



Instructions for Use
175036EN D

The Midas Rex™ Legend EHS™ System

Legend EHS™ and Legend EHS Stylus™

Customer service

For further information regarding the use of this product or to report any problems, contact Medtronic Customer Service, or contact your local distributor:

Medtronic Powered Surgical Solutions

4620 North Beach Street

Fort Worth, Texas 76137 USA

US Help Line (800) 335-9557 or (800) 874-5797

RS.DFWrepairs@medtronic.com

International Service: International Customers should contact their local Medtronic representative.

The information contained in this document is accurate at time of publication. Medtronic reserves the right to make changes to the product described in this manual. Refer to manuals.medtronic.com for the current version.

- EN** To obtain a copy of this manual in your local language contact your local Medtronic representative or go to **manuals.medtronic.com**.
- BG** За да получите екземпляр от това ръководство на Вашия език, можете да се свържете с местния представител на Medtronic или да посетите **manuals.medtronic.com**.
- CS** Máte-li zájem o kopii této příručky v místním jazyce, kontaktujte místního zástupce společnosti Medtronic nebo navštivte webové stránky **manuals.medtronic.com**.
- DA** Du kan få en kopi af denne vejledning på dit sprog ved at kontakte den lokale Medtronic-repræsentant eller gå til **manuals.medtronic.com**.
- DE** Eine Kopie dieses Handbuchs in der jeweiligen Landessprache kann vom örtlichen Medtronic-Vertreter angefordert oder unter **manuals.medtronic.com** bezogen werden.
- EL** Για να λάβετε αντίγραφο του παρόντος εγχειριδίου στην τοπική σας γλώσσα, επικοινωνήστε με τον τοπικό αντιπρόσωπο της Medtronic ή επισκεφθείτε την ιστοσελίδα **manuals.medtronic.com**.
- ES** Para obtener una copia de este manual en su idioma local, póngase en contacto con su representante local de Medtronic o visite **manuals.medtronic.com**.
- ET** Võtke ühendust oma ettevõtte Medtronic esindajaga või külastage veebisaiti **manuals.medtronic.com**, et hankida juhendist koopia kohalikus keeles.
- FI** Jos haluat tämän käyttöoppaan omalla kielelläsi, ota yhteyttä paikalliseen Medtronicin edustajaan tai siirry osoitteeseen **manuals.medtronic.com**.
- FR** Pour obtenir un exemplaire de ce manuel dans votre langue, veuillez contacter votre représentant Medtronic local ou visiter la page **manuals.medtronic.com**.
- HR** Da biste dobili kopiju ovog priručnika na svom jeziku, obratite se lokalnom predstavniku tvrtke Medtronic ili pak posjetite web-mjesto **manuals.medtronic.com**.
- HU** Ha szeretne egy saját nyelvű példányt a jelen kézikönyvből, vegye fel a kapcsolatot a Medtronic helyi képviselőjével, vagy látogasson el a **manuals.medtronic.com** weboldalra.
- IT** Per ottenere una copia del presente manuale nella lingua locale, contattare il rappresentante Medtronic di zona o visitare la pagina **manuals.medtronic.com**.
- KK** Осы нұсқаулықтың өзіңіздің жергілікті тіліңіздегі көшірмесін алу үшін, жергілікті Medtronic өкіліне хабарласыңыз немесе мына веб-сайтқа өтіңіз: **manuals.medtronic.com**.
- LT** Norėdami gauti šio vadovo kopiją vietos kalba, susisiekite su vietos „Medtronic“ atstovais arba apsilankykite adresu **manuals.medtronic.com**.
- LV** Lai saņemtu šīs rokasgrāmatas eksemplāru vietējā valodā, sazinieties ar savu vietējo Medtronic pārstāvi vai apmeklējiet vietni **manuals.medtronic.com**.
- MK** За да добиете копија од овој прирачник на вашиот локален јазик, контактирајте со вашиот локален претставник на Medtronic или појдете на **manuals.medtronic.com**.
- NL** Neem contact op met uw vertegenwoordiger van Medtronic of ga naar **manuals.medtronic.com** voor een exemplaar van deze handleiding in uw taal.
- NO** Du kan få et eksemplar av denne håndboken på ditt språk ved å kontakte din lokale Medtronic-representant eller gå til **manuals.medtronic.com**.
- PL** Aby uzyskać egzemplarz niniejszego podręcznika w wybranym języku, należy się skontaktować z lokalnym przedstawicielem firmy Medtronic lub odwiedzić stronę **manuals.medtronic.com**.
- PT-BR** Para obter uma cópia deste manual em seu idioma local, entre em contato com o representante local da Medtronic ou acesse **manuals.medtronic.com**.
- PT-PT** Para obter uma cópia deste manual no seu idioma local, contacte o seu representante local Medtronic ou visite **manuals.medtronic.com**.
- RO** Pentru a obține o copie a acestui manual în limba locală, contactați reprezentantul local Medtronic sau accesați **manuals.medtronic.com**.
- RU** Для получения экземпляра этого руководства на вашем языке обратитесь к местному представителю Medtronic или посетите сайт **manuals.medtronic.com**.
- SK** Ak chcete získať kópiu tejto príručky vo vašom miestnom jazyku, kontaktujte miestneho zástupcu spoločnosti Medtronic alebo navštívte stránku **manuals.medtronic.com**.
- SL** Če želite izvod tega priročnika v svojem jeziku, se obrnite na lokalnega predstavnika za Medtronic ali pa ga poiščite na spletnem mestu **manuals.medtronic.com**.
- SR** Da biste dobili kopiju ovog priručnika za korisnike na svom jeziku, kontaktirajte lokalno predstavništvo kompanije Medtronic ili posetite lokaciju **manuals.medtronic.com**.
- SV** För att erhålla en kopia av denna handbok på ditt språk kontaktar du din lokala representant för Medtronic eller går till **manuals.medtronic.com**.
- TR** Bu kılavuzun kendi dilinizde bir kopyasını almak için, bölgenizdeki Medtronic temsilcinize başvurun veya **manuals.medtronic.com** adresine gidin.
- UK** Щоб отримати копію цього посібника вашою місцевою мовою, зв'яжіться зі своїм місцевим представником Medtronic або відвідайте веб-сайт **manuals.medtronic.com**.

Contents

Glossary.....	1
General information	1
Legend EHS™ system description.....	1
Electric motors	1
Attachments	1
Surgical dissecting tools.....	1
System accessories	1
Indications for use	1
Target population.....	1
Intended use	1
Clinical benefits	1
Contraindications	1
Special Notices	2
Warnings	2
Precautions	3
Training requirements	3
Residual risks	3
Possible adverse events.....	3
Material composition	3
System motors.....	4
Motor cable	4
Aligning the motor collet.....	5
Attachment assembly	5
Integrated Power Console (IPC™) system set up.....	5
Connect to the IPC™ system.....	5
IPC™ system pump detection	6
IPC™ system touchscreen controls	6
Speed.....	6
Irrigation.....	6
Acceleration and deceleration	6
Rotation (FWD and REV).....	6
Multifunction FCU	7
Technical specifications and performance characteristics	7
Guidance and manufacturer's declaration - electrical safety EMC (electromagnetic compatibility).....	8
Legend EHS™ and Legend EHS Stylus™ attachments	10
Dissecting tool nomenclature	10
General guidelines for attachments and tool applications.....	11
Legend EHS™ and Legend EHS Stylus™ attachment assembly and disassembly	15
Straight attachment	15
Angled attachment	16
Fixed footed attachment.....	16
Rotating footed attachment	17
Contra-angle and right-angle attachments	17
Metal cutting attachment.....	18
Variable exposure straight and angled attachment.....	18
Telescoping tube and telescoping tube base attachment straight (AT10) and angled (AT10A).....	19

Telescoping curved bur and telescoping base attachment straight (AT10) and angled (AT10A)20

Perforator (AD01 & AD03) attachment.....21

Jacobs Chuck attachment21

Angled double lock (DK) attachment.....22

J-latch attachment22

Irrigation tubing set23

System set-up check.....23

Troubleshooting.....23

Post-operative instructions.....25

 Disconnect accessory cable from console.....25

Sterility.....26

Legend EHS™ and Legend EHS Stylus™ system reprocessing instructions26

 Motors26

 Attachments/tubes29

Return policy for devices exposed to Transmissible Spongiform Encephalopathies (TSE)30

Refurbishing or repairs30

Planned maintenance31

 Scheduled maintenance intervals 1, 2, 3, 5, 6, 7, 9, 10, 1131

 Scheduled maintenance intervals 4, 8, 1233

Storage33

Disposal.....33

Midas Rex™ Legend EHS™ system Limited Warranty* (U.S. customers only)34

Symbols.....35

Glossary

The following words and acronyms may be used in this manual:

EHS	Electric High-Speed
FCU	Foot Control Unit
FWD	Forward - Rotation is clockwise
ISM	Industrial, scientific, and medical
IPC	Integrated Power Console
REV	Reverse - Rotation is counter-clockwise
RF	Radio Frequency
Vrms	Root mean square voltage

PHYSICIAN NOTE: The physician must convey the indications, contraindications, warnings, and precautions given in this document to the patient.

General information

Read and understand this manual before using the Legend EHS™ system. 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 system by being trained in Medtronic Midas Rex™ Hands-On Workshops or by one of the local authorized representatives.

Legend EHS™ system description

Electric motors

Electric motors provide power to operate disposable surgical dissecting tools. These motors are designed to interface with a series of attachments and surgical dissecting tools using a standard quick-connect locking mechanism. Motors operate in the same manner controlled by an FCU.

Attachments

Attachments are designed to align the surgical tools with the motor to provide support and stability during various surgical procedures. Attachment options, of various lengths, include regular (straight, and angled), variable exposure (straight and angled), footed (craniotomes), and telescoping attachments and tubes. There are a variety of specialty attachments, such as the perforator, Jacobs chuck, J-latch, and metal cutting that are also available. This allows flexibility with the length and style of attachment for surgeries.

Surgical dissecting tools

Surgical dissecting tools are designed and intended to resect, drill, or saw soft and hard tissue, bone, biomaterials, and metals during various surgical procedures. The surgical dissecting tools vary in length and the distal tips of the tools vary in shape and style. The tip designs include the following universal shapes: acorn, match head, ball or round, cylinder, oval, and tapered or side-cutting. Specialized tools such as metal cutters, twist drills, hole-makers, hole saws, and reverse tapered tools are also available.

System accessories

System accessories enable the Legend EHS™ system to carry out the system's intended use. Accessories include the motor wrench, cleaning brushes, instrument trays, irrigation tubing sets, electric control switch, electrical power cables, and tool rack. All of these are considered medical devices except for the tool rack and electric power cables.

Indications for use

The Midas Rex™ Legend EHS™ Electric Drill System is an electrically operated surgical instrument system. The electric motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear Nose and Throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries.

Additionally, the Midas Rex™ Legend EHS™ Electric Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials during open and minimally invasive spine procedures, which may incorporate application of various surgical techniques during the following lumbar spinal procedures:

- Lumbar Microdiscectomy
- Lumbar Stenosis Decompression
- Posterior Lumbar Interbody Fusion (PLIF)
- Transforaminal Lumbar Interbody Fusion (TLIF)
- Anterior Lumbar Interbody Fusion (ALIF)
- Direct Lateral Interbody Fusion (DLIF)

Target population

Candidates for surgical applications stated in the Indications for use.

Intended use

The Midas Rex™ Legend EHS™ Electric Drill system is intended to be used to perform the task of removing soft and hard tissue and bone as stated in the indications for use.

Clinical benefits

Clinical Benefits of the Legend EHS™ High-Speed Drill Systems include optimized visibility and maneuverability in the surgical site, sufficient power to cut bone and biomaterials, ergonomic grip that allows precise control, sensory feedback while cutting, the ability to adjust/configure the system efficiently, and a portfolio of attachments and tools that meet different surgical needs.

Contraindications

None.

Special notices

The words warning, precaution, and note have special meanings in this manual and should be carefully reviewed:

Warning: A warning indicates that the personal safety of the patient or user may be involved. Disregarding this information could result in injury to the patient or user.

Precaution: A precaution indicates that there is a risk of damaging equipment.

Note: A note is intended to provide additional information, which may be useful but is not essential to complete the procedure.

Warnings

- W1 The system user must be familiar with this Instructions for Use (IFU) and the Intergrated Power Console (IPC™) System User's Guide, their precautions, procedures, and safety issues.
- W2 The system and its associated accessories should be used only by qualified medical professionals who are thoroughly trained and experienced in performing surgery with Medtronic powered surgery systems.
- W3 Always inspect the device before and after use for any damage. If damage is observed, do not use damaged device.
- W4 Use adequate irrigation during dissection to prevent thermal necrosis.
- W5 Do not use an overheated device, as it may cause thermal injury to the patient or user.
- W6 Heavy side loads and/or long operating periods may cause the device to overheat.
- W7 Never place an overheated device on the patient or draping during the surgery.
- W8 Do not use excessive force to pry or push bone with the attachment or dissecting tool during surgery.
- W9 Use only dissecting tools specifically designed for use with this drill system. Match the nomenclature and color code on the dissecting tool packaging to the same nomenclature and color band on the attachment.
- W10 Do not use the reusable devices without proper cleaning and sterilization.
- W11 Sterilize and dry the reusable device before storing.
- W12 All service must be performed by Medtronic qualified personnel only.
- W13 Discontinue the use of device if visualization to the surgical site is lost.
- W14 Do not attempt to remove a dissecting tool or attachment while the motor is running to prevent laceration of the user and/or cross contamination through a compromised glove.
- W15 Do not immerse the device, except when recommended by the cleaning instructions in this IFU.
- W16 The motors should only be operated when the attachment/tool is in the fully locked position.
- W17 Do not use the system if the motor continues to run after releasing the foot pedal.
- W18 Do not place the device on the patient or in an unsecured location during surgery.
- W19 Do not use an attachment and dissecting tool combination that results in tool flail or excessive vibration.
- W20 Do not use the reusable device immediately after steam sterilization. Allow an adequate cooling period after steam sterilization.
- W21 Do not place motor in the proximity of a magnetic field, such as magnetic drape or Magnetic Resonance Imaging (MRI) equipment, to avoid inadvertent motor activation.
- W22 The system complies with IEC/EN 60601-1-2, ed. 3.0 and ed. 4.0 safety standard for electromagnetic compatibility (EMC), requirements and test. However, if the system is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered, and the user should take whatever steps are necessary to eliminate or reduce the source of the interference.
- W23 Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this system's IFU.
- W24 Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.
- W25 Use of accessories other than those specified and sold by Medtronic may result in increased emissions and decreased Electromagnetic (EM) immunity of this unit.
- W26 Do not use metal-cutting attachment or metal-cutter tools to cut/resect bone.
- W27 For metal transection, observe the following safety guidelines:
 - W27a Wear eye protection.
 - W27b Irrigate well to cool the cutting surfaces.
 - W27c Protect the wound site from metal debris.
- W28 When using variable exposure attachments, surgeons should become familiar with the performance of dissecting tools before use and should explore the effect of various levels of tool exposure on tool stability. If the tool exhibits excessive chatter, vibration, or movement, decrease the tool exposure.
- W29 Failure to follow prescribed maintenance schedule on motors and attachments may result in device(s) detaching and falling from the motor or attachment which may cause patient injury. To avoid this, motors and attachments should be serviced periodically at intervals recommended by Medtronic.
- W30 Electrical contacts must be dry prior to use.
- W31 When using the non-DK variable exposure attachments, ensure that the attachment is still in the locked position after each adjustment of the tool exposure. Attempting to increase the tool exposure too far may result in the attachment accidentally being unlocked.
- W32 Remove footed attachments cautiously and slowly, as per instructions to avoid injury to the user.
- W33 Excessive side loading could cause non-DK angled attachments to unlock accidentally from motor.
- W34 Do not sterilize and supply for surgical use any device that is not visibly clean and free of particulates. If particulates are present, repeat reprocessing, starting with the Preparation for Cleaning step.
- W35 Do not load more than one motor inside the instrument tray per sterilization cycle.
- W36 The system devices must be cleaned separate from the instrument trays. Do not load system devices into instrument trays until the devices are clean.
- W37 Devices cannot be sterilized to an adequate Sterility Assurance Level (SAL) without prior cleaning.
- W38 Do not use any parts other than Medtronic device unless as noted, as damage or substandard performance could result.
- W39 Do not use cables or power cables with cracks, tears, or corrosion as use may cause injury to patient, user, or operating room staff.
- W40 Tool flutes are sharp and may perforate surgical gloves.
- W41 Keep the cutting area of the tool away from fingers and loose clothing to prevent laceration of the user and cross-contamination through a compromised glove.
- W42 Ensure proper installation of tool in footed attachment. Failure to follow instructions may result in the tool tip contacting the foot of the attachment causing damage to the attachment and/or harm to patient.
- W43 A tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease pressure supplied to the motor to prevent vibration. If vibration persists, change to a different tool size or geometry to prevent unintended tissue damage.
- W44 Excessive noise from the tool when drilling close to the cochlea or ossicular chain may cause patient hearing damage.
- W45 Dissecting tools are for single-use only. Do not attempt to sterilize them. The dissecting tools are packed sterile and not intended for repeat use. To prevent contamination, use only once.

- W46 Excessive pressure applied to a tool may cause tool fracture. Should a tool fracture in use, exercise extreme care to ensure all the fragments of the tool are removed from the patient. Unremoved tool fragments may cause tissue damage to the patient.
- W47 Do not use a dissecting tool if its packaging is damaged or opened outside the sterile field. Sterility is compromised if packaging is opened or damaged.
- W48 Do not use dull tools. Use of dull tools can reduce cutting effectiveness and can cause the system temperature to increase. Use of a dull tool may lead to heat at the cutting site.
- W49 Exposure of tool packaging to ambient light for extended periods of time may cause damage to packaging.
- W50 The system user should ensure sensitive anatomy is protected during drilling and use of the system. Failure to do so could cause injury to the patient.
- W51 When using a non-DK angled attachment, hold the motor assembly by the attachment so that the attachment does not inadvertently loosen from the motor.
- W52 After each procedure, properly clean and sterilize all reusable devices.

Precautions

- P1 Do not use a twist drill dissecting tool at an operating speed over 62,000 rpm.
- P2 Powered burs and drills should be operated in the forward mode only.
- P3 Do not run the AC-16 attachment above 62,000 rpm. This may cause overheating and damage to internal gears of attachment.
- P4 Clean the Legend EHS™ motor and cable while still connected together. This will help to reduce debris ingress. Use only recommended cleaning agents.
- P5 Disconnect cable from Legend EHS™ motor prior to sterilization.
- P6 Do not attempt to disconnect the cable from the Legend EHS Stylus™ motor.
- P7 Do not use low-temperature hydrogen peroxide gas plasma sterilization due to the lumen internal diameter and length restrictions.
- P8 Do not use low-temperature liquid peracetic acid sterilization due to immersion procedure.
- P9 Do not use chlorine-based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.
- P10 Remove and discard tools and accessories following local regulations for disposal of contaminated materials.
- P11 Do not soak or submerge system devices.
- P12 Do not use ultrasonic cleaners for system devices.
- P13 Use only nylon cleaning brushes. Non-nylon cleaning brushes leave residue that may prevent the tool from being secured properly in the motor.
- P14 Do not expose these devices to sterilization temperatures greater than 137°C (279°F). Exposure to temperatures greater than 137°C (279°F) may impact the performance of the device and also the efficacy of the sterilization cycle.
- P15 Because of the variability in cleaning efficiencies and sterilizer operating parameters, all given parameters (temperature, time, etcetera) should be validated by persons who have training and expertise in sterilization processes. Deviation from the recommended sterilization processes is at the risk of the user facility.
- P16 Do not modify device; performance could be diminished.
- P17 When not operating the motor, eliminate accidental foot control activation.
- P18 Do not operate the system without eye protection.
- P19 Use the instrument tray for sterilizing the reusable devices only.
- P20 Do not use the instrument tray for cleaning or disinfection of the reusable devices.
- P21 Tools with “L” identification are longer tools intended for light bone dissection. The increased tool head/stem configuration may affect dissection stability.
- P22 It is recommended that devices should be cleaned as soon as possible, preferably within 30 minutes following use to limit fixation of contaminants.
- P23 The use of a washer-disinfector for cleaning may cause a degradation in performance.

Training requirements

This device is intended for use by physicians, or appropriate staff, trained in the procedures described in the indications for use.

Residual risks

Residual risks related to the use of the Medtronic Midas Rex™ Legend EHS™ electric system are: General surgical complications, Thermal injury, Tissue or bone damage, Nervous system injury, Cerebrospinal fluid leakage, Infection, Hearing damage, and Electric shock.

Possible adverse events

In the event that a serious incident has occurred related to device use, immediately report the event to Medtronic and the competent authorities.

Material composition

Material contained in product that can cause an allergic reaction: nickel.

Patients can be exposed to the following material in the dissecting tool with carbide (Tool CFN with “C” in suffix), which are carcinogenic, mutagenic, and toxic for reproduction (CMR):

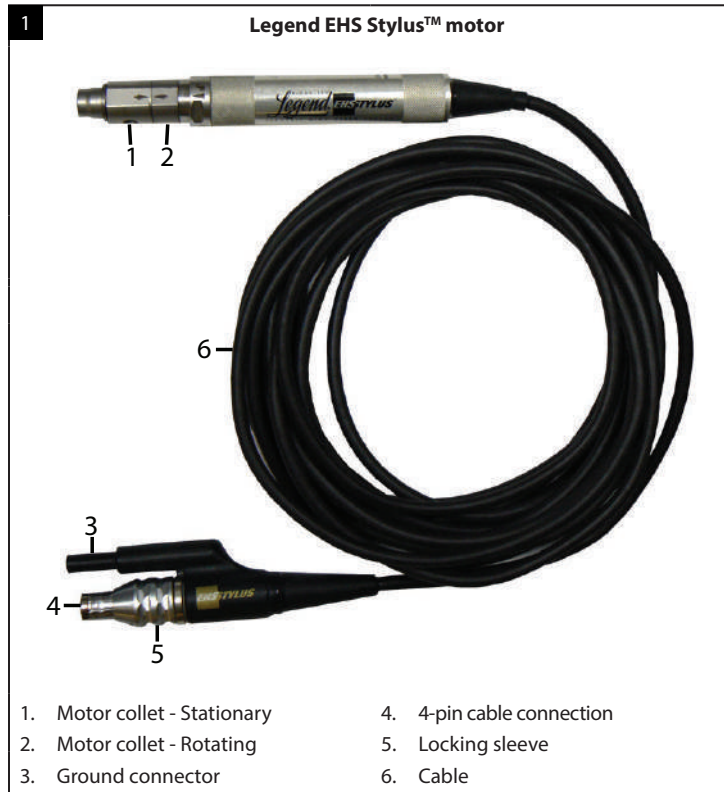
Material	CAS number
Cobalt	7440-48-4.

For additional material of concern information such as REACH, CA Prop 65, or other product stewardship programs, go to www.medtronic.com/productstewardship.

System motors

The Legend EHS™ system motors are high-speed, high-torque, reversible electric motors used to dissect bone and biomaterials at selectable speeds from 200 to 75,000 rpm.

The Legend EHS Stylus™ motor (Figure 1) is a smaller and more compact version of the Legend EHS™ motor (Figure 2).

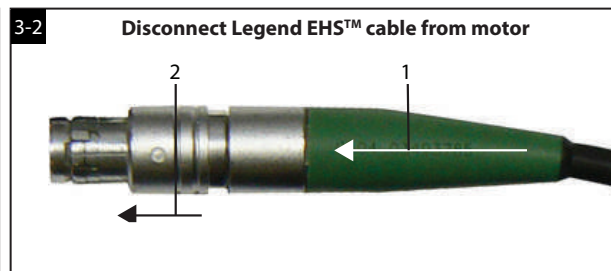
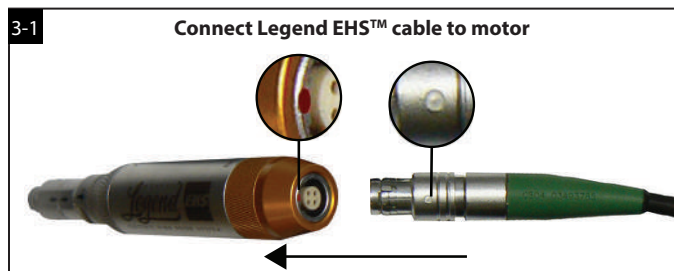


Motor cable

The Legend EHS™ motor cable can be separated from the handpiece, allowing it to connect and disconnect from the motor.

- To connect the cable to the motor, align the mark on the cable to the red mark on the motor (Figure 3-1) and connect the two pieces.
- To remove the cable from the motor, (1) push the cable towards the motor, then (2) pull out the cable by the locking ring only (Figure 3-2).

The Legend EHS Stylus™ motor cable is integrated in the handpiece and cannot be removed from the motor.



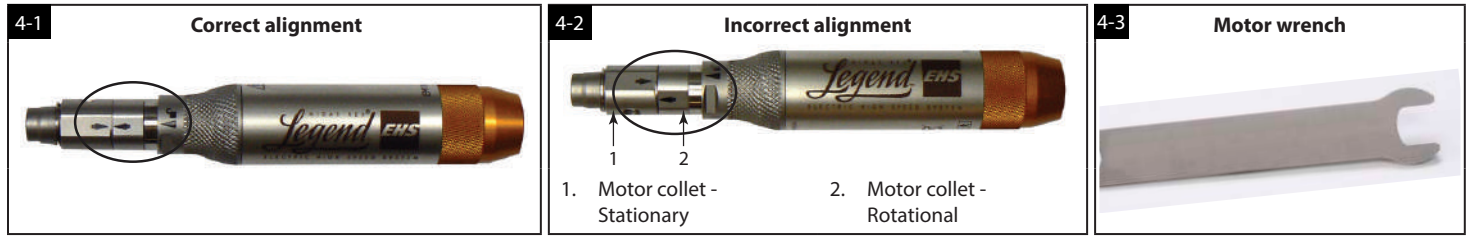
Aligning the motor collet

Note: An attachment will not seat on the Legend EHS and Legend EHS Stylus motor if the arrows on the collet flats are not aligned.

Verify alignment of motor collet arrows. Prior to installation of an attachment and dissecting tool on motor, ensure that the motor collet arrows are in proper alignment. (Figure 4-1).

If the arrows are not aligned (Figure 4-2), use the motor wrench (Figure 4-3) to turn the rotational collet until its arrow is aligned with the arrow on the stationary collet.

Note: Do not use any other components except for the motor wrench to align arrows on motor collet.



Attachment assembly

Note: Refer to the **Legend EHS™ and Legend EHS™ Stylus attachments** for attachment **Assembly** instructions.

Integrated Power Console (IPC™) system set up

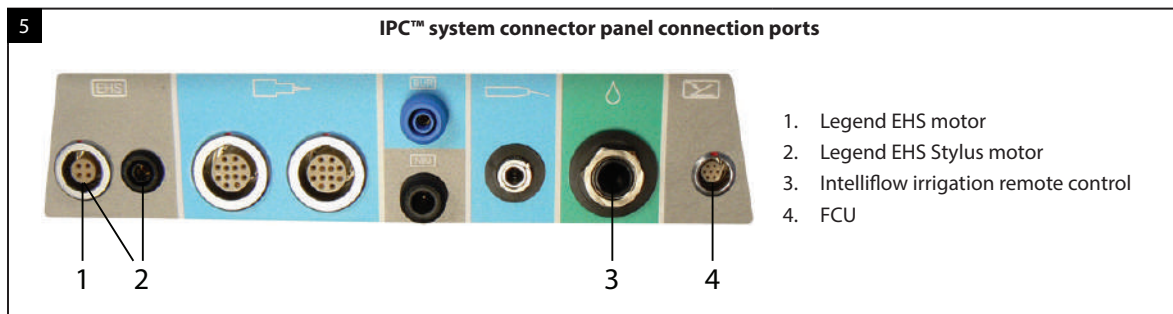
The following instructions for the Legend EHS™ and Legend EHS Stylus™ are in addition to the general assembly instructions found in the Integrated Power Console (IPC™) System User's Guide. To obtain a copy of the user's guide, please contact Medtronic or your local distributor.

Connect to the IPC™ system

Locate the Legend EHS™, Legend EHS Stylus™, and FCU ports on the IPC connector panel (Figure 5) and insert the connector.

Note: Prior to use, check for bent or missing pins in the cable connectors.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.



The Midas Rex™ Legend EHS™ system

IPC™ system pump detection

The IPC™ system incorporates the Legend EHS™ and Legend EHS Stylus™ irrigation tubing sets at Pump 1. Refer to the IPC™ System User's Guide section on Set up and Prime Pumps for more information.

When the IPC detects the Legend EHS™ or Legend EHS Stylus™, Pump 2 defaults to **None**.


When the IPC detects both the Legend EHS™ and Legend EHS Stylus™ motors, the system defaults Pump 2 to the Shared configuration. Use the pumps screen to override the Shared default by selecting the Legend EHS Stylus for Pump 1. Refer to the **IPC™ User's Guide, Set up and Prime Pumps** for more information.

Control operation of the Legend EHS and Legend EHS Stylus with the IPC™ system touchscreen and the multifunction foot pedal.

IPC™ system touchscreen controls

To set or adjust the Legend EHS™ and Legend EHS Stylus™ (Figure 6) controls, on the IPC™ system touchscreen, in the control box, adjust or set motor speed, irrigation flow rate, motor acceleration/ deceleration, and motor rotation option:

Speed

- To adjust speed in FWD or REV mode (Figures 7-1 and 7-2), in the Speed control box, press the plus button to increase speed or the minus button to decrease speed. 
- The Legend EHS Stylus™ has a default speed, 60,000 rpm and a variable speed adjustment from 200 to 75,000 rpm.
- The Legend EHS™ has a default speed, 70,000 rpm and a variable speed adjustment from 200 to 75,000 rpm.

Irrigation

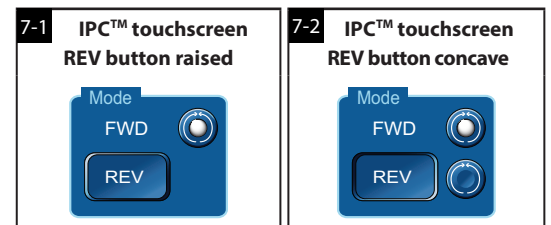
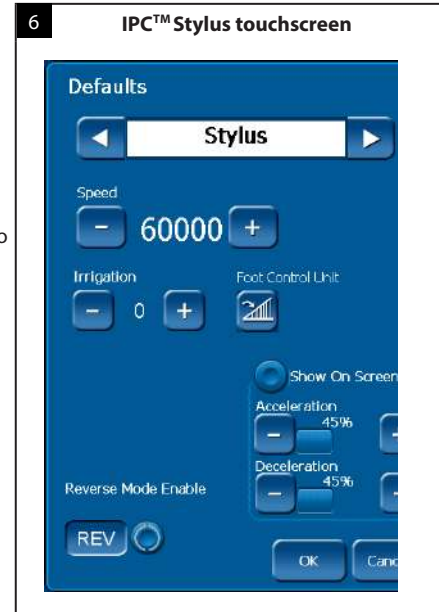
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays Intermittent when in intermittent flow mode.
Note: To adjust flow rate, you can use the touchscreen or the IntelliFlow irrigation remote control.
- Default, 0 cc per minute in FWD or REV mode.
- For additional instructions see the IPC™ System User's Guide.

Acceleration and deceleration

- To adjust acceleration and deceleration, on the Defaults menu (Figure 7-1), press the corresponding plus or minus button. Acceleration is the rate at which the motor speeds up to reach the target speed. Deceleration is the rate at which the motor slows down to reach the target speed or stop.
Note: While in the default menu, the motor will not be active to demonstrate the selected acceleration and deceleration. To determine the desired values, adjust the acceleration and deceleration during motor operation and note the preferred values.
- To enable adjustment of acceleration or deceleration during motor operation and to display the acceleration and deceleration adjustment options on the motor operational screen, on the Defaults menu, select Show On Screen and then press [OK]. To hide the acceleration and deceleration during motor operation, on the Defaults menu, deselect Show On Screen.

Rotation (FWD and REV)




- To change rotation mode, in the Mode control box, select FWD or REV.
Important: System configuration may be different from the default. If the REV button appears raised (Figure 7-1) and does not have a selectable radio button, you cannot select the REV mode. If the REV button appears concave (Figure 7-2) and has a selectable radio button, you can select the REV mode via the touchscreen or the multifunction foot pedal.

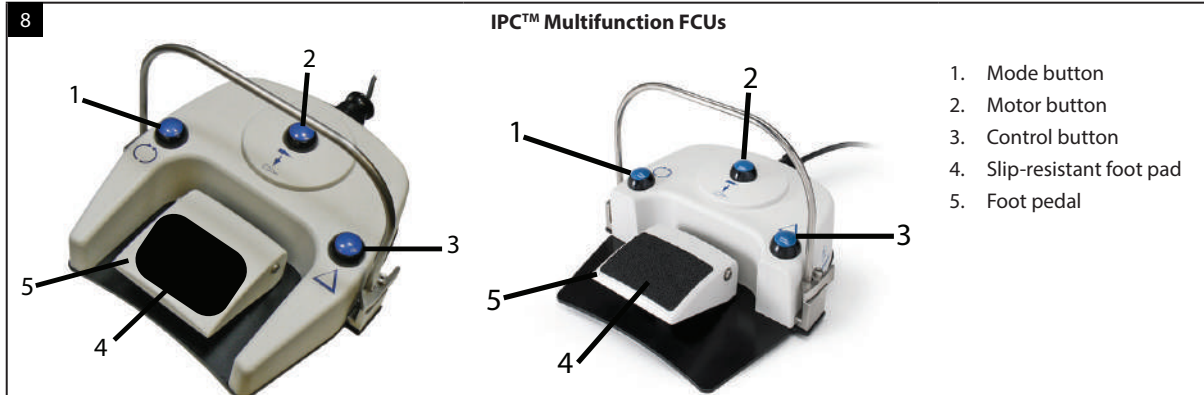


Multifunction FCU

Important: By default, press each button on the FCU for at least 100 milliseconds (mS) for the selection to become active. Use the IPC™ system touch screen settings screen to change the default value.

To use the multifunction foot pedal (Figure 8) to control the motor, do the following:

- To select FWD or REV mode, press the mode button. 
 - To change the handpiece, press the handpiece button. 
 - To toggle between the start/stop mode and variable speed mode, press the control button. 
- Note:** Functionality of the control button may be changed in the handpiece Defaults menu to pause irrigation. Refer to Change System Settings in the Pre-Operating Instructions section of the IPC™ User's Guide.
- To start or adjust the speed of a motor in variable mode, press the foot pedal.



Technical specifications and performance characteristics

Table 1: Legend EHS™ technical specifications and performance characteristics

Legend EHS™ (EM100-A)			
Size	Weight	Speed	Duty cycle for applied part
9.02 cm length x 2.03 cm diameter	180 g	75,000 rpm FWD/REV, variable speed of 200–75,000 rpm	For use in operating room temperatures up to 40°C (104°F), the motor is rated for a cutting time of 3 minutes at 70,000 rpm.
			For normal operating room temperatures (typically 20°C/68°F), the motor is rated for cutting time of 10 minutes followed by 25 minutes or rest.
			The motor is rated for intermittent use of 20 seconds ON / 20 seconds OFF, indefinitely at 70,000 rpm.

Table 2: Legend EHS™ Stylus technical specifications and performance characteristics

Legend EHS Stylus™ (EM200)			
Size	Weight	Speed	Duty cycle for applied part
7.77 cm length x 1.65 cm diameter	90 g	75,000 rpm FWD/REV, variable speed of 200–75,000 rpm	For use in operating room temperatures up to 40°C (104°F), the motor is rated for 3 minutes at 60,000 rpm followed by 25 minutes or rest.
			For normal operating room temperatures (typically 20°C/68°F), the motor is rated for cutting indefinitely at 60,000 rpm.

Guidance and manufacturer's declaration - electrical safety EMC (electromagnetic compatibility)

Functional standards for electrical systems

ANSI/AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005, CORR. 1:2009, AMMEND. 1:2012
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005, CORR. 1:2006, CORR. 2:2007, AMMEND. 1:2012
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2006, AMMEND. 12:2014
IEC 60601-1-4	Medical electrical equipment - Part 1: General requirements for safety, Part 4: Programmable electrical medical systems 1996, AMMEND. 1:1999
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety, collateral standard: electromagnetic compatibility - requirements and tests ED. 3.0:2007, ED. 4.0:2014
CAN/CSA C22.2#60601-1	Medical electrical equipment - Part 1: General requirements for safety ED. 3.0:2014

Environment of intended use:

- Professional healthcare facility environment

Part-1: Electromagnetic immunity

The Legend™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Legend™ system should assure that it is used in such an environment.

Immunity test	Test level (IEC/EN 60601-1-2)	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact	± 8 kV contact	The relative humidity should be at least 5%. Note 1 and 3
	± 15 kV air	± 15 kV air	
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 line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U _r (100 % dip in U _r) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	0 % U _r (100 % dip in U _r) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Legend™ system requires continued operation during power mains interruptions, it is recommended that the Legend™ system be powered from a uninterruptible power supply or a battery. Note 1 and 3
	0 % U _r (100 % dip in U _r) for 1 cycle at 0°	0 % U _r (100 % dip in U _r) for 1 cycle at 0°	
	40 % U _r (60 % dip in U _r) for 5 cycles	40 % U _r (60 % dip in U _r) for 5 cycles	
	70 % U _r (30 % dip in U _r) for 0.5 sec	70 % U _r (30 % dip in U _r) for 0.5 sec	
	0 % U _r (100 % dip in U _r) for 5 sec	0 % U _r (100 % dip in U _r) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note:

- U_r is the mains voltage prior to application of the test level.
- When the console is powered and connected to the FCU, application of -15KV air discharge onto the buttons may cause the console to freeze. Power cycle the console to re-establish normal operation.
- All electric motors are compliant with IEC/EN 60601-1-2, ed. 3.0 and ed. 4.0 standards. Refer to the **IPC™ System User's Guide** to determine specific standard compliance for the IPC™ system.

Part-1: Electromagnetic emissions

The Legend™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Legend™ system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	The Legend™ 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 emission CISPR 11	Class A	The Legend™ system is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the Legend™ system

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


Rated maximum power of transmitter W	Separation distance (in meters) according to frequency of transmitter						
	380MHz-390MHz $d = 0.22\sqrt{P}$	430MHz-470MHz $d = 0.22\sqrt{P}$	704MHz-787MHz $d = 0.67\sqrt{P}$	800MHz-960MHz $d = 0.22\sqrt{P}$	1.7GHz-1.99GHz $d = 0.22\sqrt{P}$	2.4GHz-2.57GHz $d = 0.22\sqrt{P}$	5.1GHz-5.8GHz $d = 0.67\sqrt{P}$
0.01	0.03	0.03	0.07	0.03	0.03	0.03	0.07
0.1	0.07	0.07	0.21	0.07	0.07	0.07	0.21
1	0.22	0.22	0.67	0.22	0.22	0.22	0.67
10	0.7	0.7	2.12	0.7	0.7	0.7	2.12
100	2.2	2.2	6.7	2.2	2.2	2.2	6.7

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

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

Part-2: Guidance and manufacturer's declaration – electromagnetic immunities

The Legend™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Legend™ system should assure that it is used in such an environment.

Immunity test	Test level (IEC/EN 60601-1-2)	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Legend™ system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may result.
	6 Vrms 150 kHz to 80 MHz in ISM bands	6 Vrms 150 kHz to 80 MHz in ISM bands	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Legend™ system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \frac{6}{E} \sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the immunity test levels in volt per meter (V/m), and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
	9 – 28 V/m Spot frequencies 385MHz to 5.785 GHz	9 – 28 V/m Spot frequencies 385MHz to 5.785 GHz	
	Pulse modulation	Pulse modulation	

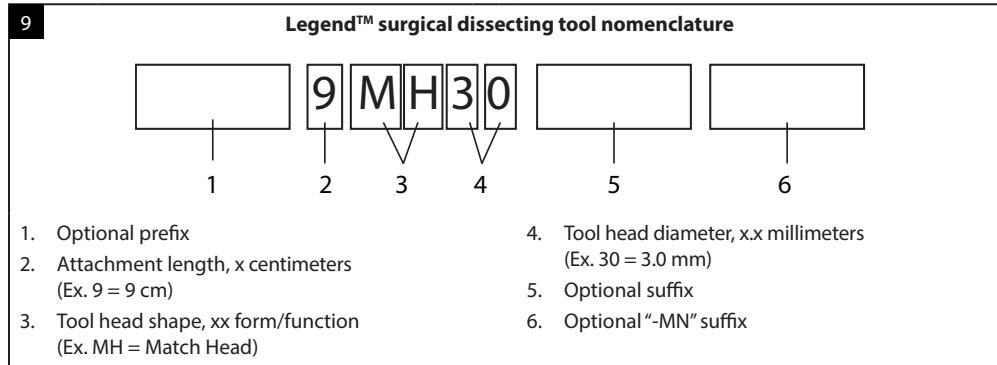
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Legend EHS™ and Legend EHS Stylus™ attachments

Dissecting tool nomenclature

Note: Match the nomenclature and color code on the dissecting tool packaging to the corresponding nomenclature and color code on the attachment.

Part numbers for dissecting tools follow a nomenclature, which is described in the diagram below (Figure 9). Standard tool part numbers consist of the associated attachment length, the tool family identifier, and the tool head diameter. Part numbers can also include a variety of prefixes to identify specific attachment types, as well as a variety of suffixes to provide additional information about the dissecting tool. Tools that use a design taken from the Mednext line are designated by an additional “-MN” suffix.



Tool number prefixes (not all inclusive)

Note: A single part number will use only one prefix.

Prefix	Tool attachments
CB	Curved Bur
F	Footed attachments
T	Telescoping tube

Tool number suffixes (not all inclusive)

Note: More than one suffix may be combined in a single part number.

Suffix	Tool head shape modifiers
B	Ball end
BR	Barrel
M	2-Flute Match style
S	Spiral flutes
T	3-Flute or SymmeTRI
W	Wing flute

Tool head shape (form/function)

AC	Acorn
BA	Ball
CY	Cylinder
HM	Hole Maker
HS	Hole Saw
MC	Metal Cutting
MH	Match Head
OV	Oval
RT	Reverse Taper
TA	Tapered or side cutter
TD	Twist Drill

Suffix Tool head cutting modifiers


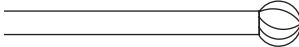
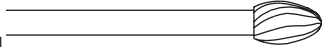
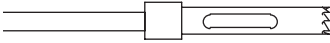
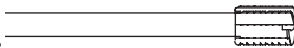
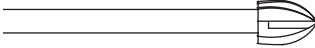


C	Carbide
D	Diamond
DC	Diamond Coarse
DF	Diamond Fine
DX	Diamond Extra Coarse
DXF	Diamond Extra Fine
F	Fine
-MN	MedNext style
X	Coarse
XF	Extra Fine


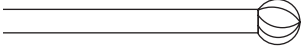

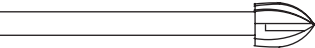
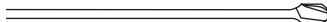


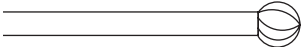


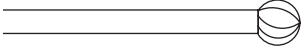
Suffix Tool length modifiers

L	Long
SH	Short
Pxx	Plus 'xx' mm (for example, P15 = Plus 15 mm)
Mxx	Minus 'xx' mm

General guidelines for attachments and tool applications

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

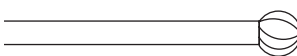
Surgical application	Commonly used attachments	Commonly used dissecting tools
Spine	8-B, 9-M, 14-AM straight or angled, 15-A straight or angled	 <p>Match head Elongated spherical design allows controlled, delicate dissection. For laminotomy, foramenotomy, entry hole, nerve decompression, osteophyte removal, etc.</p>
		 <p>Ball Helical cutting flutes dissect bone from a variety of approach angles. For debridement, decortication, corpectomy, osteophyte removal, etc.</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, etc.</p>
		 <p>Hole maker and hole 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, etc.</p>
		 <p>Acorn Curved designs varies dissection efficiency with varied approach angles. For entry hole, laminotomy, bone shaping, debridement, corpectomy, decortication, fusion takedown, etc.</p>
Telescoping		 <p>Match head Elongated spherical design allows controlled, delicate dissection. For laminotomy, foramenotomy, entry hole, nerve decompression, osteophyte removal, etc.</p>
Footed		 <p>Tapered Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, laminectomy, etc.</p>

Surgical application	Commonly used attachments	Commonly used dissecting tools
Neurosurgical–Cranial	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>Match head Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, mastoidectomy, acoustic neuroma, skull base, etc.</p>
		 <p>Ball Helical cutting flutes dissect bone from a variety of approach angles. For debridement, decortication, entry hole, nerve decompression, mastoidectomy, acoustic neuroma, etc.</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, etc.</p>
Telescoping		 <p>Match head Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, mastoidectomy, acoustic neuroma, skull base, etc.</p>
Footed		 <p>Tapered Slender design for precise dissection with minimal bone loss. For craniotomy, transection, osteotomy, etc.</p>
General surgery and plastic surgery (craniofacial/ maxillofacial/ sternotomy)	7-6ST straight or angled, 8-B, 9-M, 10-9ST straight or angled, 14-AM straight or angled	 <p>Match head Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, etc.</p>
		 <p>Ball Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, sinus dissection, etc.</p>
		 <p>Tapered Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, entry hole, suture hole, midface advancement, etc.</p>
		 <p>Twist drill Helical design with stop produces a hole with a precise depth. Ideal for plating.</p>
Ear, nose, and throat (otology, neurootology)	7-6ST straight or angled, 10-9ST straight or angled	 <p>Ball Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, mastoidectomy, facial recess, cochlear implant bed, ossiculoplasty, labyrinthectomy, middle fossa approach, acoustic neuroma, etc.</p>

Surgical application	Commonly used attachments	Commonly used dissecting tools
----------------------	---------------------------	--------------------------------

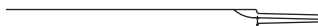
Orthopaedics

8-B, 9-M, 14-AM straight or angled, 21-TU, 26-R, footed, telescoping



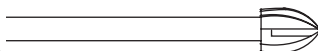
Ball

Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, cement removal, acetabular revision, etc.



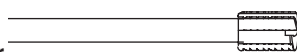
Tapered

Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, suture hole, etc.



Acorn

Curved designs varies dissection efficiency with varied approach angles. For bone shaping, debridement, decortication, cement removal, acetabular revision, etc.



Cylinder

Effective bone sculpturing and planing. For graft shaping, debridement, decortication, cement removal, acetabular revision, etc.

Footed

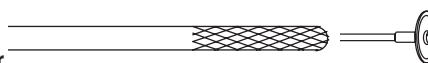


Tapered

Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, etc.

Biometals/
bioceramics/
biomaterials

MC



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, etc.











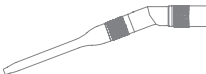









Warning: Match the nomenclature and color code on the Legend dissecting tool packaging to the same nomenclature and color code on the Legend attachment.

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

Table 3: Glossary

Surgical procedures				Tool head designs	
LM	Lumbar Microdiscectomy	PH	Pilot Hole	MH	Match Head dissecting tool with an elongated spherical design allows controlled, delicate dissection.
LSD	Lumbar Stenosis Decompression	ND	Nerve Decompression	BA	Ball dissecting tool, cutting flutes to dissect bone or cement effectively from a wide variety of approach angles.
LIF	Posterior Lumbar Interbody Fusion (PLIF)	OR	Osteophyte Removal	AC	Acorn dissecting tool, curved design varies dissection efficiency with varied approach angles and effective in bone shaping.
	Transforaminal Lumbar Interbody Fusion (TLIF)	DB	Debridement	CY	Cylinder dissecting tool effective in bone sculpturing and planning.
	Anterior Lumbar Interbody Fusion (ALIF)	DC	Decortication	HM/S	Hole Maker/Hole Saw dissecting tool, matched sets of hole makers and hole saws are efficient and effective.
	Direct Lateral Interbody Fusion (DLIF)	CT	Corpectomy	OV	Oval dissecting tool with helical cutting flutes and curved design blend acorn and ball styles to vary dissection efficiency with approach angle.
FT	Fusion Takedown	MI	Minimally Invasive procedure	T	Fluted dissecting tool, cutting flutes to allow faster, and efficient bone removal.
LT	Laminotomy			TA	Tapered dissecting tool with slender design for precise dissection with minimal bone loss.
FRT	Foramenotomy			MC	Metal Cutting dissecting tool to facilitate the cutting and shaping of metal.

Table 4: General guidelines for attachment and tool applications

Surgical application - Spine													Commonly used attachments	Tools											
Incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials.														MH	BA	AC	CY	HM/S	OV	T	TA	MC			
LM	LSD	LIF	FT	LT	FRT	PH	ND	OR	DB	DC	CT	MI													
X	X	X	X	X	X	X	X	X	X	X	X	X	Straight 				X	X	X	X	X	X	X	X	-
X	X	X	X	X	X	X	X	X	X	X	X	X	Angled 				X	X	X	X	X	X	X	X	-
X	X	X	X	X	X	X	X	X	X	X	X	X	Base	Tube			X	X	X	-	-	X	X	-	-
													Straight 	Straight 	Angled 	Curved 									
X	X	X	X	X	X	X	X	X	X	X	X	X	Angled 				X	X	X	-	-	X	X	-	-
X	X	X	-	X	X	X	X	X	X	X	X	X	Footed 				-	-	-	-	-	-	-	X	-
X	X	X	X	X	X	X	X	X	X	X	X	X	Curved bur 				X	X	-	-	-	-	X	-	-
X	X	X	-	X	X	X	X	X	X	X	X	X	Contra angle 				X	-	-	-	-	-	-	X	-
X	X	X	X	X	X	X	X	X	X	X	X	X	ASMC 				-	-	-	-	-	-	-	-	X

Legend EHS™ and Legend EHS Stylus™ attachment assembly and disassembly

Warnings:

- Always inspect the device before and after use for any damage. If damage is observed, do not use damaged device.
- The motors should only be operated when the attachment/tool is in the fully locked position.
- Do not use excessive force to pry or push bone with the attachment or dissecting tool during surgery.
- Excessive pressure applied to bur may cause bur fracture. Should a tool fracture in use, extreme care must be exercised to ensure that all fragments of the tool are removed from the patient. Unremoved tool fragments may cause tissue damage to the patient.

Straight attachment

Caution: Match the nomenclature and color code on the tool packaging to the nomenclature and color code on the attachment.

Notes:

- An attachment will not seat on the motor if the arrows on the collet flats are not in alignment.
- The motors will not run properly unless the attachment is in the locked position.

Assembly:

1. Slide a straight attachment over the motor collet aligning the triangular arrows on the attachment and the motor case (Figure 10-1). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Insert the tool into the attachment with a slight rotational motion (Figure 10-2). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
3. Rotate the attachment in the direction indicated by arrow on the attachment until the attachment alignment mark is directly in line with the locked symbol (Figure 10-3). You will hear two clicks as the attachment is rotated.

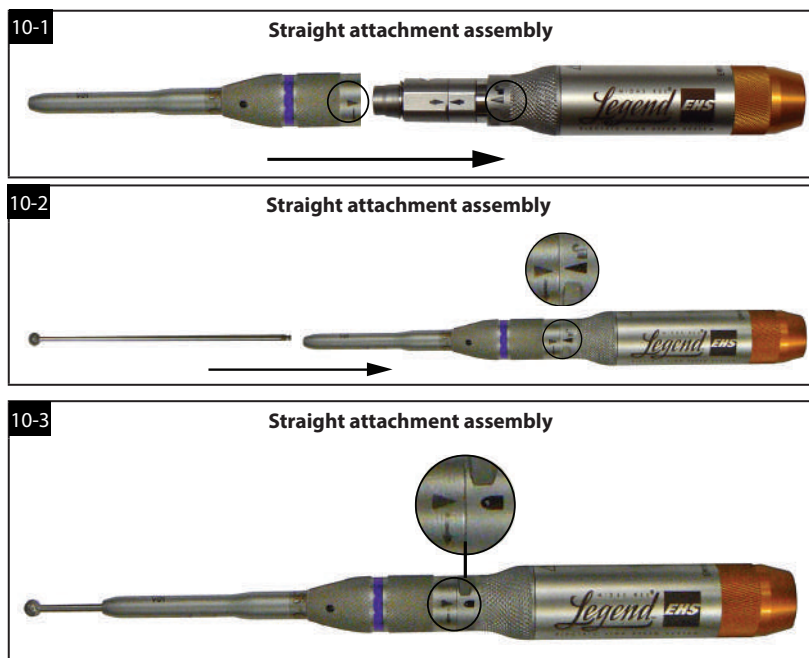
Note: Only when the second click is heard is the attachment fully seated and the collet brake fully released.

4. Gently pull on the tool to ensure that it is locked into the motor.

Note: Tool should rotate freely. If not, unlock the attachment, re-seat the tool, and re-lock the attachment.

Disassembly:

1. Hold the motor in the palm of your hand. Rotate the attachment to the unlocked position. In this position, the arrows in the attachment and motor will line up (Figure 10-2).
2. Remove the dissecting tool from the attachment and discard the tool.
3. Use thumb and index finger to lift the attachment off of the motor.



Angled attachment

Warning: Excessive side loading could cause non-DK angled attachments to unlock accidentally from motor.

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

Notes:

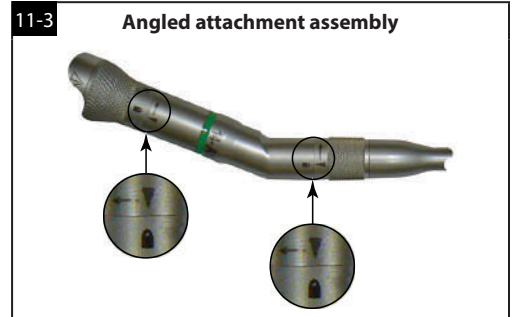
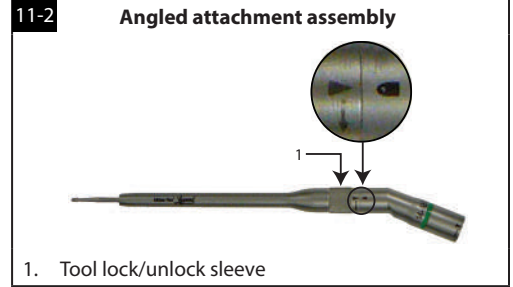
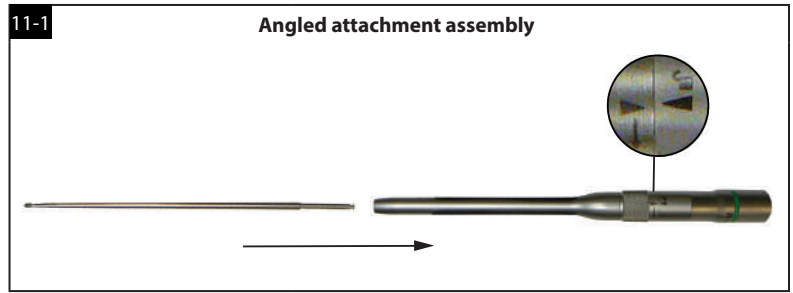
- A dissecting tool may be installed and locked in the attachment before the angled attachment is installed onto the motor.
- Angled and straight attachments with the same length, marking, and color band share the same dissecting tools.

Assembly:

1. With the tool lock in the unlocked position, insert a tool into the angled attachment with a slight rotational motion (Figure 11-1). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Rotate the tool lock/unlock sleeve in the direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol (Figure 11-2).
3. Gently pull on the tool to ensure that it is locked into the motor.
Note: Tool should rotate freely. If not, unlock the attachment, re-seat the tool, and re-lock the attachment.
4. Slide the angled attachment over the motor collet aligning the triangular arrows on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
5. Rotate the attachment in the direction indicated by the arrow until the attachment alignment mark is directly in line with the locked symbol. You will hear two clicks as the attachment is rotated.
Note: Only when the second click is heard is the attachment fully seated and the collet brake fully released.
6. Verify that both the attachment to motor alignment mark and the tool lock alignment mark are directly in line with the locked symbols (Figure 11-3).

Disassembly:

1. Rotate the tool lock to the unlocked position to remove the tool from the attachment.
2. Rotate the attachment to the unlocked position and lift the attachment off of the motor.



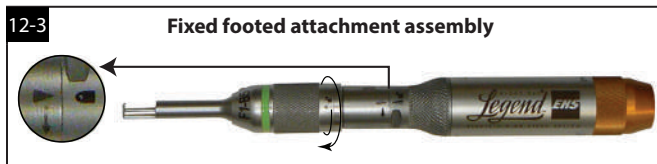
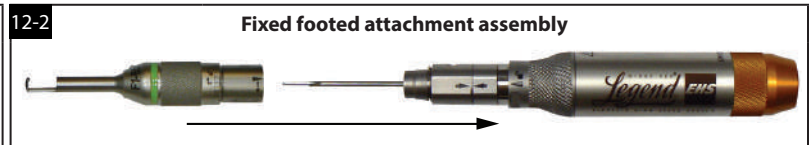
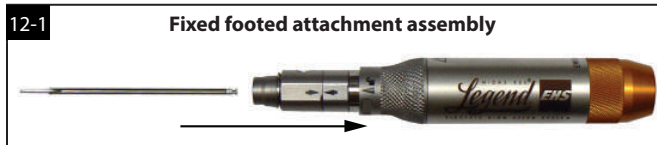
Fixed footed attachment

Warning: Ensure proper installation of tool in footed attachment. Failure to follow instructions may result in the tool tip contacting the foot of the attachment causing damage to the attachment and/or harm to patient.

Note: Fixed and rotated footed attachments with the same length, marking and color band share the same dissecting tools.

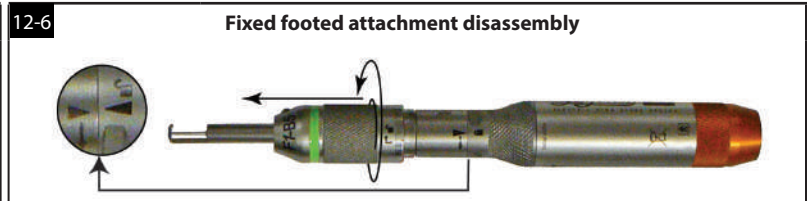
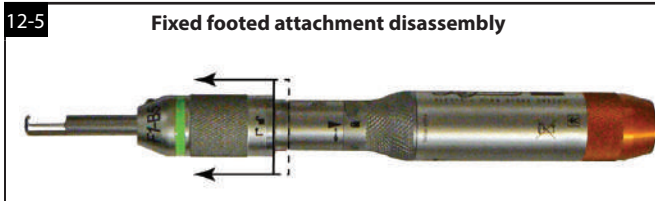
Assembly:

1. Insert a dissecting tool into the motor collet with a slight rotational motion (Figure 12-1). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Slide the fixed footed attachment over the dissecting tool onto the motor aligning triangular arrows on the attachment and the motor case (Figure 12-2).
3. Pull the fixed footed attachment towards the motor and rotate the attachment to the locked position on the motor case (Figure 12-3).
4. Check to ensure a gap exists between the tip of the tool and the foot of the attachment (Figure 12-4). This will prevent damage to the attachment and/or injury to patient.



Disassembly:

1. To remove the fixed footed attachment, hold the motor in the palm of your hand. Push the sleeve on the fixed footed attachment distally while rotating the attachment to the unlocked position on the motor case and then release the sleeve (Figure 12-5).
2. To avoid injury from the dissecting tool, use thumb and index finger to cautiously and slowly lift the attachment off of the motor and away from the dissecting tool (Figure 12-6).
3. Pull the dissecting tool out of the motor collet and discard the tool (Figure 12-7).



Rotating footed attachment

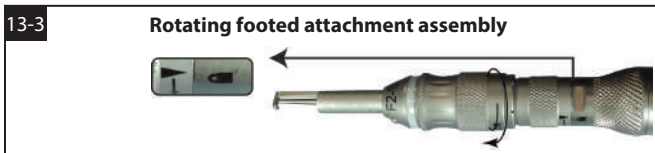
Warning: Ensure proper installation of tool in footed attachment. Failure to follow instructions may result in the tool tip contacting the foot of the attachment causing damage to the attachment and/or harm to patient.

Notes:

- Rotating and fixed footed attachments with the same length, marking and color band share the same dissecting tools.
- The footed end of the attachment has 360° of unrestricted rotation.

Assembly:

1. Insert a dissecting tool into the motor collet with a slight rotational motion (Figure 13-1). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Slide the rotating footed attachment over the dissecting tool onto the motor aligning triangular arrows on the attachment and the motor case (Figure 13-2).
3. Pull the rotating footed attachment towards the motor and rotate the attachment to the locked position on the motor case (Figure 13-3).
4. Check to ensure a gap exists between the tip of the tool and the foot of the attachment (Figure 13-4). This will prevent damage to the attachment and/or injury to patient.



Disassembly:

1. Hold the motor in the palm of your hand. Rotate the attachment to the unlocked position. In this position, the arrows in the attachment and motor will line up.
2. Use thumb and index finger to lift the attachment off of the motor.
3. Remove the dissecting tool from the motor collet and discard the tool.

Contra-angle and right-angle attachments

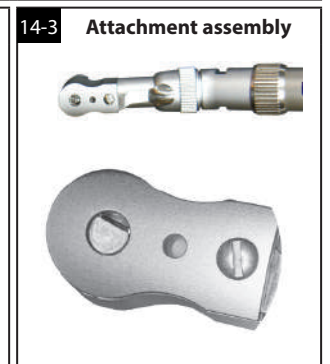
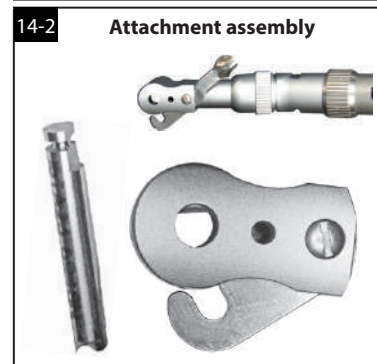
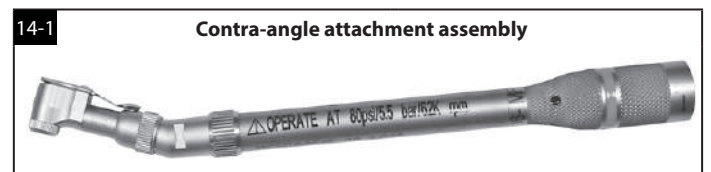
Assembly:

Note: The input speed of the attachment should be no more than 62,000 rpm. Set speed on the IPC Console to be 62,000 rpm or less.

1. Slide the contra-angle attachment over the motor collet aligning triangular arrows on the attachment and the motor case.
2. Rotate the attachment to the locked position on the motor case (Figure 14-1).
3. Rotate the attachment head's lever laterally to the open position and insert a dissecting tool (Figure 14-2).
4. Align the flat in the tool with the corresponding flat in the attachment and fully insert tool into the attachment.
5. Close lever (Figure 14-3) to lock tool in the attachment.
6. Gently pull on the dissecting tool shaft to ensure it is locked in the attachment.

Disassembly:

1. Rotate the lever on the attachment head laterally to unlock the tool and then remove the dissecting tool.
2. Discard the dissecting tool.
3. Rotate the attachment to the unlocked position and lift the attachment off of the motor.



The Midas Rex™ Legend EHS™ system

Metal cutting attachment

Warning: For metal transection, observe the following safety guidelines:

- Wear eye protection.
- Irrigate copiously to cool the cutting surfaces.
- Protect the wound site from metal debris.

Important: The metal cutting attachment uses the tungsten carbide or diamond wheel dissecting tools. All metal cutter dissecting tools have an "MC" attachment prefix in their nomenclature (for example, MC254 and MC30). Metal cutter dissecting tools should not be installed into any other attachment.

Assembly:

1. Slide the metal cutting attachment over the motor collet aligning triangular marks on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Rotate the attachment to the locked position on the motor case.
3. Unscrew tool lock sleeve several turns and while holding the attachment upright, insert a dissecting tool into the attachment (Figure 15).
4. Rotate the dissecting tool until it drops into position and is fully seated (Figure 15).
5. Lock the tool in the attachment by rotating the locking sleeve in the direction shown on the attachment until the tool is secured.
6. Gently pull on the tool to ensure that it is secured in the attachment.

Disassembly:

1. Unscrew the tool lock with several turns, then remove the dissecting tool.
Note: Do not rotate past the point where resistance is felt.
2. Discard tool.
3. Rotate the attachment to the unlocked position on the motor case and lift attachment off of the motor.

Variable exposure straight and angled attachment

Warnings:

- When using variable exposure attachments, surgeons should become familiar with the performance of dissecting tools before use and should explore the effect of various levels of tool exposure on tool stability. If the tool exhibits excessive chatter, vibration, or movement, decrease the tool exposure.
- When using the non-DK variable exposure attachments, ensure that the attachment is still in the locked position after each adjustment of the tool exposure. Attempting to increase the tool exposure too far may result in the attachment accidentally being unlocked.

Note: The 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.

Assembly:

1. Assemble the variable exposure straight attachment using the **Straight attachment Assembly** instructions and the variable exposure angled attachments using the **Angled attachment Assembly** instructions.
2. After assembly, use the tube adjustment ring to adjust the exposure of the dissecting tool (Figure 16). 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.

Disassembly:

Remove the variable exposure straight attachment using the **Straight attachment Disassembly** instructions and the variable exposure angled attachments using the **Angled attachment Disassembly** instructions.



Telescoping tube and telescoping tube base attachment – straight (AT10) and angled (AT10A)

Assembly:

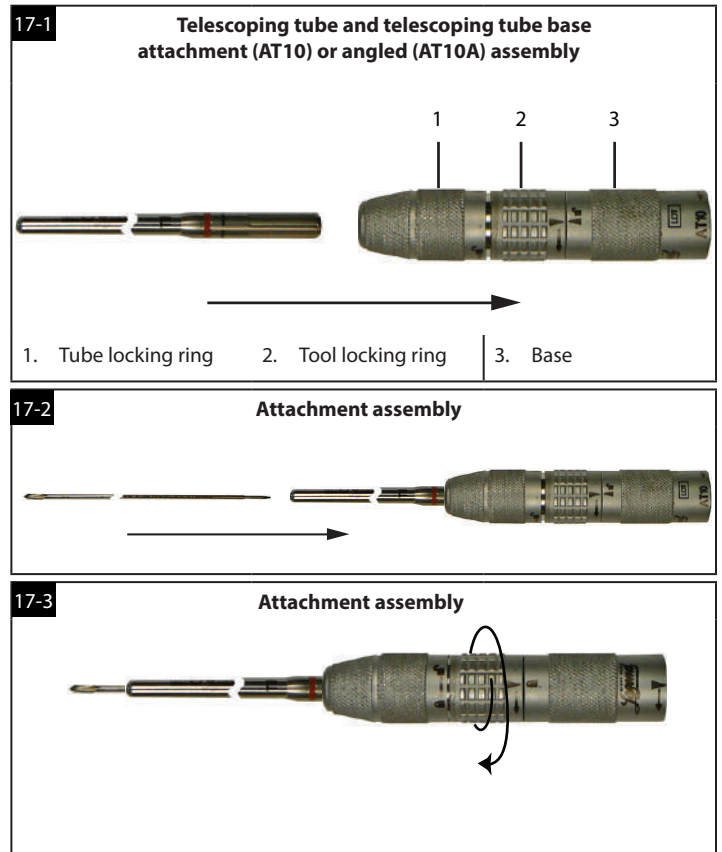
1. Assemble the telescoping base attachment straight (AT10), or angled (AT10A) to the motor using the **Straight attachment Assembly** instructions.
2. Insert the base end of the telescoping tube into the AT10, or AT10A attachment until the hub is fully seated. To secure the tube, turn the tube locking ring on the AT10, or AT10A attachment until finger tight (Figure 17-1).

Note: Do not over tighten.

3. Verify that the telescoping tube is secure by gently pulling on the tube.
 4. Rotate the tool locking ring to the unlocked position.
 5. Insert the tool into the telescoping tube. Apply a slight amount of inward pressure on the tool (Figure 17-2). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
 6. Turn the tool locking ring to the locked position (Figure 17-3).
 7. Verify that the tool is secured by gently pulling on the tool.
 8. To vary the tube position/tool exposure, rotate the tube locking ring toward the unlocked position, re-position the tube, then rotate the tube locking ring toward locked position until finger tight.
- Note:** Do not over tighten.
9. Gently pull on the dissecting tool, then the tube, to ensure they are secure.

Disassembly:

1. Rotate the tube locking ring towards the unlocked position.
2. Rotate the tool locking ring to the unlocked position.
3. Remove the tool and then the telescoping tube from the AT10, or AT10A attachment.
4. Discard the tool.
5. For AT10, rotate the attachment to the unlocked position on the motor case and lift the attachment off the motor.
6. For AT10A, hold the motor in the palm of your hand, and push the sleeve on the attachment distally while turning the attachment to the unlocked position. Release the sleeve and remove the attachment.



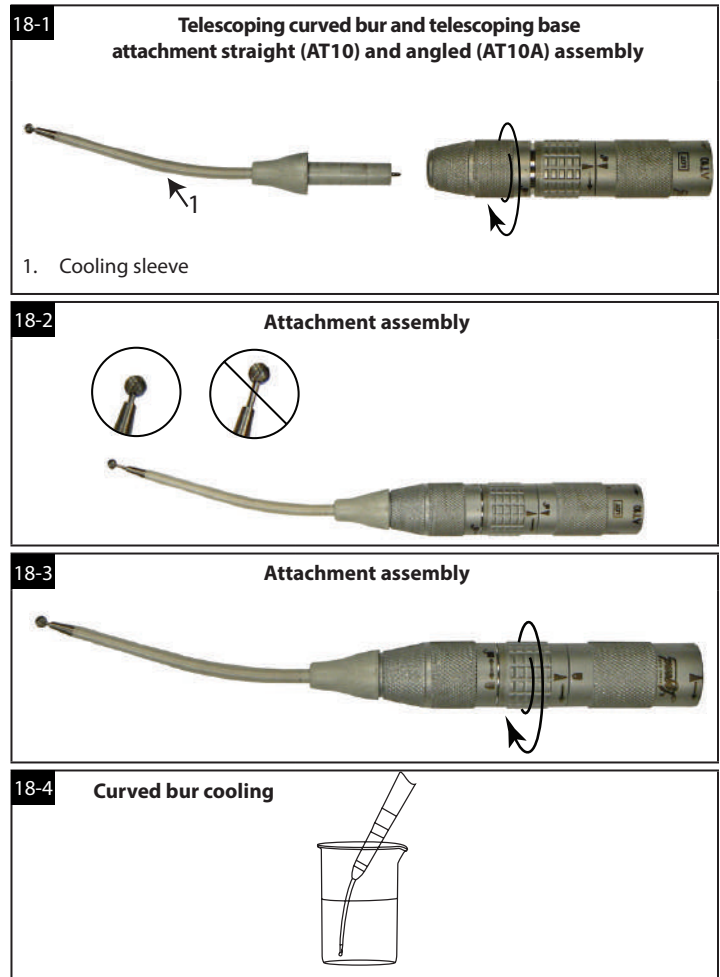
Telescoping curved bur and telescoping base attachment—straight (AT10) and angled (AT10A)

Assembly:

1. Assemble the attachment straight (AT10), or angled (AT10A) using the **Straight attachment Assembly** instructions.
2. Insert the base end of the curved bur into the AT10, or AT10A attachment until the hub is fully seated. To lock in place, turn the tube locking ring until finger tight (Figure 18-1).
Note: Do not over tighten.
3. Verify that the hub is in place by gently pulling on the bur.
4. Seat the bur in the AT10, or AT10A attachment by gently pushing on the bur (Figure 18-2). An audible click, heard and perceptible by touch, confirms that the bur is fully seated. Verify bur is seated by checking the bur head exposure (Figure 18-2).
5. Rotate the tool locking ring until the tool lock alignment mark is directly in line with the locked symbol (Figure 18-3).
6. Verify that the bur is secured by gently pulling on the bur.
7. Prior to initial use, soak the cooling sleeve by dipping it into a cup of saline or deionized (DI) water (Figure 18-4).
8. During use, copiously irrigate the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

Disassembly:

1. Rotate the tube locking ring towards the unlocked position.
2. Rotate the bur locking ring to the unlocked position.
3. Remove the curved bur from the AT10, or AT10A attachment.
4. Discard the curved bur.
5. Rotate the AT10, or AT10A attachment to the unlocked position on the motor case and lift the attachment off the motor.



Perforator (AD01 & AD03) attachment

Warning: A tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease the pressure supplied to the motor to prevent vibration. If vibration persists, change to a different tool size or geometry to prevent unintended tissue damage.

Notes:

- Refer to the cranial perforator manufacturer device IFU for the recommended speed specifications.
- A cranial perforator device may be installed in the attachment before the perforator attachment is installed on the motor.

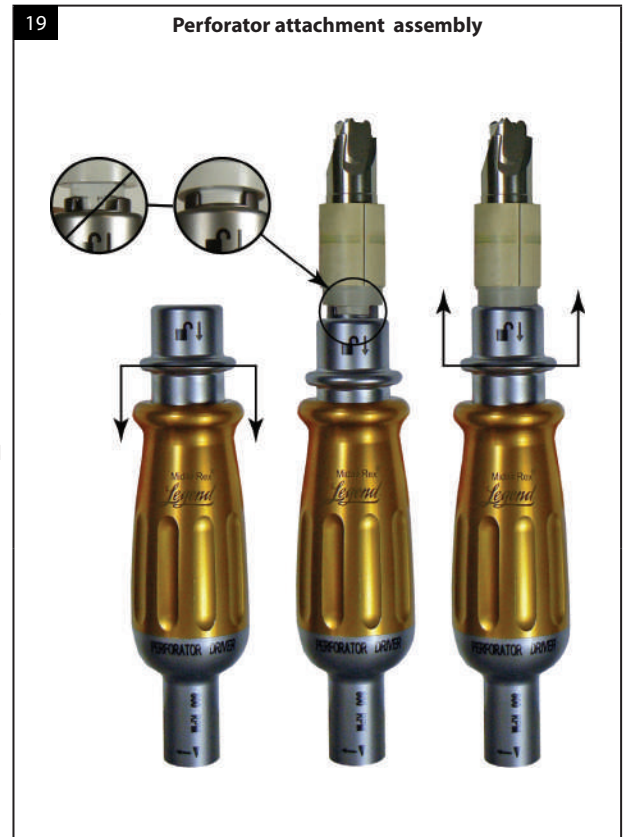
Assembly:

1. Assemble the attachment onto the motor using the **Straight attachment Assembly** Instructions.
2. To install a cranial perforator device with a hudson shank, pull back proximally on the collar of the perforator attachment. Insert a device and release the collar to its original position (Figure 19).
3. The speeds achievable by the AD01 and AD03 attachments are provided in **Table 5**.

Disassembly:

1. Pull back proximally on the collar of the perforator attachment and then remove the cranial perforator device.
2. Rotate the perforator attachment to the unlocked position and lift the attachment off of the motor.

Console setting	AD01	AD03
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	1,020 rpm
75,000 rpm	805 rpm	1,035 rpm



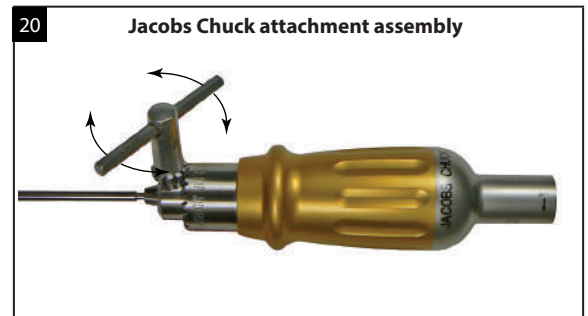
Jacobs Chuck attachment

Assembly:

1. Assemble the attachment onto the motor using the **Straight attachment Assembly** instructions.
2. Install the Jacobs Chuck key (Figure 20) and rotate it counterclockwise to open the ridged collar. Insert drill bit and tighten collar by turning the Jacobs Chuck key clockwise (Figure 20) until the tool is secure.

Disassembly:

1. Using the Jacobs key, open the collar.
2. Remove and discard the drill bit.
3. Rotate the Jacobs Chuck attachment to the unlocked position and lift the attachment off of the motor.



Angled double lock (DK) attachment

Notes:

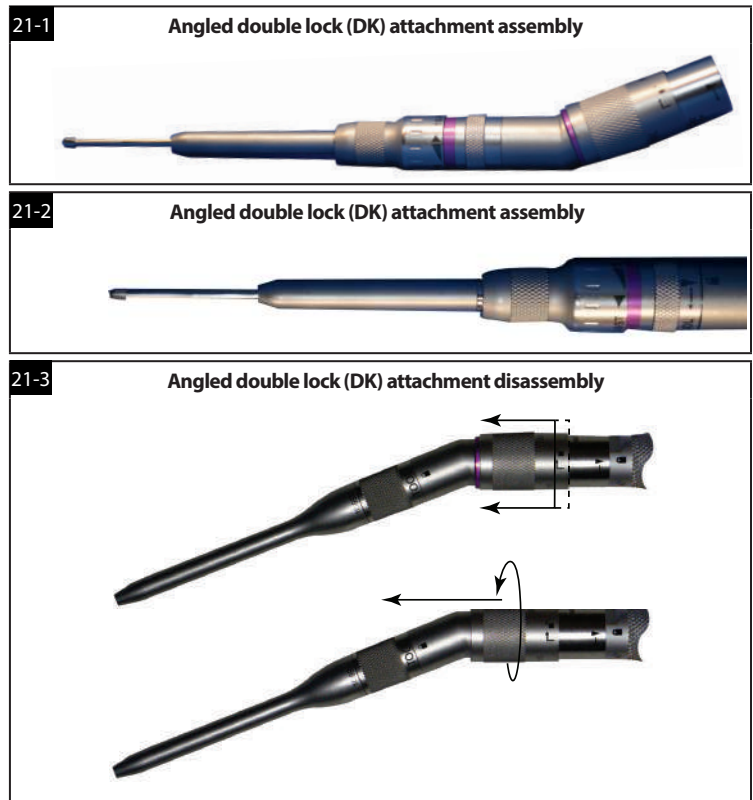
- Angled attachments with the same length, marking, and color band share the same dissecting tools.
- A dissecting tool may be installed and locked in the attachment before the angled attachment is installed onto the motor.

Assembly:

1. Assemble the attachment onto the motor using the **Angled attachment Assembly** instructions.
2. Insert the tool into the attachment with a slight rotational motion. An audible click, perceptible by touch, confirms that the tool is fully seated (Figure 21-1).
3. Rotate the tool lock in direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol (Figure 21-2).
Note: Pull on the tool to ensure that it is secured in the attachment.
4. The tool should rotate freely. If not, unlock the attachment, re-seat the tool, and re-lock the attachment.
5. Verify that both the attachment to motor and the tool-lock alignment mark is directly in line with the corresponding locked symbol.

Disassembly:

1. To remove the attachment, hold the motor in the palm of your hand, and push the sleeve on the attachment distally while turning the attachment to the unlocked position (Figure 21-3).
2. Release the sleeve and remove the attachment.

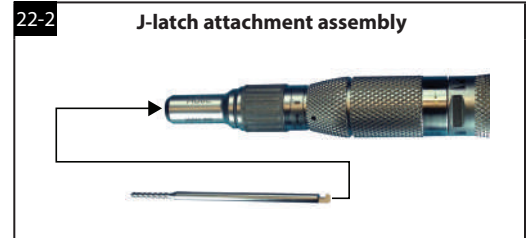
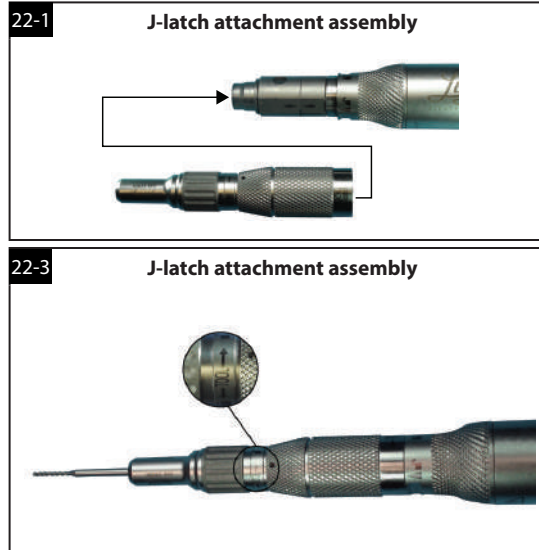


J-latch attachment

This attachment is designed for use with industry standard J-latch dissecting tools. Refer to the dissecting tool's labeling for information on specific operating requirements and limitations.

Assembly:

1. Assemble and secure the attachment onto the motor using the **Straight attachment Assembly** instructions (Figure 22-1).
2. Insert the tool into the attachment with a slight rotational motion. An audible click, perceptible by touch, confirms that the tool is fully seated (Figure 22-2).
3. Turn the tool lock sleeve in the direction shown on the attachment to lock the tool (Figure 22-3). Pull on the shaft of the dissecting tool to verify tool is secure.



Disassembly:

1. Turn the tool lock sleeve in the direction shown on the attachment to unlock the tool (Figure 22-3).
2. Remove the dissecting tool from the attachment and discard it.
3. Rotate the attachment on motor to the unlocked position.
4. Lift the attachment off of the motor.

Irrigation tubing set

Refer to the IPC™ System User's Guide for instructions to attach the tubing set to the IPC™ System.

Note: Clip may not fasten to small bore attachment after having been used on large bore attachment.

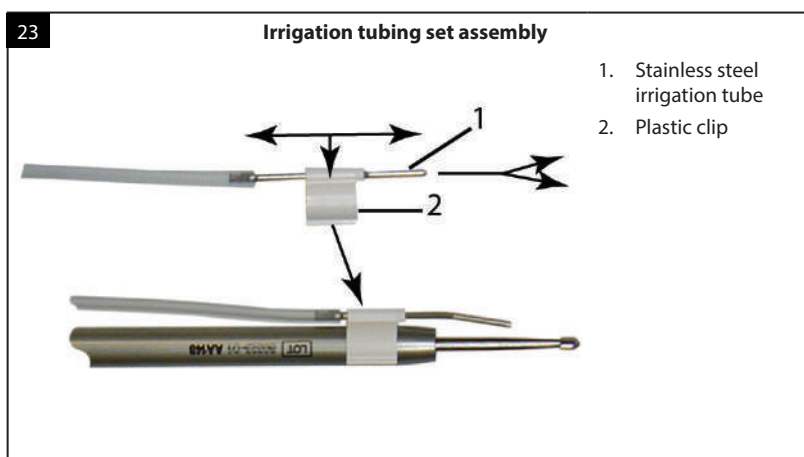
Note: Not for use with the curved bur.

Assembly:

1. Adjust the location of plastic clip on the stainless-steel irrigation tube (Figure 23).
2. Bend the irrigation tube to the desired angle.
3. Snap the clip onto the distal end of attachment (near the tool).

Disassembly:

1. Remove irrigation tubing set from attachment by pulling on the clip to detach it.
2. Similarly detach all clips.
3. Discard of the irrigation tubing set.



System set-up check

During set-up of system, verify functionality system prior to use:

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

Troubleshooting

If system devices require servicing or refurbishing, return devices to Medtronic Customer Service for quality assured service by factory-trained personnel who use genuine Medtronic system parts as required.

All system devices returned for servicing or refurbishing should be properly cleaned and sterilized prior to shipping.

Motor

Problem	Possible cause	Recommendations
Motor is too hot to touch/hold.	Inadequate cool down period following sterilization.	Motor must be allowed to cool down following steam sterilization.
	Attachment transferring heat to the motor.	Switch attachments to determine whether the heat is being generated by the motor or the attachment.
	Heavy side loading during dissection.	Discontinue use and rest the motor by using it intermittently or wrap the motor with a moist sterile towel.
Attachment will not seat properly on the motor.	Inadequate irrigation.	Ensure adequate irrigation to surgical site during bone dissection.
	Motor collet flats are not aligned.	Use the Legend motor wrench to rotate the flat closest to the motor case until its marker is aligned with the marker on the flat farthest away from the motor case.
	Motor does not run.	
Motor does not run.	Cables not properly connected.	Ensure motor and foot control cables are properly connected.
	Speed setting is too low.	Ensure that a speed greater than 10,000 rpm (EHS) or 3,000 rpm (Stylus) is selected. Check the IPC™ system for error status.
Motor with attachment rotates, but an abnormal noise is heard.	Attachment not properly installed and locked onto the motor.	Remove and reinstall the attachment and dissecting tool to ensure proper installation.
	Internal failure of motor and/or IPC™ system.	Replace motor or IPC™ system to isolate the problem.
	FCU not properly functioning.	Check for obstruction under the foot pedal. Replace FCU to isolate problem.
	Cables damaged.	Check cables for cracks, splits, or bent connector pins.
	Bearings are worn.	Change the attachment to isolate the location of the problem.
	Poor electrical connection.	Check all connections from electrical source to IPC™ system. Ensure motor and foot control cables are properly connected.
	Internal failure of motor, IPC™ system, or cable.	Change motor, console, or cable to isolate the failing component.

Problem	Possible cause	Recommendations
Attachments and telescoping tubes		
Attachment or telescoping tube has uncomfortable temperature to touch/hold.	Heat from worn attachment/tube bearings.	Do not use. Try another attachment/tube. Contact Medtronic Customer Service. Telescoping tubes are multi-use disposable. If problem is resolved with a new Telescoping tube, discard the over-heated tube.
	Attachment/tube is unclean due to improper cleaning procedures.	Check that appropriate cleaning procedures are being followed.
	Heavy side loading during dissection.	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 Customer Service.
Attachment/telescoping tube is bent, loose, damaged or missing a component.	Attachment mishandled, failed due to extended use or excessive force applied during use.	Do not use. Dispose of telescoping tube. Telescoping tubes are multi-use disposable. Contact Medtronic Customer Service.
Color band on attachment/telescoping tube fades or discolors.	Incorrect cleaning or sterilization method.	Use nomenclature markings on the attachment to match with a corresponding dissecting tool or contact Medtronic Customer Service.
	Use of chlorine based or corrosive agents.	Use recommended cleaning agents.
	Aging.	Telescoping tubes are multi-use disposable.
Tool is difficult to remove from attachment.	Aging of attachment.	Contact Medtronic Customer Service.
	Use of reprocessed tools.	Do not use reprocessed tools. Use only new tools.
	Device refurbished by a non-Medtronic service center.	For optimal performance, devices must be refurbished only by Medtronic.
	Improper cleaning.	Clean the attachment thoroughly according to the instructions in this manual.
Attachment has excess lubrication.	Over lubrication during cleaning process.	Visually inspect and wipe excess lubrication. Avoid over lubrication.
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.	Do not use. Contact Medtronic Customer Service. Check motor collet for debris. If confirmed, contact Medtronic Customer Service. Check for proper installation of tool in collet prior to installation of footed attachment.
	Bend caused by incorrect use.	Use proper technique when using attachment.
Contra-angle attachment is overheating.	The 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 of the angle head.	If heat continues or is excessive, contact Medtronic Customer Service.
Smoke is generated by the attachment or motor.	Attachment is not in the locked position.	Ensure the attachment is in the locked position.
		Ensure the tool is locked in the angled attachment.
When using a footed or rotating footed attachment, a gap does not exist between the tip of the tool and the foot of the attachment.	Improper installation of tool.	Remove attachment and tool and reinstall per instructions. Ensure the tool is fully seated in collet by verifying tactile click when installing the tool.
	Debris in collet.	Check motor collet for debris. If confirmed, contact Medtronic Customer Service.

Problem	Possible cause	Recommendations
Legend surgical dissecting tools		
Dissecting tool flails.	A non-Legend™ tool is being used.	Do not use. Replace with a Legend™ tool.
	Worn attachment or tube bearings.	Do not use. Replace attachment or tube to isolate the location of the problem. If flail is produced by a specific attachment, contact Medtronic Customer Service.
	Attachment/telescoping tube and tool are not compatible.	If the telescoping tube is failing, dispose of telescoping tube. Telescoping tubes are multi-use disposable.. Do not use. Check that the color code on the tool packaging matches the color code on the attachment/telescoping tube.
	Motor may be damaged.	Contact Medtronic Customer Service.
	Tool's size and geometry may contribute to flail at certain speeds.	Adjust the speed by changing the speed setting or foot/finger control. Do not use if flail persists. Change to a new tool.
Tool vibrates excessively.	Tool's size and geometry may create excessive vibration at certain speeds.	Adjust the speed. Change to a new tool.
Tool is dull.	Extended use of tool.	Change to a new tool.
	Reprocessed tool was used.	Do not use reprocessed tools. Use only new tools.
	Incorrect geometry.	Contact Medtronic Customer Service.
Tool will not seat properly in the motor or attachment collet.	Debris in collet of attachment or motor.	Clean the attachment or motor thoroughly according to the instructions in this manual. If cleaning does not correct the problem, Contact Medtronic Customer Service.
	A non-Legend™ tool is being used.	Replace with a Legend™ tool.

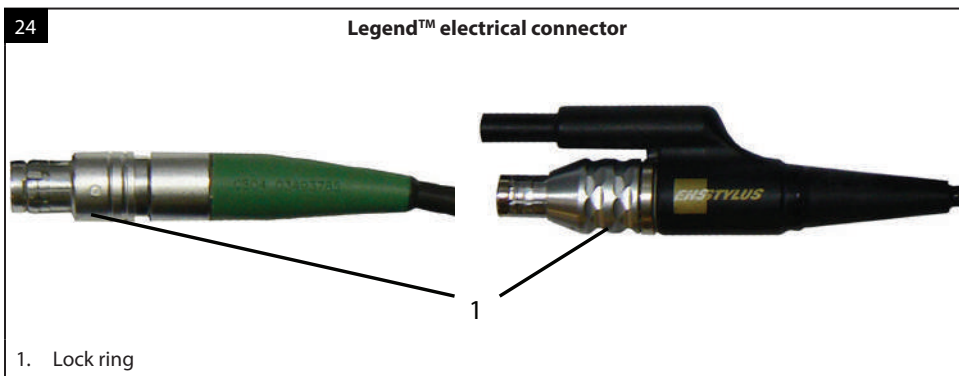
Post-operative instructions

Disconnect accessory cable from console

To disconnect non-silicone multi-pin cables from the IPC™ system, push the cable toward the IPC™ system and then pull out by the lock ring.

Note: Silicone insulated multi-pin and single-pin cable connectors do not have a lock ring (Figure 24). Remove these types of cable connectors straight from the connector panel.

Note: After disconnecting insulated connectors from the console, connectors that have debris under the insulator must be cleaned according to cleaning and sterilization instructions. If debris is still present after cleaning and sterilization, return to Medtronic Customer Service.



The Midas Rex™ Legend EHS™ system

Sterility

The Midas Rex™ Legend EHS™ system is REUSABLE and provided NON-STERILE. Components must be cleaned and sterilized prior to the first use and any reuse. The Midas Rex™ Legend EHS™ surgical dissecting tools and irrigation tubing set are provided STERILE and SINGLE USE only.

Legend EHS™ and Legend EHS Stylus™ system reprocessing instructions

Cleaning is the removal of organic soil. Effective cleaning:

- Minimizes the organic soil transfer from one patient to another.
- Prevents accumulation of residual soil throughout the device’s useful life.
- Allows for successful follow-up sterilization. Adequate reprocessing is contingent upon the thoroughness of cleaning.

Cleaning is the initial step. Sterilization occurs later in reprocessing and is intended to kill microorganisms to reduce the likelihood of transmission and possibilities of infection. To ensure acceptable reprocessing, there should be no delay between the cleaning, inspection, and sterilization.

Blood-borne pathogens - Universal precautions for handling this device after use should be observed by all hospital personnel according to OSHA standard 29 CFR 1910.1030, occupational exposure to blood-borne pathogens.

Motors	
Warnings and precautions	Do not soak/submerge devices. Do not use ultrasonic cleaners to clean 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 degradation in performance. Allow an adequate cooling period after steam sterilization.
Limitations on reprocessing	Dispose of attachments and telescoping tubes in accordance with hospital, administrative, or government policies. Due to safety and environmental concerns, Medtronic requests the return of electric motors for proper disposal at the end of the product useful life. End of useful life is normally determined by wear and damage due to use. Note: See the “Maintenance, inspection, and testing” section in this document to determine if the device is at its end of useful life.
Point of use	Reprocessing begins at the point of use. Do not allow blood, debris, or bodily fluids to dry on the device. Remove excess soil using cold running tap water 10–22°C (50–72°F). Tap water is defined as potable water with hardness value between 0.7 mmol/L to 2.0 mmol/L.
Containment and transportation	It is recommended that devices should be cleaned as soon as possible, preferably within 30 minutes, following use to limit fixation of contaminants. If the device cannot be reprocessed immediately, keep the device moist during transport. It is recommended that devices are reprocessed as soon as is practical following use. To prolong the life of the device, reprocess immediately after use.
Preparation for decontamination	Detach attachment from Legend EHS™ and Legend EHS Stylus™ motor. Remove and discard tool. Do not soak devices.
Preparation for cleaning: Automated	Rinse devices under running tap water with collet pointed down until no visible soil is noticed. A nylon brush may be used to aid in cleaning. Remove devices from instrument case before placing into washer-disinfector and allow devices to drain. Verify devices are visually clean prior to placing in instrument washer. Orient devices in the washer-disinfector by following manufacturer recommendations. Clean per recommended washer cycle below.

Motors**Cleaning: Automated****Warnings:**

- Use the instrument tray and the rigid sterilization container for sterilizing the re-usable devices only.
- Do not use the instrument tray and sterilization container for cleaning or disinfection of the reusable devices.
- Do not use alkaline cleaning for the instrument tray or the rigid sterilization container.

Precaution: Do not use ultrasonic cleaner. Review the washer-disinfector warnings above, before using this cleaning method.

Table 6: Neutral wash cycle parameters**Legend EHS™ and Legend EHS Stylus™ automated wash cycle using a neutral enzymatic detergent (pH 6.0-8.0)**

Phase	Recirculation time	Water temperature	Detergent type
Pre-wash	2 minutes (02:00)	Cold water 10 -16°C (50 -61°F)	Not applicable
Wash	5 minutes (05:00)	66°C (151°F) (set point)	Neutral enzymatic detergent, pH 6.0–8.0
Rinse	1 minute (01:00)	Hot tap water 43–55°C (109–131°F)	Not applicable

Table 7: Alkaline wash cycle parameters**Legend EHS™ and Legend EHS Stylus™ automated wash cycle using an alkaline detergent (pH 8.0-10.5)**

Phase	Recirculation time	Water temperature	Detergent type
Pre-wash	2 minutes (02:00)	Cold tap water 10–16°C (50–61°F)	Not applicable
Wash	5 minutes (05:00)	43°C (109°F) (set point)	Alkaline detergent*, pH 8.0–10.5
Rinse	1 minute (01:00)	Hot tap water 43–60°C (109–140°F)	Not applicable
Thermal rinse	1 minute (01:00)	90°C (194°F) (set point)	Not applicable
Purified water rinse	1 minute 30 seconds (01:30)	66°C (151°F) (set point)	Not applicable

If visible soil remains, repeat cleaning.

*Alkaline detergent manufacturers provide alkaline detergents concentrated. The alkaline detergents must be diluted per the detergent manufacturer's instructions for cleaning medical devices. Medtronic has verified alkaline detergent compatibility for working solutions up to 10.5 pH.

Cleaning: Manual

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 specific requirements.

Drying

If necessary, dry the devices with a clean, lint-free towel. Refer to the motor, attachment/tube, instrument tray, and sterilization container cleaning sections on specific drying instructions.

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

Note: The temperatures and times for sterilization are the minimum required.

Table 8: Legend EHS™ and Legend EHS Stylus™ steam sterilization

Cycle	Pre-vac	Gravity	Pre-vac	Pre-vac
Temperature	132°C (270°F)	132°C (270°F)	134°C (273°F)	134°C (273°F)
Time	4 minutes (04:00)	25 minutes (25:00)	3 minutes (03:00)	18 minutes (18:00)
Drying	15 minutes (15:00)	15 minutes (15:00)	10 minutes (10:00)	20 minutes (20:00)
STERRAD	Not validated for use with low temperature hydrogen peroxide gas plasma sterilization.			

Motors	
Maintenance, inspection and testing	<p>Do not reprocess for surgical use a device that has obvious damage or corrosion. Return to Medtronic for service.</p> <p>Visually inspect the reprocessed devices following cleaning. Inspection should be performed with adequate lighting. Magnification is not required. A device that shows or exhibits the properties listed below is at the end of its useful life. Attachments and telescoping tubes may be disposed of at the end of their useful life according to hospital, administrative, or government policies. Due to safety and environmental concerns, Medtronic requests the return of electric motors for proper disposal at the end of the product's useful life.</p> <ul style="list-style-type: none"> • Obvious damage or corrosion • Pitting, cracks, fractures, or bending • Illegible laser etchings, engravings, and other markings • Discoloration, corrosion, stains or rust. • Mechanisms that are rough or stuck. These are indications of bad O-rings, or damaged internal components for example, variable exposure collars, tool lock collar, and sleeves.
Storage	<p>Make sure that the container is dry before storage, and stored in cool, dry conditions at ambient room temperature. Store sterile devices in such a way that the sterile package is not compromised.</p>

Attachments/tubes	
Warnings and precautions	<p>Do not soak/submerge devices.</p> <p>Do not use ultrasonic cleaners to clean devices.</p> <p>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.</p> <p>The use of a washer-disinfector for cleaning may cause a degradation in performance.</p> <p>Allow an adequate cooling period after steam sterilization.</p>
Limitations on reprocessing	<p>Dispose of attachments and telescoping tubes in accordance with hospital, administrative, or government policies. Due to safety and environmental concerns, Medtronic requests the return of electric motors for proper disposal at the end of the product useful life.</p> <p>End of useful life is normally determined by wear and damage due to use.</p> <p>Note: See the "Maintenance, inspection, and testing" section in this document to determine if the device is at its end of useful life.</p>
Point of use	<p>Reprocessing begins at the point of use.</p> <p>Do not allow blood, debris, or bodily fluids to dry on the device. Remove excess soil using cold running tap water 10–22°C (50–72°F). Tap water is defined as potable water with hardness value between 0.7 mmol/L to 2.0 mmol/L.</p>
Containment and transportation	<p>It is recommended that devices should be cleaned as soon as possible, preferably within 30 minutes, following use to limit fixation of contaminants.</p> <p>If the device cannot be reprocessed immediately, keep the device moist during transport.</p> <p>It is recommended that devices are reprocessed as soon as is practical following use.</p> <p>To prolong the life of the device, reprocess immediately after use.</p>
Preparation for decontamination	<p>Detach attachment from motor. Remove and discard tool. Do not soak devices.</p>
Preparation for cleaning: Automated	<p>Rinse attachments/tubes under running tap water, until no visible soil is noticed.</p> <p>Attachments with moving parts must be actuated through their full range of motion under running tap water.</p> <p>While rinsing under running tap water, an appropriately sized nylon brush must be used internally (for straight, footed attachments and telescoping tubes only) and/or externally to aid in cleaning attachments.</p> <p>Remove devices from instrument case before placing into washer-disinfector and allow devices to drain.</p> <p>Variable exposure attachments (AVAXX, AVAXXDK, AVSXX) must be placed in the washer with their tube in the fully extended position.</p> <p>Verify devices are visually clean prior to placing in instrument washer.</p> <p>Orient devices in the washer-disinfector by following manufacturer recommendations.</p> <p>Clean per recommended washer cycle below.</p>

Attachments/tubes																																																									
Cleaning: Automated	<p>Precaution: Do not use ultrasonic cleaner. Review the washer-disinfector warnings above, before using this cleaning method.</p> <table border="1"> <thead> <tr> <th colspan="4">Table 9: Neutral wash cycle parameters</th> </tr> <tr> <th colspan="4">Legend™ attachments/tubes automated cleaning - neutral enzymatic detergent (pH 6.0–8.0)</th> </tr> <tr> <th>Phase</th> <th>Recirculation time</th> <th>Water temperature</th> <th>Detergent type</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>2 minutes (02:00)</td> <td>Cold water 10 -16°C (50 -61°F)</td> <td>Not applicable</td> </tr> <tr> <td>Wash</td> <td>5 minutes (05:00)</td> <td>66°C (151°F) (set point)</td> <td>Neutral enzymatic detergent, pH 6.0–8.0</td> </tr> <tr> <td>Rinse</td> <td>1 minute (01:00)</td> <td>Hot tap water 43 -55°C (109 -131°F)</td> <td>Not applicable</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="4">Table 10: Alkaline wash cycle parameters</th> </tr> <tr> <th colspan="4">Legend™ attachments/tubes automated cleaning - alkaline detergent (pH 8.0 -10.5)</th> </tr> <tr> <th>Phase</th> <th>Recirculation time</th> <th>Water temperature</th> <th>Detergent type</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>2 minutes (02:00)</td> <td>Cold tap water 10 -16°C (50 -61°F)</td> <td>Not applicable</td> </tr> <tr> <td>Wash</td> <td>5 minutes (05:00)</td> <td>43°C (109°F) (set point)</td> <td>Alkaline detergent* pH 8.0–10.5</td> </tr> <tr> <td>Rinse</td> <td>1 minute (01:00)</td> <td>Hot tap water 43 -60°C (109 -140°F)</td> <td>Not applicable</td> </tr> <tr> <td>Thermal rinse</td> <td>1 minute (01:00)</td> <td>90°C (194°F) (set point)</td> <td>Not applicable</td> </tr> <tr> <td>Purified water rinse</td> <td>1 minute 30 seconds (01:30)</td> <td>66°C (151°F) (set point)</td> <td>Not applicable</td> </tr> </tbody> </table> <p>If visible soil remains, repeat cleaning.</p> <p>*Alkaline detergent manufacturers provide alkaline detergents concentrated. The alkaline detergents must be diluted per the detergent manufacturer's instructions for cleaning medical devices. Medtronic has verified alkaline detergent compatibility for working solutions up to 10.5 pH.</p>	Table 9: Neutral wash cycle parameters				Legend™ attachments/tubes automated cleaning - neutral enzymatic detergent (pH 6.0–8.0)				Phase	Recirculation time	Water temperature	Detergent type	Pre-wash	2 minutes (02:00)	Cold water 10 -16°C (50 -61°F)	Not applicable	Wash	5 minutes (05:00)	66°C (151°F) (set point)	Neutral enzymatic detergent, pH 6.0–8.0	Rinse	1 minute (01:00)	Hot tap water 43 -55°C (109 -131°F)	Not applicable	Table 10: Alkaline wash cycle parameters				Legend™ attachments/tubes automated cleaning - alkaline detergent (pH 8.0 -10.5)				Phase	Recirculation time	Water temperature	Detergent type	Pre-wash	2 minutes (02:00)	Cold tap water 10 -16°C (50 -61°F)	Not applicable	Wash	5 minutes (05:00)	43°C (109°F) (set point)	Alkaline detergent* pH 8.0–10.5	Rinse	1 minute (01:00)	Hot tap water 43 -60°C (109 -140°F)	Not applicable	Thermal rinse	1 minute (01:00)	90°C (194°F) (set point)	Not applicable	Purified water rinse	1 minute 30 seconds (01:30)	66°C (151°F) (set point)	Not applicable
Table 9: Neutral wash cycle parameters																																																									
Legend™ attachments/tubes automated cleaning - neutral enzymatic detergent (pH 6.0–8.0)																																																									
Phase	Recirculation time	Water temperature	Detergent type																																																						
Pre-wash	2 minutes (02:00)	Cold water 10 -16°C (50 -61°F)	Not applicable																																																						
Wash	5 minutes (05:00)	66°C (151°F) (set point)	Neutral enzymatic detergent, pH 6.0–8.0																																																						
Rinse	1 minute (01:00)	Hot tap water 43 -55°C (109 -131°F)	Not applicable																																																						
Table 10: Alkaline wash cycle parameters																																																									
Legend™ attachments/tubes automated cleaning - alkaline detergent (pH 8.0 -10.5)																																																									
Phase	Recirculation time	Water temperature	Detergent type																																																						
Pre-wash	2 minutes (02:00)	Cold tap water 10 -16°C (50 -61°F)	Not applicable																																																						
Wash	5 minutes (05:00)	43°C (109°F) (set point)	Alkaline detergent* pH 8.0–10.5																																																						
Rinse	1 minute (01:00)	Hot tap water 43 -60°C (109 -140°F)	Not applicable																																																						
Thermal rinse	1 minute (01:00)	90°C (194°F) (set point)	Not applicable																																																						
Purified water rinse	1 minute 30 seconds (01:30)	66°C (151°F) (set point)	Not applicable																																																						
After cleaning: Automated	<p>After cleaning, lubricate attachments using an aerosol spray lubricant (such as Pana Spray) and perform the following steps to lubricate attachments:</p> <ol style="list-style-type: none"> 1. Holding the can approximately 10–15 cm (3–6 in.) away from the attachment, spray all movable components with three quick squirts. 2. Actuate movable components to ensure proper lubrication. 3. Remove excess lubricant with a clean cloth. 																																																								
Cleaning: Manual	<p>Wipe all attachments and telescoping tubes with a cloth, dampened with a prepared cleaner.</p> <p>Immerse the head of contra-angle attachments in prepared cleaner and run the motor for 1 minute.</p> <p>Other attachments and tubes may be mechanically agitated in cleaning solution, but not soaked or immersed.</p> <p>Use a nylon brush dampened with a prepared cleaner to clean the external surfaces and internal connecting surfaces of the attachments and tubes.</p> <p>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 prepared cleaner through the attachment or telescoping tube from rear to front to loosen and remove debris trapped inside.</p> <p>Actuate any moveable parts through their full range of motion to allow cleaner to thoroughly clean attachment, for example, sleeve on footed attachment, perforator attachment.</p> <p>Clean variable exposure attachments without adjusting the tube length first, then with the tube fully extended, and finally with the tube fully retracted.</p> <p>Rinse thoroughly with tap water.</p>																																																								
After cleaning: Manual	<p>After cleaning, lubricate attachments using an aerosol spray lubricant (such as Pana Spray) and perform the following steps to lubricate attachments:</p> <ol style="list-style-type: none"> 1. Holding the can approximately 10–15 cm (3–6 in.) away from the attachment, spray all movable components with three quick squirts. 2. Actuate movable components to ensure proper lubrication. 3. Remove excess lubricant with a clean cloth. 																																																								
Drying	<p>Thoroughly dry attachments. An air gun may be used to blow moisture out from rear to front of attachment.</p> <p>Note: Medtronic no longer recommends using the Legend attachment cleaning nozzle (PA120), as this may cause some attachments to overheat.</p>																																																								
Disinfection	No specific requirements.																																																								
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.																																																								

Attachments/tubes					
Sterilization	Note: The temperatures and times for sterilization are the minimum required.				
	Table 11: Legend attachments/tubes steam sterilization				
	Cycle	Gravity	Pre-vac	Pre-vac (FR/WHO)	Pre-vac (UK)
	Temperature	132°C (270°F)	132°C (270°F)	134°C (273°F)	134°C (273°F)
	Time	25 minutes (25:00)	4 minutes (04:00)	18 minutes (18:00)	3 minutes (03:00)
	Drying	15 minutes (15:00)	15 minutes (15:00)	20 minutes (20:00)	10 minutes (10:00)
STERRAD	Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.				
STERIS	Do not use liquid peracetic acid sterilization due to immersion procedure.				
Maintenance, inspection and testing	<p>Do not reprocess for surgical use a device that has obvious damage or corrosion. Return to Medtronic for service.</p> <p>Visually inspect the reprocessed devices following cleaning. Inspection should be performed with adequate lighting. Magnification is not required. A device that shows or exhibits the properties listed below is at the end of its useful life. Attachments and telescoping tubes may be disposed of at the end of their useful life according to hospital, administrative, or government policies. Due to safety and environmental concerns, Medtronic requests the return of electric motors for proper disposal at the end of the product's useful life.</p> <ul style="list-style-type: none"> • Obvious damage or corrosion • Pitting, cracks, fractures, or bending • Illegible laser etchings, engravings, and other markings • Discoloration, corrosion, stains or rust. • Mechanisms that are rough or stuck. These are indications of bad O-rings, or damaged internal components for example, variable exposure collars, tool lock collar, and sleeves. 				
Storage	Make sure that the container is dry before storage, and stored in cool, dry conditions at ambient room temperature. Store sterile devices in such a way that the sterile package is not compromised.				

Return policy for devices exposed to Transmissible Spongiform Encephalopathies (TSE)

Reusable devices that have been used on patients with suspected TSEs or Creutzfeldt-Jakob Disease (CJD) should be quarantined and not reused until a diagnosis is confirmed or excluded. Medtronic Powered Surgical Solutions (MPSS) will not authorize or accept the return of MPSS products that directly contacted a patient or are contaminated with a patient's body fluids that is suspected or confirmed with TSE or CJD diagnosis. Furthermore, MPSS recommends that all MPSS product used on a patient confirmed with or suspected of a TSE/CJD diagnosis be incinerated. If TSE/CJD is excluded as a diagnosis, the quarantined reusable device 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 device processing. Contact your Sales Representative for temporary device while original device is quarantined or for replacement of product incinerated under this policy.

Refurbishing or repairs

When the Legend EHS™ System requires servicing or refurbishing, contact Medtronic Powered Surgical Solutions Repair Services for a return authorization and instructions for returning the equipment. MPSS provides quality assured service by factory-trained personnel who use genuine Legend parts as required. All items being returned for servicing or refurbishing should be properly cleaned and sterilized prior to shipping.

US Customers Contact:

Refurbishing or repairs:

Medtronic Powered Surgical Solutions Repair Services
 800 335 9557 or 817 788 6440
 mmrcustomerservice@medtronic.com

Purchasing additional or replacement products:

800 433 7080 or 817 788 6440

Customers Outside the US:

Contact your Medtronic Sales Representative

Peak performance, reliability and maximum service life from your Legend EHS™ system may be assured by using only those Legend products for your Legend EHS™ system that are manufactured by and sold through MPSS, Fort Worth, Texas. While MPSS 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 number or e-mail address listed above. Due to safety and environmental concerns, MPSS requests the return of electric high-speed motors for proper disposal at the end of the product life cycles.

Planned maintenance

Planned maintenance information is provided as a guide to assist the customer in getting the greatest ownership value from their Legend EHS™ systems, while helping to maximize its performance, safety, and reliability. Maintenance is in addition to the required routine cleaning after each use.

The frequency of maintenance depends on how often the system is used and the conditions which the system is subjected to, such as during cleaning and sterilization. The demands on the system can vary greatly from facility to facility. The time between scheduled maintenance is determined by tool usage per motor per year and per month per motor. Adhere to the scheduled maintenance intervals in Table 12.

Maintenance level	Number of tools used per motor per year	Usage rate uses per month per motor	Number of uses per month per attachment**	Time interval
A	150–200	12–16*	19–23	3 months
B	100–149	8–11	15–18	4 months
C	50–99	4–7	12–15	5 months
D	<50	<4	<11	6 months

*A motor with usage rates greater than 16 uses per month should be returned for factory Medtronic maintenance at a 6-month interval.
 **Usage per month for most attachments. Some attachments may require more frequent checks.

Notes:

- If any damage, wear, rust or corrosion is observed with the product or if action is required beyond cleaning, do not use the product and return to Medtronic for service.
- The planned maintenance steps have been designed for a facility's biomedical department or equivalent to perform.
- The console, motor, cables, tool rack, and rigid sterilization containers have a limited warranty period of 1 year from the date of purchase. The attachments and telescoping tubes have a limited warranty period of 90 days from the date of purchase. After the warranty period, any costs incurred for repairing or refurbishing the system becomes the responsibility of the customer. This limited warranty does not include the cost associated with any of the factory-level service requirements identified in the planned maintenance schedule. Extended maintenance agreements are available.
- Failure to follow recommended service and planned maintenance schedules for attachments or motors may prevent tool from being secured properly. Identifying and following the scheduled maintenance intervals for the system will assist in reducing the potential for unanticipated down time as a result of wear.

For scheduled maintenance intervals 1, 2, 3, 5, 6, 7, 9, 10, and 11

Follow the detailed instructions for servicing the system in accordance with the 12 maintenance intervals.

Date of system purchase: _____ **Maintenance level:** _____

Scheduled maintenance	Level A months	Level B months	Level C months	Level D months	Date performed	Performed by
1st	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6		
2nd	<input type="checkbox"/> 6	<input type="checkbox"/> 8	<input type="checkbox"/> 10	<input type="checkbox"/> 12		
3rd	<input type="checkbox"/> 9	<input type="checkbox"/> 12	<input type="checkbox"/> 15	<input type="checkbox"/> 18		
4th	<input type="checkbox"/> 12	<input type="checkbox"/> 16	<input type="checkbox"/> 20	<input type="checkbox"/> 24	Factory service recommended - contact Medtronic	
5th	<input type="checkbox"/> 15	<input type="checkbox"/> 20	<input type="checkbox"/> 25	<input type="checkbox"/> 30		
6th	<input type="checkbox"/> 18	<input type="checkbox"/> 24	<input type="checkbox"/> 30	<input type="checkbox"/> 36		
7th	<input type="checkbox"/> 21	<input type="checkbox"/> 28	<input type="checkbox"/> 35	<input type="checkbox"/> 42		
8th	<input type="checkbox"/> 24	<input type="checkbox"/> 32	<input type="checkbox"/> 40	<input type="checkbox"/> 48	Factory service recommended - contact Medtronic	
9th	<input type="checkbox"/> 27	<input type="checkbox"/> 36	<input type="checkbox"/> 45	<input type="checkbox"/> 54		
10th	<input type="checkbox"/> 30	<input type="checkbox"/> 40	<input type="checkbox"/> 50	<input type="checkbox"/> 60		
11th	<input type="checkbox"/> 33	<input type="checkbox"/> 44	<input type="checkbox"/> 55	<input type="checkbox"/> 66		
12th	<input type="checkbox"/> 36	<input type="checkbox"/> 48	<input type="checkbox"/> 60	<input type="checkbox"/> 72	Factory service recommended - contact Medtronic	

The Midas Rex™ Legend EHS™ system

Console, motor, foot control, and cables

1. Visually inspect the power cord to verify that it does not have any damage to the insulation or to the blade of the connector and that there is no debris evident. Do not use the product if damage is found and return to Medtronic Customer Service.
2. Turn the rotational collet of the motor (Figure 25-1) using motor wrench PA130 to the position (Figure 25-2).
3. Run the motor and verify that the pedal smoothly controls the motor speed.
4. If the display shows any errors, then the motor is not properly connected or the motor cable may need servicing or the connectors of the motor or motor cable are dirty, or the motor or console may need servicing.
5. Press the REV button on the foot control several times and verify that the console display toggles between << REV and FWD >>. Leave the console in the << REV mode. Press the foot pedal to start the motor in REV and listen for 3 beeps when the motor starts in REV.
6. Run motor for 3 minutes at 70,000 rpm for EHS or 5 minutes at 60,000 rpm for EHS Stylus. Verify that the motor case, attachment base and tip do not become uncomfortably hot to the touch.
7. Verify that when the foot pedal is released the motor stops and does not continue to run. If the motor continues to run when the foot pedal is released, do not use and return system to Medtronic Customer Service.
8. Using the motor wrench, turn the rotational collet such that it aligns with stationary collet (Figure 25-3).

25-1 Turn the rotational collet



25-2 Rotational collet turned and ready for testing



1. Motor collet - Stationary
2. Motor collet - Rotational

25-3 Rotational collet aligned with the stationary collet



Attachments: Straight, footed, perforator, Jacobs Chuck, and telescoping

Note: Telescoping tubes are multi-use disposable and do not receive scheduled maintenance. Discard if excessive heat or vibration is present.

1. Visually inspect the etching and color ring to ensure it remains legible and the color is distinguishable.
2. Visually inspect the attachment tube and base for any signs of debris or damage.
3. Connect an attachment to the motor and verify a tactile and audible click when the attachment is locked on the motor.
4. Visually and physically inspect (pull and twist by hand) the attachment for any loose or loosening components. If any components are loose, do not use and return the attachment to Medtronic Customer Service.
5. Straight/footed: Visually inspect the attachment tip for any signs of wear. The tip should remain round with no evidence of deformation.
6. Footed: Visually inspect the foot. The foot and/or leg of the attachment should not be bent, or damaged.
7. Perforator and Jacobs Chuck: Visually inspect the perforator collet for any signs of wear or deformation.
8. Heat check
 - For telescoping attachment, insert an appropriate telescoping tube into the base.
 - Attach and lock the attachment onto the motor. Check to ensure that there is a tactile and an audible click when the attachment is locked on the motor.
 - Connect the motor to an IPC™ system with FCU attached.
 - Turn the IPC™ system on.
 - Run the motor for 3 minutes.
 - Feel the motor case, the attachment base, and the attachment tip (except telescoping) to ensure they are not uncomfortably hot to the touch.
9. Repeat steps 1-7 for each straight/footed/telescoping/perforator/Jacobs Chuck drive attachment in this system.

Attachments: Angled, contra, and metal cutting

1. Visually inspect the etching and color ring to ensure it remains legible and the color is distinguishable.
2. Visually inspect the attachment tube and base for any signs of debris or damage.
3. Connect an attachment to the motor and verify a tactile and audible click when the attachment is locked on the motor.
4. Visually and physically inspect (pull and twist by hand) the attachment for any loose or loosening components. If any components are loose, do not use and return the attachment to Medtronic Customer Service.
5. Visually inspect the attachment tip for any signs of wear. The tip should remain round with no evidence of deformation.
6. Heat check angled and metal cutting attachment
 - Attach and lock the attachment onto the motor. Check to ensure that there is a tactile and an audible click when the attachment is locked on the motor. Turn the tool locking ring to the locked position on the angled attachment.
 - Connect the motor to an IPC™ system with FCU attached.
 - Turn the IPC™ system on and run motor for 3 minutes.
 - Feel the motor case, the attachment base, the knuckle (angled area for angled attachment only), and the attachment tip to ensure they are not uncomfortably hot to the touch. Turn the tool locking ring to the unlocked position on conclusion of the inspection.
7. Visually inspect the head to tube joint for the contra-angled attachment for stability, that is, there is no loosening of this joint.
8. Heat check contra-angled attachment
 - Attach and lock the contra-angled attachment onto the motor. Check to ensure that there is a tactile and an audible click when the attachment is locked on the motor.
 - Connect the motor to an IPC™ system with FCU attached.
 - Set speed to 62,000 rpm using the speed down button for EHS or the speed up button for EHS Stylus.
 - Turn the IPC™ system on and run the motor for 1 minute.
 - Feel the motor case, the attachment base, the knuckle (contra-angled area), and the attachment tip to ensure they are not uncomfortably hot to the touch.

For scheduled maintenance intervals 4, 8, 12**Motor and attachments: straight, footed, perforator, Jacobs chuck, telescoping, angled, and metal cutting**

At these maintenance intervals, it is important that the units be returned to Medtronic Customer Service for factory level inspection and service.

Note: The costs associated with any of the factory level service requirements are not included in the limited warranty. Extended maintenance agreements are available.

Storage

Store devices in a clean, dry area with other sterile devices.

Disposal

Dispose of these devices in accordance with hospital, administrative, or government policies.

Midas Rex™ Legend EHS™ system Limited Warranty* (U.S. customers only)








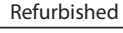




















































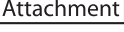

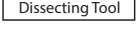
- A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic Midas Rex™ Legend EHS™ System. This Limited Warranty is extended only to the buyer purchasing the Legend EHS™ System directly from Medtronic or from its affiliate or its authorized distributor or representative. The Midas Rex™ Legend EHS™ System includes the motor, instrumentation cases and trays (hereafter referred to as System Components), motor attachments (hereinafter referred to as "Attachments"), telescoping tubes (hereinafter referred to as Semi-reusable Components) and dissecting tools and other accessories not listed above and jointly referred to as Legend EHS™ System, unless specifically noted.
1. Should a System Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (one year from the date of sale of a new System Component or 90 days from the date of sale of a refurbished or used System Component), Medtronic will either repair or replace the Motor Component or any portion thereof.
 2. Should an Attachment fail to function to Medtronic's published specifications during the term of this Limited Warranty (90 days from the date of sale of a new Attachment), Medtronic will either repair or replace the Attachment or any portion thereof.
 3. Should a Semi-reusable Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (30 days from the date of sale of a new Semi-reusable Component), Medtronic will replace the Semi-reusable Component or any portion thereof.
 4. Should a Single Use Component fail to function to Medtronic's published specifications prior to its "use by" date Medtronic will replace the Single Use Component.
- B. To qualify for this Limited Warranty, these conditions must be met:
1. The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
 2. The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
 3. Medtronic must be notified in writing within 30 days following discovery of a defect.
 4. The Product must be returned to Medtronic within 30 days of Medtronic receiving notice as provided for in (3) above.
 5. Upon examination of the Product by Medtronic, Medtronic shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services, if applicable, have been performed on the Product
 6. Only Legend EHS System dissecting tools that are manufactured, authorized, and quality controlled by Medtronic may be used.
- 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.

After the warranty period, any costs incurred for repair/refurbishing become the responsibility of the customer. This limited warranty does not include the cost associated with any of the factory level service requirements identified in the preventive maintenance schedule. Extended Maintenance Agreements are available.

Symbols

The following symbols can appear on this device and related packaging.

	Responsible person in Great Britain (England, Wales and Scotland).		Quantity		Instrument Case
	Authorized Representative in the European Community		Is Approximately Equal To		Motor
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.		Use With		Refurbished
	Consult Instructions for Use		AC Power		Multi-Use Disposable Attachment
	Follow Instructions for Use		Protective Earth		Part Number
	Caution		Applied Part Duty Cycle		Do not use if package is damaged and consult instructions for use
	Do Not Immerse		On/Off Button		Do not re-sterilize
	Do Not Oil		Start/Stop		Contains Hazardous Substances
	Do Not Dispose Of This Product In The Unsorted Municipal Waste Stream. Dispose Of This Product According to Local Regulations. See Recycling.Medtronic.com for Instructions On Proper Disposal Of This Product.		Unlocked		Medical Device
	Do not re-use.		Locked		Single sterile barrier system
	Non-Sterile		Forward		Single sterile barrier system with protective packaging inside
	Sterilized using EO		Reverse		Single sterile barrier system with protective packaging outside
	Sterilized using Irradiation		Pump Head 1		Single sterile barrier system with protective packaging outside
	Protected Against Vertical Water Drops		Pump Head 2		Double sterile barrier system
	Contains DEHP (di-2-ethyl hexyl phthalate)		Handpiece		Importer
	RF Transmitter (Interference May Occur)		Top FCU Button / Handpiece Button		Distributor
	Type BF Applied Part		Foot Pedal Connector		Diameter
	Manufacturer		Left FCU Button / Mode Button		
	Date of Manufacture		Right FCU Button		
	Use By Date		Fine Irrigant Adjustment		
	Serial Number		Output		
	Catalog Number		Accessory		
	Lot Number		Adapter		
	Package Contents		Attachment		
			Brush		
			Dissecting Tool		
			Electrical High Speed Motor Connector		

175036EN D

2022-04

May be covered by U.S. Patents:
Medtronic.com/patents

©2022 Medtronic, Inc.
Made in USA. Printed in USA.
All rights reserved.

Medtronic, Medtronic logo and
Further, Together are
trademarks of Medtronic.

TM* Third party brands are trademarks
of their respective owners.
All other brands are trademarks
of a Medtronic company.



Medtronic Powered Surgical Solutions

4620 North Beach Street
Fort Worth, Texas 76137 USA
1 800-433-7080



**Authorized Representative in the
European Community**

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
+31 45 566 8000



Medtronic Limited

Building 9, Croxley Park
Hatters Ln
Watford
WD18 8WW
United Kingdom
+44(0) 1923 212 213

Medtronic Australian Sponsor:

Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park, NSW 2113 Australia

Medtronic of Canada Ltd

99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
+1 905 460 3800

**Europe/Middle East/Africa
Medtronic International Trading Sàrl**

Route du Molliou 31
Case Postale 84
CH- 1131 Tolochenaz
Switzerland
+41 21 802 7000

medtronic.com
manuals.medtronic.com

RxOnly C €2797
UK CA0086

Medtronic