on the motor.

Medtronic Powered Surgical Solutions does not provide cranial perforator devices.

The Legend EHS Motors will not run properly unless the attachment is in the “” position, or when the insertion of the tool becomes difficult.

To Remove:

Pull back proximally on the collar of the Perforator Attachment to remove cranial perforator device. Rotate the Perforator Attachment to the “” position and lift attachment off of the motor.

WARNING

CONSULT the cranial perforator device labeling for the recommended speed specifications.

Jacobs® Chuck Attachment

The Jacobs Chuck Attachment is a non-cannulated 5/32" chuck with key for drilling.

To Install:

1. Slide Jacobs Chuck Attachment over motor collet aligning triangular arrows on attachment and motor case. A tactile and audible click will be observed when Jacobs Chuck Attachment is fully seated.



2. Rotate Jacobs Chuck Attachment to the "🔒" position on the motor case.



3. To install a drill bit, turn Jacobs key to open ridged collar. Insert drill bit and tighten collar with key.



NOTE

A drill bit may be installed in the attachment before the Jacobs Chuck attachment is installed on the motor.

Medtronic Powered Surgical Solutions does not provide drill bits.

The Legend EHS Motors will not run properly unless the attachment is in the "🔒" position, or when the insertion of the tool becomes difficult.

To Remove:

Use Jacobs key to open collar. Remove and discard drill bit in an appropriate container. Rotate the Jacobs Chuck Attachment to the "🔓" position and lift attachment off of the motor.

Contact your Medtronic Neurologic Technologies sales representative, or call:

Medtronic Powered Surgical Solutions Technical Services:

8 a.m. to 6 p.m. (Central Standard Time)

Telephone: 800-643-2773 or 817-788-6400

Outside the U.S.A., contact your Medtronic Regional Distributor or Medtronic Neurological Sales Representative.

NO LATEX POLICY:

Medtronic Powered Surgical Solutions guarantees that all Legend equipment and products identified in this manual manufactured by and/or for Medtronic Powered Surgical Solutions do not contain latex.

Medtronic Powered Surgical Solutions' packaging materials, labels, pouches, package inserts or similar items do not contain latex.

LEGEND EHS SYSTEM CLASSIFICATION AND RATING:

The Legend EHS System is classified for electrical safety as Class I, requiring connection to a reliable power source that has a protective ground circuit. Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital only" or "Hospital Grade."

The Legend EHS Motors are rated as type BF Non-Cardiac Floating, Applied Part.

The Legend EHS Motors are NOT immersible.

The Legend EHS Foot Control is rated IPX8, Submersible.

The Legend EHS Console is rated IPX1, Drip-proof.

The Legend EHS System is not suitable for use in the presence of flammable anesthetics.

The Legend EHS System is supplied with 2 fuses in the power entry module. The fuses should be replaced with fuses of the same type and rating as indicated on the rear panel fuse label. The fuses should be replaced only by customer appointed technical personnel.

SOFTWARE LICENSE NOTICE

MIDAS REX LEGEND EHS High Speed System products contain software that is installed in the products by Medtronic Powered Surgical Solutions. Medtronic Powered Surgical Solutions owns this software; this software is never sold.

Each sale of a software-containing product is not a sale of such software; it includes only a license to use the software in the product in which the software was initially installed.

Any license granted by Medtronic Powered Surgical Solutions to use the software contained in its products does not give the licensee the right to copy, alter, disassemble, reverse engineer, create derivative works of such software or to use such software in either original or modified form in any product other than the Medtronic Powered Surgical Solutions product in which the software was initially installed by Medtronic Powered Surgical Solutions.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Legend EHS Electric High Speed System is intended for use in the electromagnetic environment specified below. The customer or the user of the Legend EHS Electric High Speed System should assure that it is used in such an environment.		
Emissions Test 1	Compliance Level	Electromagnetic Environment – Guidance
RF Emissions CISPR 1	Group 1	The Legend EHS Electric High Speed System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	
Harmonic Distortion IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

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 and/or cables.
- Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- Consult the manufacturer or field service technician for help.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Legend EHS Electric High Speed System is intended for use in the electromagnetic environment specified below. The customer or the user of the Legend EHS Electric High Speed System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5GHz	3 V (V ₁) 3 V/m (E ₁)	Portable and mobile RF communications equipment should be used no closer to any part of the Legend EHS Electric High Speed System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ 150 kHz to 80 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 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, 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:
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input/Output Lines	±2 kV for Power Supply Lines ±1 kV for Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common Mode	±1 kV Differential ±2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Power Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% U _T (>95% Dip in U _T) for 0.5 Cycle 40% U _T (60% Dip in U _T) for 5 Cycles 70% U _T (30% Dip in U _T) for 25 Cycles <5% U _T (>95% Dip in U _T) for 5 Seconds	<5% U _T (>95% Dip in U _T) for 0.5 Cycle 40% U _T (60% Dip in U _T) for 5 Cycles 70% U _T (30% Dip in U _T) for 25 Cycles <5% U _T (>95% Dip in U _T) for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Legend EHS Electric High Speed System requires continued operation during power mains interruptions, it is recommended that the Legend EHS Electric High Speed System be powered from an uninterruptible power supply or battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

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

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

a Field strengths from fixed transmitters, 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 Legend EHS Electric High Speed System is used, exceeds the applicable RF compliance level above, the Legend EHS Electric High Speed System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Legend EHS Electric High Speed System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V₁] V/m.

LEGEND EHS SYSTEM TROUBLESHOOTING

If Legend components require servicing or refurbishing, return components to Medtronic Powered Surgical Solutions for quality assured service by factory-trained personnel who will utilize genuine MIDAS REX LEGEND parts as required.

All Legend EHS motors, motor cables, and attachments returned for servicing or refurbishing should be properly cleaned and sterilized prior to shipping according to the directions provided in the Instruction Manual.

PROBLEM	POSSIBLE CAUSE	RECOMMENDATIONS
LEGEND EHS CONSOLE		
Console power switch is in the ON "I" position, but is not lighted. The display is blank and no beeps are heard.	<p>Power cord not properly connected or power source not providing correct power</p> <p>One or both fuses blown</p> <p>Internal failure of console</p>	<p>Ensure that console is connected to a reliable power supply.</p> <p>If blown fuse(s) are suspected, the fuses should only be replaced with fuses of the same type and rating as indicated on the rear panel fuse label by customer appointed technical personnel.</p> <p>Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p>
Console power switch is in the ON "I" position, but green light on power switch is not lighted	Front panel switch indicator failure	Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Console starts up but no beep is heard	Internal failure of console	Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Console power switch is in the ON "I" position, but some or all of front panel buttons are not working	Internal failure of console	Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Characters in the digital display not visible, faint or intermittent	Internal component of console failed	Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Console displays wrong handpiece / motor type.	Console misidentified the handpiece / motor.	<p>Disconnect and reconnect the motor cable. Turn Console Off then On. Change motor, motor cable, or console to isolate the problem.</p> <p>Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p>

LEGEND SYSTEM TROUBLESHOOTING *(continued)*

PROBLEM	POSSIBLE CAUSE	RECOMMENDATIONS
LEGEND EHS MOTORS		
Motor does not run or is low on power	<p>Cables not properly connected</p> <p>Operating power supply inadequate</p> <p>Attachment not properly installed and locked onto the motor (possible smoking condition)</p> <p>One or both fuses blown</p> <p>Internal failure of console and/or motor</p> <p>Foot control not properly functioning</p> <p>Cables Damaged</p>	<p>Check all connections from electrical source to console. Ensure motor and foot control cables are properly connected at both ends.</p> <p>Ensure that a speed greater than 10,000 rpm (EHS) or 3,000 rpm (Stylus) is selected on the digital display.</p> <p>Remove and re-install attachment and dissecting tool to ensure proper installation and locking of attachment onto motor.</p> <p>If blown fuse(s) are suspected, the fuses should only be replaced with fuses of the same type and rating as indicated on the rear panel fuse label by customer appointed technical personnel.</p> <p>Change motor or console to isolate location of problem. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Check for obstruction under foot pedal. If foot control continues not to function properly, Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Check cables for cracks, splits or bent connector pins.</p>
Motor is missing a component or a component has detached from the motor.	Motor failed	DO NOT use. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Motor rotates, but an abnormal noise is heard	<p>Bearings of motor or attachment are worn</p> <p>Poor connection of motor with console</p> <p>Motor, motor cable or console failed</p> <p>Attachment not in proper locked position</p>	<p>Change attachment to isolate location of problem to the attachment or motor. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Check all connections from electrical source to console. Ensure motor and foot control cables are properly connected at both ends.</p> <p>Change motor, motor cable or console to isolate location of problem. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>See instructions for proper locking of attachments.</p>

LEGEND SYSTEM TROUBLESHOOTING *(continued)*

PROBLEM	POSSIBLE CAUSE	RECOMMENDATIONS
LEGEND EHS MOTORS <i>(continued)</i>		
<p>Motor is heating to an uncomfortable temperature to touch/hold</p>	<p>Inadequate "cool down" period following sterilization</p> <p>Attachment transferring heat to motor</p> <p>Heavy side loading during dissection</p> <p>Inadequate irrigation</p>	<p>Handpiece must be allowed to cool down following steam sterilization. If Handpiece continues to overheat, contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Change attachment to isolate location of problem to the attachment or Handpiece. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Duty Cycle (To avoid overheating): For continuous use in operating room temperatures up to 40°C (104°F), the Legend EHS Motor model EM-100A is rated for a cutting time of 3 minutes, model EM100 is rated for 90 seconds, both at 70,000 rpm, and the Stylus Motor is rated for 3 minutes at 60,000 rpm, all followed by 25 minutes of rest. For normal operating room temperatures (typically 20°C / 68°F) the Legend EHS Motor model EM100-A is rated for a continuous cutting time of 10 minutes and the model EM100 is rated for 3 minutes, both followed by 25 minutes of rest. The Stylus Motor is rated for continuous cutting indefinitely at 60,000 rpm. The Legend EHS Motor model EM100-A is rated for intermittent use of 20 seconds ON / 20 seconds OFF, indefinitely at 70,000 rpm. The model EM100 motor is rated 20 cycles of 20 seconds ON / 20 seconds OFF, followed by 25 minutes of rest.</p> <p>Ensure adequate irrigation to surgical site during bone dissection.</p>
<p>Motor/collet displays excessive rust.</p>	<p>Incorrect cleaning or sterilization method</p> <p>Use of chlorine based or corrosive agents</p> <p>Aging</p>	<p>Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p>

LEGEND SYSTEM TROUBLESHOOTING *(continued)*

PROBLEM	POSSIBLE CAUSE	RECOMMENDATIONS
LEGEND ATTACHMENTS or TELESCOPING TUBES		
Attachment or Telescoping Tube has uncomfortable temperature to touch/hold	<p>Heat from worn attachment/tube bearings</p> <p>Attachment/tube unclean due to improper cleaning procedures</p> <p>Heavy side loading during dissection</p>	<p>DO NOT use. Try another attachment/tube. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Telescoping Tubes are multi-use disposable. If problem is resolved with a new Telescoping Tube, discard the over-heated tube.</p> <p>Check that appropriate cleaning procedures are being followed.</p> <p>Discontinue use and rest the attachment by using intermittently, try another identical attachment or wrap the attachment interface with a moist sterile towel. If attachment continues to overheat, Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p>
Attachment/telescoping tube is bent, loose, damaged or missing a component	<p>Attachment mishandled, failed due to extended use or excessive force applied during use</p>	<p>DO NOT use. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Dispose of telescoping tube. Telescoping Tubes are multi-use disposable.</p>
Color band on Attachment/Telescoping Tube fades or discolors	<p>Incorrect cleaning or sterilization method</p> <p>Use of chlorine based or corrosive agents</p> <p>Aging</p>	<p>Use nomenclature markings on the attachment to match with a corresponding dissecting tool or Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Telescoping Tubes are multi-use disposable.</p>
Attachment/Telescoping Tube displays excessive rust	<p>Incorrect cleaning or sterilization method</p> <p>Use of chlorine based or corrosive agents</p> <p>Aging</p>	<p>DO NOT use. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.</p> <p>Dispose of telescoping tube.</p> <p>Telescoping Tubes are multi-use disposable.</p>
Attachment will not properly seat on motor	<p>Motor collet flats are not in proper alignment</p>	<p>Use Legend Motor Wrench to rotate the flat closest to the motor case until its arrow is aligned with the arrow on the flat farthest away from the motor case.</p>

LEGEND SYSTEM TROUBLESHOOTING *(continued)*

PROBLEM	POSSIBLE CAUSE	RECOMMENDATIONS
LEGEND ATTACHMENTS or TELESCOPING TUBES <i>(continued)</i>		
Attachment has excess lubrication	Over lubrication during cleaning process	Visually inspect and wipe excess lubrication.
Difficulty removing tool from attachment	Aging of attachment Improper cleaning Use of re-processed tools Use of unauthorized re-furbisher	Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Footed attachment has a component missing from leg/foot area or foot is bent	Attachment damaged by dissecting tool drilling out part or all of leg/foot area. Bend caused by incorrect use.	DO NOT use. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Overheating of 16-MF Contra-Angle Attachment	Contra-Angle attachment operates by a set of internal gears to engage the drive shaft. It is normal for some heat to be generated approximately 2 cm from the distal end of the attachment and at the right angle head.	Verify no-load speed setting is no higher than 62,000 rpm. DO NOT use if heat continues or is excessive. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions.
Perforator running too slow or too fast	Speed set incorrectly or not set according to perforator Instructions for Use.	Verify that the no-load speed setting is set correctly. Refer to Speed Chart on Page 30.
LEGEND DISSECTING TOOLS		
Dissecting Tool flails	Device other than Legend Dissecting Tool used Worn attachment/tube bearings Attachment/tube and tool combination improper If proper attachment/tube and tool combination is being used, motor may be damaged Dissecting tool's size and geometry may create flailing at certain speeds	DO NOT use. Replace with a Legend Dissecting Tool. DO NOT use. Try another attachment/tube to isolate location of problem. If flail is produced by a specific attachment, then Contact Medtronic Powered Surgical Solutions Repair Services for return instructions. Dispose of the telescoping tube. Telescoping tubes are multi-use disposable. DO NOT use. Check for the correct nomenclature and color code on the dissecting tool packaging to the same nomenclature and color code on the attachment/tube. Increase or decrease speed on console. DO NOT use if flailing persists. Change to a new dissecting tool.

LEGEND SYSTEM TROUBLESHOOTING *(continued)*

PROBLEM	POSSIBLE CAUSE	RECOMMENDATIONS
LEGEND DISSECTING TOOLS <i>(continued)</i>		
Excessive vibration	Dissecting tool's size and geometry may create excessive vibration at certain speeds.	Increase or decrease speed setting on console. Change to a new dissecting tool. If problem continues, contact MPSS Customer Service
Dissecting tool sterile packaging damaged. Tool outside the tube or tube opened.	Shipping damage - dissecting tool is no longer sterile. Storage Damage - dissecting tool is no longer sterile.	Do not use, contact Medtronic Powered Surgical Solutions Customer Service or Sales Representative.
Dissecting tool sterile packaging opened, tool not used or contaminated	Dissecting tool not used during surgical procedure - Dissecting tool no longer sterile	See instruction for re-processing tools under Sterilization guidelines section.
Expired shelf life	Old product - Dissecting tool may no longer be sterile.	Do not use, contact Medtronic Powered Surgical Solutions Customer Service or Sales Representative.
Dissecting tool fractures or breaks	Excessive pressure Reprocessed tool Tool Failure	Remove all tool debris from patient. Check if reprocessed tool was used. Contact MPSS Customer Service or Sales Representative
Dissecting tool dull	Extended use Reprocessed tool Incorrect geometry	Change to a new tool Check if reprocessed tool was used Contact MPSS Customer Service or Sales Representative
Dissecting tool rusts	Incorrect storage Reprocessed unused dissecting tool	DO NOT use; Contact Medtronic Powered Surgical Solutions Repair Services for return instructions. DO NOT re-use or re-process a used dissecting tool.
Dissecting tool will not seat properly in motor collet or angled attachment collet	Debris in collet of angled attachment or motor Device other than Legend Dissecting Tool being used	Clean angled attachment or motor thoroughly per instructions. If cleaning does not correct the problem, DO NOT use. Contact Medtronic Powered Surgical Solutions Repair Services for return instructions. DO NOT use. Replace with a Legend Dissecting Tool.

Legend EHS Console Error Codes

Note: All errors are signalled by an audible beep.

DISPLAYED ERROR MESSAGE	ACTION
<p>Blank screen with continuous beep</p>  <p>(MEMORY ERROR)</p>	<p>Power off console. Power on console. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>COHERENCE ERROR </p>	<p>Power off console. Power on console. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>STACK FULL </p>	<p>Power off console. Power on console. If problem is not solved, contact Medtronic Powered Surgical Solutions Technical Support.</p>
<p>BRIDGE OUT </p>	<p>Power off console. Power on console. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>TOO MUCH POW </p>	<p>Power off console. Power on console. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>ERROR 1 CHECK MOTOR CONNECTION </p>	<p>Display may show ERROR 1, 2, or 3. Occasionally if motor is re-started during the braking phase, this error may occur. Let motor come to a complete stop. Press the foot pedal to re-start the motor. If motor does not re-start, release foot pedal. Disconnect and reconnect the motor cable at the motor and the console. Try another motor cable and/or motor if available. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>HANDPIECE NOT RECOGNIZED </p>	<p>Ensure that an attachment is installed and in the locked position on the handpiece. Disconnect and reconnect the handpiece cable at the Handpiece (EHS only) and the Console. If the problem is not solved, try another Handpiece, Cable and/or Console if available. If problem is not solved, power off the Console and call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>CHECK TOOL CONNECTION </p>	<p>Release foot pedal. Power off console. Unlock the attachment. Remove and re-seat the tool. Lock the attachment and ensure that the tool is locked into position and can turn freely. Power on console. If problem is not solved, disconnect and reconnect the motor cable at the motor and the console. If problem is not solved, try another motor cable and/or motor if available. If problem is not solved call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>NO MOTOR </p>	<p>Release foot pedal. Disconnect and reconnect the motor cable at the motor and the console. If problem is not solved, try another motor cable and/or motor if available. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>CHECK PEDAL CONNECTION </p>	<p>Release foot pedal. Disconnect and reconnect the foot pedal cable at the foot pedal and the console. If problem is not solved, try another foot pedal cable and/or foot pedal if available. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>
<p>CALIBRATION ERROR </p>	<p>Power off Console. Power on Console. If problem is not solved, call Medtronic Powered Surgical Solutions Technical Support.</p>

REFURBISHING OR REPAIRS

When the MIDAS REX LEGEND EHS System requires servicing or refurbishing, contact Medtronic Powered Surgical Solutions Repair Services for a return authorization and instructions for returning the equipment to Medtronic Powered Surgical Solutions, Fort Worth, Texas. Medtronic Powered Surgical Solutions provides quality assured service by factory-trained personnel who will utilize genuine Midas Rex Legend parts as required.

Contact:

Medtronic Powered Surgical Solutions Repair Services:

(800) 335-9557 or (817) 788-6440

mmrcustomerservice@medtronic.com

Peak performance, reliability and maximum service life from your MIDAS REX LEGEND System may be assured by using only those MIDAS REX LEGEND products for your MIDAS REX LEGEND System that are manufactured by and sold through Medtronic Powered Surgical Solutions, Fort Worth, Texas. While Medtronic Powered Surgical Solutions guarantees complete compatibility among its products within a specific product line, the dissecting tools are designed for single-use only, and Medtronic disclaims any responsibility when reprocessed dissecting tools are used. If you would like more information about the patient and product risks associated with reprocessed tools, please contact the numbers listed above.

Due to safety and environmental concerns, Medtronic Powered Surgical Solutions requests the return of EHS motors and consoles for proper disposal at the end of product life cycles.

LEGEND HAS EHS PREVENTIVE MAINTENANCE/SERVICE PROGRAM

The MIDAS REX LEGEND EHS System Preventive Maintenance Manual has been developed to assist the customers in getting the greatest ownership value from your MIDAS REX LEGEND EHS System, while helping to maximize its performance, safety and reliability. The scheduled preventive maintenance/service program is in addition to the required routine cleaning after each use. Please refer to the preventive maintenance manual for the specific steps necessary to maintain your MIDAS REX LEGEND EHS System.

MANUFACTURER'S RECOMMENDATION

It is strongly recommended that surgeons, operating room personnel, and service personnel become thoroughly familiar with all MIDAS REX LEGEND Systems prior to use in surgery. To assist in this effort, Medtronic Powered Surgical Solutions offers several Hands-On Workshops. Contact your Medtronic Neurologic Technologies Sales Representative or your Medtronic Regional Distributor for schedules.

MEDTRONIC POWERED SURGICAL SOLUTIONS MIDAS REX LEGEND EHS SYSTEM LIMITED WARRANTY* (U.S. CUSTOMERS ONLY)

- A. This Limited Warranty provides the following assurance to the purchaser who receives a Medtronic Midas Rex Legend EHS System. The Midas Rex Legend EHS System includes the motor, console, foot control and their cables (motor, console, and foot control) and instrumentation cases and trays (hereafter referred to as Motor Components), the attachments, dissecting tools and other accessories not listed above and telescoping tubes (hereafter referred to as Accessory Components) and jointly referred to as Legend EHS System, unless specifically noted.
- (1) Should a Motor Component fail to function within normal tolerances due to a defect in materials or workmanship within period of one year from the date of shipment of the new Motor Component, or 180 days from the date of shipment of the serviced or refurbished Motor Component to the purchaser (but not less than the one year period from the date of shipment of the new Motor Component), or
 - (2) Should an Accessory Component fail to function within normal tolerances due to a defect in materials or workmanship within a period of 90 days from the date of shipment of a new Accessory Component or serviced or refurbished Accessory Component to the purchaser.

Medtronic will at its option: (a) issue a credit to the purchaser of the replacement Motor Component or Accessory Component equal to the Purchase Price, as defined in Subsection A(3), against the purchase of any same Motor Component or Accessory Component requested as its replacement, or, (b) provide a functionally comparable replacement Motor Component or Accessory Component at no charge.

- (3) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original or current functionally comparable, or replacement Motor Component or Accessory Component.

B. To qualify for this Limited Warranty, these conditions must be met:

- (1) The Legend EHS System must be used in accordance with the labeling and instructions for use provided with the products.
- (2) Only Legend EHS System dissecting tools that are manufactured, authorized, and quality controlled by Medtronic may be used.
- (3) No reprocessed dissecting tools may be used.
- (4) The Legend EHS System may not be damaged by accident, abuse, misuse or tampering.
- (5) The Legend EHS System may not be modified without the written permission of Medtronic.

C. This Limited Warranty is limited to its express terms. In particular:

- (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE LEGEND EHS SYSTEM TO FUNCTION WITHIN NORMAL TOLERANCES WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER TORT OR OTHERWISE.
- (2) This Limited Warranty is made only to the purchaser. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PURCHASER SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.
- (3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights that vary from state to state.
- (4) No person has any authority to bind Medtronic to any representation, condition, or warranty, except this Limited Warranty.

*This Limited Warranty is provided by Medtronic Powered Surgical Solutions, 4620 North Beach Street, Fort Worth, Texas 76137-4116. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for terms of the warranty.



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