PTSC224

Medtronic

MIDAS REX® MR7

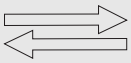
Pneumatic High-Speed System
Pneumatyczny system wysokoobrotowy
Pneumatický vysokorychlostní systém
Nagy sebességű pneumatikus rendszer

Instruction Manual
Instrukcja obsługi
Návod
Használati útmutató

Rx Only

Symbols

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

	Attention, see Instructions for Use.	TUBE	Tube Control
Rx Only	United States federal law restricts this device to sale by or on the order of a physician.		Air Pressure Relief
REF	Reference Number		Use with
LOT	Lot Number	MULTI-USE DISPOSABLE ATTACHMENT	Multi-Use Disposable Attachment
SN	Serial Number	Instrument Case	Instrument Case
	Quantity	Lubricant/Diffuser	Lubricant/Diffuser
	For single patient use only. Do not re-use, re-process, or re-sterilize this product. Re-use, re-processing or re-sterilization may compromise the structural integrity of the device and/ or create a risk of contamination of the device, which could result in patient injury, illness, or death.	Dissecting Tool	Dissecting Tool
≈	Approximately equal to	Attachment	Attachment
STERILE	Non-Sterile	Control Unit	Control Unit
STERILE R	Sterilized by Gamma Irradiation	Refurbished	Refurbished
	Use by date	Accessory	Accessory
	Date of manufacture	REGULATOR	Regulator
	Temperature Limitations	Bone Mill	Bone Mill
	Unlock	MOTOR	Motor
	Lock	Brush	Brush
	On	Adapter	Adapter
	Off	! USA	USA Only
	Finger-Operated Control		Manufacturer
	Foot-Operated Control		Do not dispose to unsorted municipal waste.
CE 0086	Compliant with European Council Directive MDD 93/42/EEC.	TOOL	Tool Control
EC REP	Authorized Representative in the European Community		Consult Instructions for Use

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General Information

Read and understand this manual before use of the MR7 System.

The Midas Rex® MR7 system is designed for use by medical professionals familiar with powered surgical instrumentation. The surgeon is responsible for learning the proper techniques in the use of this system, as inappropriate use may potentially be harmful. It is strongly recommended that the surgeon and dedicated operating room personnel are knowledgeable with the use of this equipment by being trained in Medtronic Midas Rex Hands-On Workshops or by one of the local authorized representatives.

The MR7 system consists of the following components:

- MR7 or MR7 Touch Motor
- MR7 Pneumatic Control Unit with Various Connectors
- MR7 Regulator Hose
- MR7 Lubricant/Diffuser Cartridge
- MR7 Triton® Adapter (optional)
- Legend® Attachments*
- Legend® Dissecting Tools*

*The MR7 system uses the same attachments and dissecting tools as the Legend® Pneumatic High-Speed System.

Indications for Use

The Medtronic Midas Rex MR7 System is a pneumatically operated surgical instrument system. The pneumatic motors provide 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.

Contraindications

None

Special Notices

The words warning, caution 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 physician may be involved. Disregarding this information could result in injury to the patient or physician.

CAUTION: A caution 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.

General Safety Precautions

WARNINGS:

- Do not use the Midas Rex MR7 System before proper cleaning and sterilization.
- Do not operate the Midas Rex MR7 System in the presence of Magnetic Resonance Imaging devices.
- Do not use damaged, faulty, or modified Midas Rex MR7 System components. Inspect the Midas Rex MR7 System for damage prior to each use:
    - Check the motor's exhaust hose for cracks or tears.
    - Visually inspect attachments and tools. Do not use bent or damaged tools.
    - Install attachment and dissecting tool, then briefly run motor.
        * Check motor for overheating and leaking lubricant.
        * Check attachment for overheating.
        * Check dissecting tool for flail.
- Do not operate the Midas Rex MR7 System without eye protection.
- Motors and attachments which fail due to extended use may allow a component to detach and fall from the motor or attachment, and may cause patient injury.
- Heavy side loads and/or long operating periods may cause the device to overheat. If overheating occurs:
    - Never place an overheated motor on the patient or draping during surgery.
    - Discontinue use and rest the motor by using intermittently, or wrap the motor/attachment interface with a moist sterile towel.
    - If the motor is passed off, the receiver should grasp the motor by the proximal end close to the motor hose.
- To avoid injury to the patient or user, do not place the handpiece on the patient or in an unsecured location, when not in use.
- Midas Rex MR7 motors should only be operated when the attachment is in the 🔒 position.

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

High Vacuum Steam: 270° F (132° C) for 5 minutes

Gravity Displacement: 270° F (132° C) for 15 minutes

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

No Latex Policy

Legend and MR7 products, packaging materials, labels, package inserts, and similar items manufactured by and/or for Medtronic Powered Surgical Solutions (MPSS) do not contain latex.

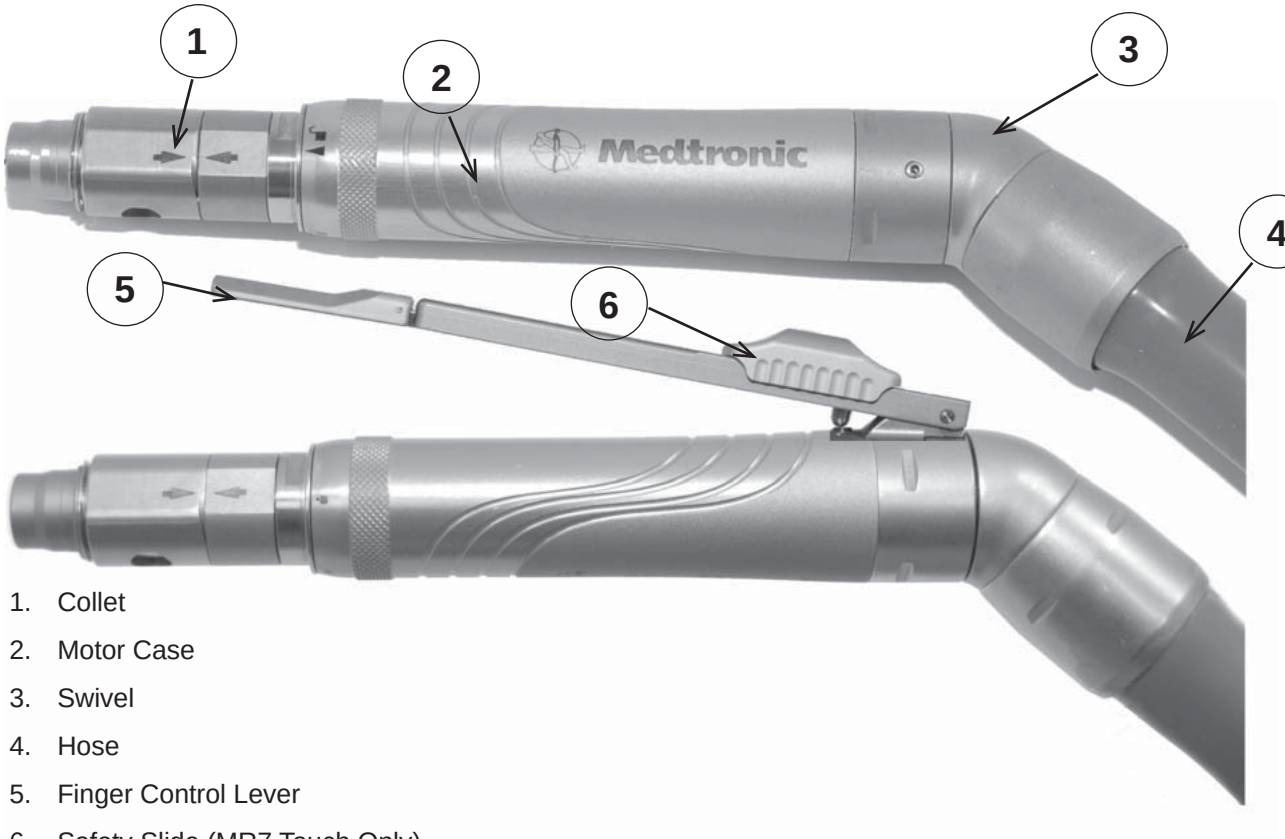
System Components

Non-Disposable Components

MR7 Motor

The MR7 motor is a high-speed, high-torque motor used to dissect bone and biomaterials.

Figure 1: Motor Components



1. Collet
2. Motor Case
3. Swivel
4. Hose
5. Finger Control Lever
6. Safety Slide (MR7 Touch Only)

In addition to the components listed in Figure 1, each MR7 motor has a lubricant/diffuser housing at the end of the motor hose, as seen in Figure 2.

Figure 2: Lubricant/Diffuser Housing

WARNING: Use only Medtronic Midas Rex Legend or MR7 devices with an MR7 motor. Use of other devices may cause injury or damage equipment, and will void the manufacturer's warranty.

Pneumatic Control Unit

The pneumatic control unit (Figure 3) provides variable speed motor control controls through a foot pedal. It also allows the user to switch between finger and foot control of the motor (if applicable).

Regulator

The regulator (Figure 4) controls the delivery pressure of compressed gas to the pneumatic control unit. The pressure gauges monitor cylinder pressure (right gauge) and delivery pressure (left gauge).

Note: Outlet pressure gauge accurate to +/- 12 psi.

Instrument Case

The instrument case (Figure 5) is used to organize equipment.

Regulator Hose

Connects from the gas source to the pneumatic control unit to deliver compressed gas.

Figure 3: Pneumatic Control Unit

Figure 4: Regulator

Figure 5: Instrument Case

N2 DISS to Male Schrader Adapter

The N2 DISS to male Schrader adapter (Figure 6) allows for the regulator hose to be attached to a female Schrader in-house gas connection. A N2 DISS to female Schrader adapter is also available for connection of the regulator hose to a male Schrader in-house gas connection.

Figure 6: N2 DISS to Male Schrader Adapter

N2 DISS to Air DISS Adapter

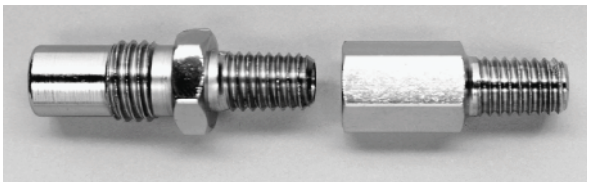
The N2 DISS to air DISS adapter (Figure 7) allows for the regulator hose to be attached to an Air DISS in-house gas connection.

Figure 7: N2 DISS to Air DISS Adapter

N2 DISS to WF4 Adapter

The N2 DISS to WF4 adapter (Figure 8) allows for the regulator hose to be attached to a Midas Rex safety valve regulator previously used for Midas Rex Classic or Midas Rex III motors. The in-line oiler must be removed from the safety valve regulator.

Figure 8: N2 DISS to WF4 Adapter



Motor Wrench

The motor wrench (Figure 9) is used to align arrows on motor collet flats prior to installation of a Legend attachment.

Figure 9: Motor Wrench

Triton Adapter

The Triton adapter (Figure 10) allows the Triton handpiece to be driven by the MR7 pneumatic control unit. It functions much the same way as the Triton port on the Legend pneumatic control unit, except that it is connected between the control unit and the gas source, rather than being integrated into the control unit

Figure 10: Triton Adapter

Legend Attachments

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

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

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

Be sure to match the color code and nomenclature on the Legend Dissecting Tool packaging with the color band and nomenclature on the Legend Attachment.

Disposable Components

WARNING: Use only Medtronic Midas Rex Legend or MR7 devices with an MR7 motor. Use of other devices may cause injury or damage equipment, and will void the manufacturer's warranty.

Lubricant/Diffuser Cartridge

The lubricant/diffuser cartridge (Figure 11) provides lubrication to the motor and filters oil from exhausted air.

Figure 11: Lubricant/Diffuser Cartridge

Telescoping Tubes

Telescoping tubes (Figure 12) provide support to the rotating dissecting tool. Telescoping tubes are disposable following multiple uses and should be discarded when heat or excessive vibration is noticed or insertion of tools becomes difficult.

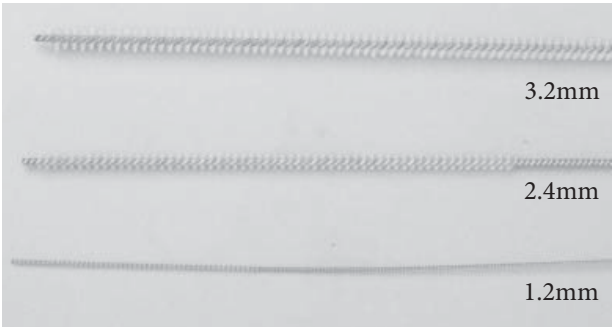
Figure 12: Telescoping Tube

Cleaning Brushes

Cleaning brushes (Figure 13) are used to clean debris from lumen of attachments and telescoping tubes. Sized for an internal bore diameter of 3.2 mm, 2.4 mm or 1.2 mm in Legend Attachments and Telescoping Tubes.

NOTE: Cleaning brushes will not pass through angled, contra-angle, metal cutting, perforator, or Jacobs Chuck attachments, because they are not cannulated.

Figure 13: Cleaning Brushes

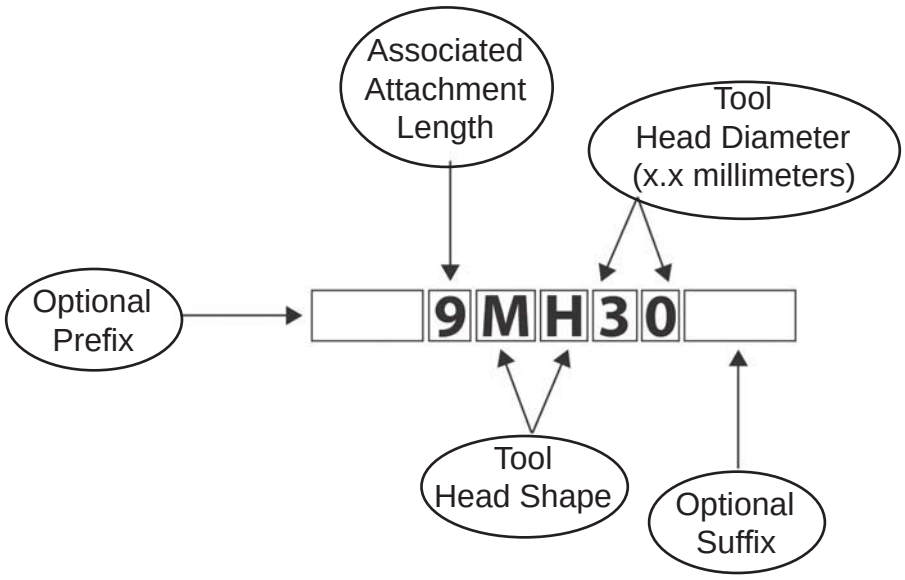


Legend® Dissecting Tools

Legend dissecting tools are sterile cutting tools, intended for cutting bone and biomaterials.

Dissecting Tool Nomenclature

Part numbers for Legend dissecting tools follow a standard naming convention, which is described in the diagram below. A basic part number consists of the associated attachment length, the tool head shape, and the tool head diameter. Part numbers may 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)

F...	For use with footed attachments
MC	For use with metal cutting attachments
T	For use with telescoping attachments

Tool Head Shapes (not all inclusive)

AC	Acorn	**MH**	Match Head
BA	Ball	**OV**	Oval
CY	Cylinder	**RT**	Reverse Taper
HM	Hole Maker	**TA**	Tapered
HS	Hole Saw	**TD**	Twist Drill

Tool Number Suffixes (note that more than one of the suffixes listed may be combined in a single part number)

L	Long	**S**	Spiral
D	Diamond	**SH**	Short
X	Extra	**DC**	Diamond Coarse
F	Fine	**DX**	Diamond Extra Coarse
C	Carbide	**MN**	Mednext Tool Design

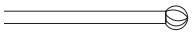
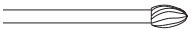
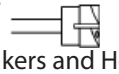
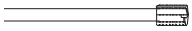
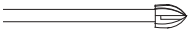
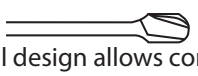
WARNINGS:

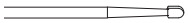
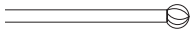
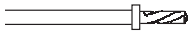
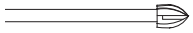
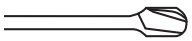
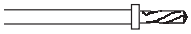
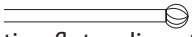
- Dissecting tools are for single-use only. Do not attempt to sterilize them. The dissecting tools are packed sterile and are not intended for repeat use. To prevent contamination, use only once.
- Do not use an attachment and dissecting tool combination that results in tool flail or excessive vibration.
- Do not attempt to remove a tool while the motor is running.
- Do not attempt to remove a tool from an overheated motor or attachment.
- Do not use the device if the package is opened or damaged.

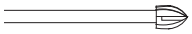
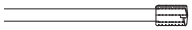
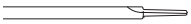
General Guidelines For Attachment and Tool Applications

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

WARNING: Be sure to match the color code and nomenclature on the Legend Dissecting Tool packaging with the color band and nomenclature on the Legend Attachment. Failure to do so could result in injury to the patient or operating room staff.

Surgical Application	Commonly Used Attachments	Commonly Used Dissecting Tools	Suggested Motor(s)
Spine	8-B, 9-M, 14-AM, 15-A	**Match Head**  Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, etc. **Ball**  Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, sinus dissection, etc. **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. **Hole Maker/Saw**  Matched sets of Hole Makers and Hole Saws are efficient and effective for interbody fusion. **Cylinder**  Effective bone sculpting and planing. For graft shaping, debridement, corpectomy, decortication, interbody fusion, fusion takedown, etc. **Acorn**  Curved design varies dissection efficiency with varied approach angles. For entry hole, laminotomy, bone shaping, debridement, corpectomy, decortication, fusion takedown, etc.	MR7, MR7 Touch
	Telescoping	**Match Head**  Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, etc.	MR7, MR7 Touch
	Footed, Straight	**Tapered** Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, entry hole, suture hole, midface advancement, etc.	

Surgical Application	Commonly Used Attachments	Commonly Used Dissecting Tools	Suggested Motor(s)
Neurosurgical–Cranial	7-6ST, 8-B, 9-M, 10-9ST, 14-AM, 15-A	**Match Head**  Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, etc. **Ball**  Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, sinus dissection, etc. **Twist Drill**  Helical design with stop produces a hole with a precise depth. Ideal for plating. **Acorn**  Curved design varies dissection efficiency with varied approach angles. For entry hole, laminotomy, bone shaping, debridement, corpectomy, decortication, fusion takedown, etc.	MR7
	Telescoping	**Match Head**  Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, etc.	
	Footed	**Tapered** Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, entry hole, suture hole, midface advancement, etc.	
General Surgery and Plastic Surgery (Craniofacial/ Maxillofacial/ Sternotomy)	7-6ST, 8-B, 9-M, 10-9ST, 14-AM	**Match Head** Elongated spherical design allows controlled, delicate dissection. For entry hole, nerve decompression, osteophyte removal, sinus dissection, etc. **Ball**  Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, sinus dissection, etc. **Tapered** Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, entry hole, suture hole, midface advancement, etc. **Twist Drill**  Helical design with stop produces a hole with a precise depth. Ideal for plating.	MR7, MR7 Touch
Ear, Nose, and Throat (Otology, Neurootology)	7-6ST, 10-9ST	**Ball**  Helical cutting flutes dissect bone or cement effectively from a wide variety of approach angles. For debridement, decortication, sinus dissection, etc.	MR7

Surgical Application	Commonly Used Attachments	Commonly Used Dissecting Tools	Suggested Motor(s)
Orthopaedics	8-B, 9-M, 14-AM, 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, sinus dissection, etc. **Tapered**  Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, entry hole, suture hole, midface advancement, etc. **Acorn**  Curved design varies dissection efficiency with varied approach angles. For entry hole, laminotomy, bone shaping, debridement, corpectomy, decortication, fusion takedown, etc. **Cylinder**  Effective bone sculpting and planing. For graft shaping, debridement, corpectomy, decortication, interbody fusion, fusion takedown, etc.	MR7, MR7 Touch
	Footed	**Tapered**  Slender design for precise dissection with minimal bone loss. For transection, osteotomy, graft harvesting, bone shaping, entry hole, suture hole, midface advancement, 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.	MR7, MR7 Touch

Setting up the Operating Room

Power Source Requirements

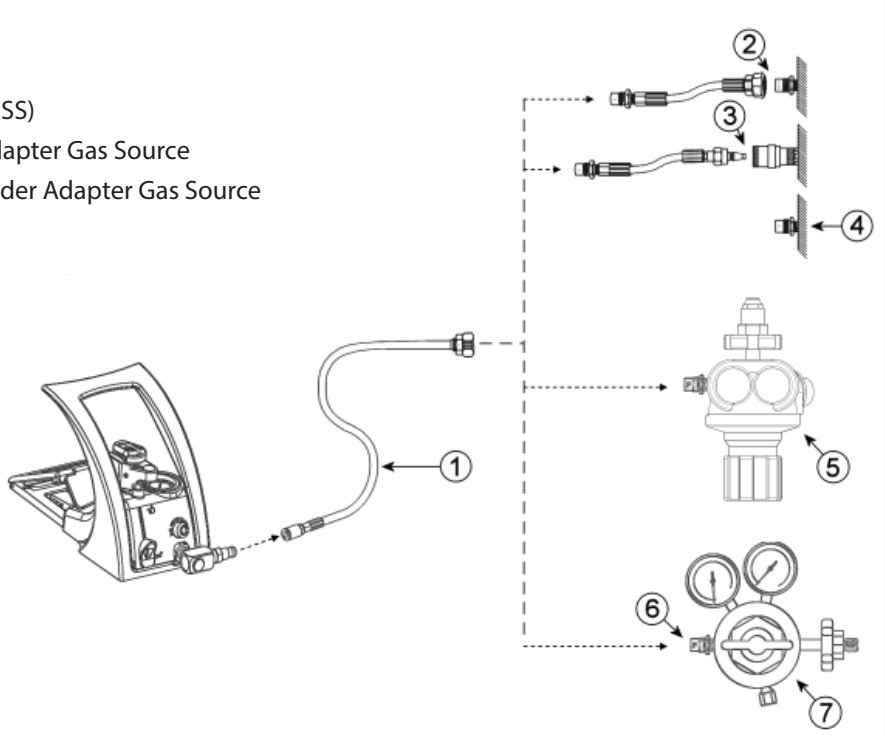
Required Operating (Dynamic) Pressure	Nominal Operating (Dynamic) Pressure	Approximate Flow Rate Required	Gas Type
80–120 psi	100 psi	12 cubic feet/min.	Nitrogen or Dry-Filtered Compressed Air
5.5–8.3 bar	6.9 bar	340 liters/min.	

CAUTION: Do not run the motor at an operating pressure above or below the required operating pressure range. Operating pressure below 80 psi (5.5 bar) may not provide proper lubrication to the motor. Operating pressure above 120 psi (8.3 bar) may damage or reduce the life of the motor.

Pneumatic Connections

Figure 14: Gas Connection Options

1. Regulator Hose (N2 DISS)
2. N2 DISS to Air DISS Adapter Gas Source
3. N2 DISS to Male Schrader Adapter Gas Source
4. Gas Source (N2 DISS)
5. Regulator
6. DISS/WF4 Adapter
7. Regulator



CAUTION: If you are using the Midas Rex Safety Valve Regulator instead of the Legend Regulator, you must replace the in-line oiler with the DISS/WF4 adapter before use.

Setting up the MR7 System

Installing the Oiler Cartridge

WARNING: Do not use the MR7 system with the Midas Rex in-line oiler. The MR7 motor is sufficiently lubricated by the lubricant/diffuser on the motor hose, and will be over-lubricated if the Midas Rex in-line oiler is used.

1. Set the non-running (static) pressure to 80–120 psi (5.5–8.3 bar) at the gas source. Operating (dynamic) pressure may be adjusted later.
2. Hold the lubricant/diffuser cartridge perpendicular to the housing (Figure 15), and press the cartridge's circular fitting onto the housing's circular receptacle (Figure 16), breaking the foil seal.
3. Rotate the cartridge down until it clicks into place.
4. Verify that the 🔒 symbol on the cartridge is lined up with the notch on the housing (Figure 17).

WARNINGS:

- Failure to properly secure the lubricant/diffuser cartridge may cause injury to operator and/or operating room staff.
- Do not attempt to remove the lubricant/diffuser cartridge while the system is pressurized.

CAUTIONS:

- Do not use an MR7 motor without a lubricant/diffuser installed.
- Do not use a lubricant/diffuser cartridge for more than one hour of drill time.
- Do not re-use a lubricant/diffuser cartridge. It is a single-use product.
- Do not attempt to refill a used lubricant/diffuser cartridge.
- Do not use a lubricant/diffuser cartridge if it appears to be damaged, or if the inner foil seal is punctured.

Figure 15: Aligning the Lubricant/Diffuser Cartridge with the Housing

Figure 16: Pressing the Cartridge onto the Housing

Figure 17: Correctly Installed Lubricant/Diffuser Cartridge

Connecting the Motor

Connect the motor hose to the motor port on the top of the pneumatic control unit, by swinging the port cover to the side and pressing the end of the hose into the port (Figure18).

WARNING: Do not pinch, kink, obstruct, cut, tear, or step on the motor/exhaust hose. This may cause the hose to burst, potentially injuring the patient or user.

NOTES:

- If using the MR7 Touch motor, slide the control slide on the pneumatic control unit to the position (Figure 19). This will automatically depress and lock the foot pedal. The control will not lock into the position unless the motor hose is connected into the motor port. When the motor hose is removed from the motor port, the foot pedal will return to normal position.
- If using the Triton Power Surgical Instrumentation System in conjunction with the MR7 motor, use the optional Triton adapter to connect the Triton hose. Refer to the documentation accompanying the adapter for connection instructions.
- The motor's exhaust hose may have an oily film on the external surface from pressure and/or temperature differentials following sterilization. Wipe the exhaust hose with a sterile cloth prior to use. If motor continues to have oil on the exhaust hose, return the motor to MPSS for refurbishing.

WARNING: To avoid injury to the patient or user, do not use the pneumatic control unit to operate systems other than the MR7, Legend, and Triton systems.

Prior to installation of a Legend attachment and dissecting tool, ensure that the arrows on the motor collet flats are aligned (Figure 20). If the arrows are not aligned, use the motor wrench to turn the collet flat closest to the motor case until its arrow is aligned with the arrow on the other collet flat.

WARNING: To avoid injury when using the MR7 Touch motor, ensure the safety slide is in the "O" position before installing the attachment and tool.

Figure 18: Connecting the Motor Hose to the Motor Port

Figure 19: Finger/Foot Control Slide

Figure 20: Aligning the collet flats

Installing an Attachment and Tool

WARNING: Dissecting tool flutes are sharp and may perforate surgical gloves. Tools may be grasped with a hemostat to aid in installation and removal.

Straight Attachments

Installation:

1. Slide the attachment over the motor collet, aligning the triangular markers (Figure 21). You will feel and hear the attachment click into place when it is fully seated.
2. Insert the dissecting tool into the attachment with a slight rotational motion (Figure 22). You will feel and hear the tool click into place when it is fully seated in the attachment.
3. Turn the attachment to the position on the motor case (Figure 23). Gently pull on the shaft of the dissecting tool to verify proper installation.

Removal:

Removal is the reverse of installation.

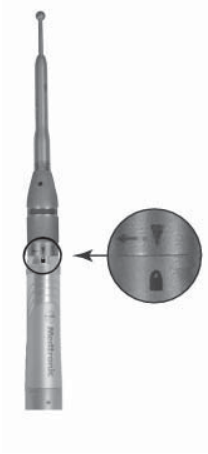
Specialized Attachments

See *Appendix A—Specialized Attachments* for installation and removal instructions for other attachments.

Figure 21: Sliding the Attachment over the Motor Collet

Figure 22: Inserting the Dissecting Tool into the Attachment

Figure 23: Attachment in the Locked Position



Activating the Motor

NOTE: In order to activate the MR7 Touch motor, the safety slide on the finger control switch must be in the | position, and the control slide on the foot control must be in the position. The control slide will not lock in the position unless a motor is connected to the motor port.

1. Activate the motor by pressing on the foot control pedal (Figure 24), or by pressing on the finger control lever (MR7 Touch motor only).
2. Adjust operating pressure as needed at the compressed gas source until supply pressure gauge on pneumatic control unit reads within a range of 80–120 psi (5.5–8.3 bar) as required. Operating pressure (with motor running) will decrease slightly from the non-running (static) pressure setting when the motor is activated.

Figure 24: Foot Control Pedal

Figure 25: MR7 Finger Control Switch

WARNINGS:

- Do not use excessive force to pry or push bone with the attachment or tool during dissection. This could cause the tool to break and cause injury to the patient or operating room staff.
- Use adequate irrigation during dissection, to prevent thermal necrosis.
- MR7 motors should only be operated when the attachment is in the position.

NOTE: To decrease pressure, turn down the in-house compressed gas source or loosen the pressure handle on the regulator. Push down on the pressure relief at the pneumatic control unit to exhaust excess pressure in the hoses. Then re-adjust pressure as needed.

Disassembling the MR7 System

Depressurize the System

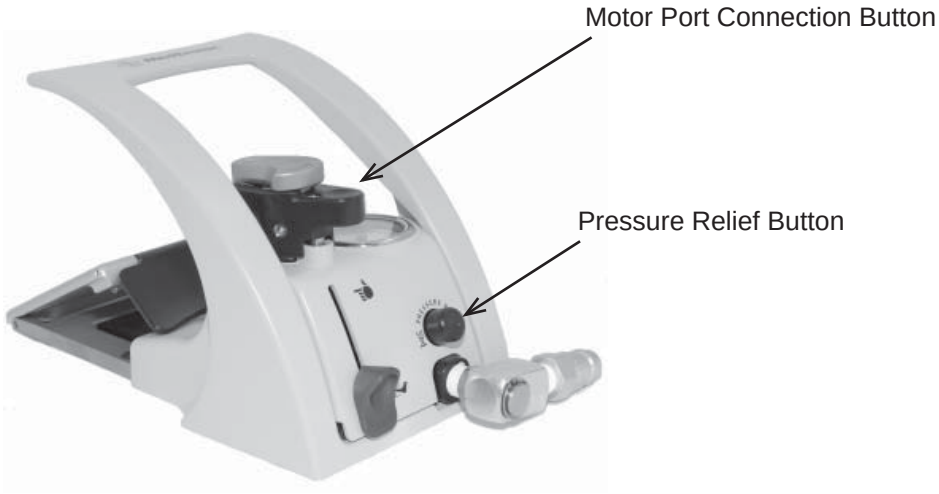
1. Turn off the compressed gas at the source.
2. Press the pressure relief button on the pneumatic control unit, to release remaining gas.

WARNING: Do not disassemble equipment before the gas is released from control unit.

Disconnect Hoses

Release the motor hose from the control unit, by holding the hose firmly and pressing the motor port connection button.

Figure 26: Motor Port Connection and Pressure Relief Buttons



Discard the Lubricant/Diffuser Cartridge

Remove the lubricant/diffuser cartridge from the housing and discard it.

CAUTION: Do not re-use a lubricant/diffuser cartridge. It is a single-use product.

Remove the Attachment and Tool

1. Follow the applicable removal instructions in the *Installing an Attachment and Tool* section of this manual to remove the attachment and tool from the motor.

WARNING: Dissecting tool flutes are sharp and may perforate surgical gloves. Tools may be grasped with a hemostat to aid in installation and removal.

2. Discard used dissecting tools in an appropriate container.

Cleaning & Sterilizing the MR7 System

MR7 Motor

Warnings and Precautions	Do not soak/submerge MR7 devices. Do not use ultrasound to clean MR7 devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization. Use ONLY nylon cleaning brushes. Non-nylon cleaning brushes leave residue that may prevent the tool from being secured properly in the handpiece.
Limitations	Verify functionality prior to re-use.

INSTRUCTIONS					
Point of Use	No particular requirements. Follow hospital procedures.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	No particular requirements. Follow hospital procedures.				
Cleaning: Automated (Do NOT use ultrasonic washer)	Review the washer-disinfector warning above, before using this cleaning method. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. Verify that devices are visually clean after automated cleaning. Recommended Washer Cycle Pre-Wash: Cold tap water, 2 min. Wash: 66oC, 5 min. using a neutral enzymatic detergent, pH 6.0–8.0 Rinse: Hot tap water, 1 min.				
Cleaning: Manual	Wipe all external surfaces of the motor and hose, and wipe inner surface of oiler housing 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. If using the MR7 Touch motor, be sure to brush under the finger control lever. 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.				
Disinfection	No particular requirements. Follow hospital procedures.				
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization:				
	Cycle:	Gravity	Pre-vac	Pre-vac (FR/WHO)	Pre-vac (UK)
	Temperature:	132°C	132°C	134°C	134°C
	Time:	25 min.	4 min.	18 min.	3 min.
	Drying:	15 minutes	15 minutes	20 minutes	10 minutes
	*Items contaminated with Transmissible Spongiform Encephalopathies (TSE) agents may be decontaminated using steam autoclave at a temperature of 134–137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles as referenced in NHS Estates HTM 2010 parts 4 & 6: Appendix 2, Items Contaminated With TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. Medtronic recommends that all products used on a patient suspected or confirmed with a TSE diagnosis be incinerated.				
	STERRAD Sterilization: Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.				
	100% EtO Sterilization Parameters: Preconditioning: 51–59°C, 70 ±5% relative humidity, 30 min. Temperature: 51–59°C Relative humidity: 70 ±5% Ethylene oxide concentration: 725 ± 25mg/L Gas exposure time (full-cycle): 4 hours Aeration: 18 hours at 51–59°C				
	Steris: Do not use liquid peracetic acid sterilization due to immersion procedure.				

Maintenance, Inspection and Testing	Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. After cleaning and sterilization, verify functionality prior to re-use.
Storage	Store with other sterile devices.

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

Legend Attachments / Tubes

Warnings and Precautions	Do not soak/submerge Legend devices. Do not use ultrasound to clean Legend devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization. Use ONLY nylon cleaning brushes. Non-nylon cleaning brushes leave residue that may prevent the tool from being secured properly in the handpiece.
Limitations	Verify functionality prior to re-use.

INSTRUCTIONS	
Point of Use	No particular requirements.
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.
Preparation for Decontamination	No particular requirements. Follow hospital procedures.
Cleaning: Automated (Do NOT use ultrasonic washer)	Review the washer-disinfector warning above, before using this cleaning method. Manually rinse attachments/tubes under tap water, until no visible soil is noticed, before placing them into the automatic washer. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. Recommended Washer Cycle Pre-Wash: Cold tap water, 2 min. Wash: 66°C, 5 min. using a neutral enzymatic detergent, pH 6.0–8.0 Rinse: Hot tap water, 1 min.
Cleaning: Manual	Wipe all attachments and telescoping tubes with a cloth, dampened with a surgical instrument cleaning solution. Immerse the head of Contra-Angle attachments in surgical instrument cleaning solution and run the motor for 1 minute. Other attachments and tubes may be mechanically agitated in cleaning solution, but not soaked or immersed. A nylon brush dampened with a surgical instrument cleaning solution may be used to clean the external surfaces and internal connecting surfaces of the attachments and tubes. Straight attachments, footed attachments and telescoping straight tubes have special cleaning brushes sized to the attachment's or telescoping tube's internal diameter. Push the brush wet with surgical instrument cleaning solution through the attachment or telescoping tube from rear to front to loosen and remove debris trapped inside. Move any moveable parts back and forth to allow solution to thoroughly clean attachment, e.g., sleeve on footed attachment, perforator attachment. Rinse thoroughly with tap water. Thoroughly dry attachments. An air gun may be used to blow moisture out from rear to front of attachment. Using an aerosol spray lubricant (such as Pana Spray), perform the following steps to lubricate attachments: Holding the can approximately 10–15 cm (3–6 in.) away from the attachment, spray all components that move, rotate, or slide with three quick squirts. Articulate movable components to ensure proper lubrication. Remove excess lubricant with a clean cloth.
Disinfection	No particular requirements Follow hospital procedures.
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.

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

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

MR7 Pneumatic Control Unit / Regulator Hose / Triton Adapter / Instrument Case

Warnings and Precautions	Do not soak/submerge MR7 devices. Do not use ultrasound to clean MR7 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. Do not sterilize the MR7 pneumatic control unit, regulator hose, or Triton adapter.
Limitations	Verify functionality prior to re-use.

INSTRUCTIONS	
Point of Use	No particular requirements. Follow hospital procedures.
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.
Preparation for Decontamination	No particular requirements. Follow hospital procedures.
Cleaning: Automated (Do NOT use ultrasonic washer)	Not validated.
Cleaning: Manual	Wipe the pneumatic control unit, regulator hose, Triton adapter, and instrument case with a cloth dampened with surgical instrument cleaning solution after each use.
Disinfection	No particular requirements. Follow hospital procedures.
Packaging	No particular requirements. Follow hospital procedures.
Sterilization	Do not sterilize pneumatic control unit, regulator hose, or Triton adapter.
Maintenance, Inspection and Testing	Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. Verify functionality prior to re-use.
Storage	Do not store with sterile devices.

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

Transmissible Spongiform Encephalopathies (TSE) Return Policy

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

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

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

Troubleshooting

NOTE: All Legend and MR7 devices returned for servicing or refurbishing should be properly cleaned and sterilized prior to shipping.

Motor not Running or Low on Power:

Possible Cause	Solution
Hoses not properly connected.	Make sure all connections are secure.
Operating pressure inadequate.	Check gas supply pressure gauge. Increase pressure according to compressed gas requirements, if necessary.
Attachment not properly installed and locked onto the motor.	Remove and re-install attachment and tool to ensure proper installation and locking of attachment onto motor.
Foot pedal on pneumatic control unit not functioning properly.	Check for obstructions under the foot pedal. If foot pedal continues to fail, return the pneumatic control unit to MPSS to be refurbished.
Motor stalls.	Manually spin the dissecting tool, then activate the motor. If the motor continues to stall, return it to MPSS to be refurbished.

Motor Continues to Run:

Possible Cause	Solution
Pneumatic control unit is not functioning properly.	Depressurize the system and return the pneumatic control unit to MPSS to be refurbished.
Finger control is not functioning properly.	Return motor to MPSS to be refurbished.
Pneumatic control unit is locked in the finger control position.	Move the finger control lever to the foot control position.

System Makes an Abnormal Noise:

Possible Cause	Solution
Inadequate lubrication.	Check for proper installation of the lubricant/diffuser cartridge. If the problem persists, replace the cartridge. If replacing the cartridge doesn't fix the problem, return the motor to MPSS for refurbishing.
Motor's exhaust hose is damaged, or internal pressure hose is detached.	Depressurize the system and return the motor to MPSS to be refurbished.
Worn bearings.	Switch attachments to determine whether the bearings are failing in the motor or in the attachment. Return the failing component to MPSS to be refurbished.
Attachment not properly installed and locked onto the motor.	Remove and reinstall attachment and tool to ensure proper installation and locking of the attachment onto the motor.
Safety relief valve has been activated by high air pressure.	Ensure that air operating/dynamic air pressure is no higher than 120 psi.

Motor is Too Hot to Touch/Hold:

Possible Cause	Solution
Inadequate cool down period following sterilization.	Motor must be allowed to cool down following steam sterilization.
Inadequate lubrication.	Check for proper installation of the lubricant/diffuser cartridge.
Attachment transferring heat to the motor.	Switch attachments to determine whether the heat is being generated by the motor or the attachment. Return the failing component to MPSS for refurbishing.
Heavy side loading during dissection.	Discontinue use and rest the motor by using it intermittently or wrap the motor with a moist sterile towel. If overheating continues, return the motor to MPSS for refurbishing.
Inadequate irrigation.	Ensure adequate irrigation to surgical site during bone dissection.

Attachment Will not Properly Seat on the Motor:

Possible Cause	Solution
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.

Tool is Difficult to Remove from Attachment:

Possible Cause	Solution
Aging of attachment. Improper cleaning. Use of reprocessed tools. Use of an unauthorized refurbisher.	Return to MPSS to be refurbished, or purchase new equipment.

16-MF Contra-Angle Attachment is Overheating:

Possible Cause	Solution
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 2cm from the distal end of the attachment and at the right of the angle head.	Verify pressure setting of 80 psi (5.5 bar). If heat continues or is excessive, return the attachment to MPSS to be refurbished or purchase new equipment.

Perforator is Running too Slow:

Possible Cause	Solution
Pressure set incorrectly.	Check the pressure setting at the foot control.

Dissecting Tool Flails:

Possible Cause	Solution
A non-Legend dissecting tool is being used.	Replace with a Legend dissecting tool.
Worn attachment or tube bearings.	Try another attachment or tube to isolate the location of the problem. If the attachment is failing, return it to MPSS. If the tube is failing, dispose of it and use a new tube.
Attachment/tube and tool are not compatible.	Match color code on the dissecting tool packaging to the color code on the attachment/tube.
Motor is damaged.	Return motor to MPSS to be refurbished.
Dissecting tool's size and geometry may contribute to flailing at certain speeds.	Adjust the speed by changing the pressure setting or foot/finger control. Do not use if flailing persists. Change dissecting tools.

Dissecting Tool Vibrates Excessively:

Possible Cause	Solution
Dissecting tool's size and geometry may create excessive vibration at certain speeds.	Adjust the speed by changing the pressure setting or foot/finger control. Change dissecting tools.

Dissecting Tool Will not Seat Properly in the Motor or Attachment Collet:

Possible Cause	Solution
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, return the attachment or motor to MPSS to be refurbished.
A non-Legend dissecting tool is being used.	Replace with a Legend dissecting tool.

Smoke is Generated by the Attachment or Motor:

Possible Cause	Solution
Attachment is not in the locked position.	Make sure the attachment is in the locked position.

Refurbishing or Repairs

When the MR7 System requires servicing or refurbishing, contact Medtronic Powered Surgical Solutions Repair Services for a return authorization and instructions for returning the equipment. Medtronic Powered Surgical Solutions provides quality assured service by factory-trained personnel who will utilize genuine Midas Rex Legend parts as required. All items being returned for servicing or refurbishing should be properly cleaned and sterilized prior to shipping.

Contact:

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

Peak performance, reliability and maximum service life from your MR7 System may be assured by using only those Midas Rex Legend products for your MR7 System that are manufactured by and sold through Medtronic Powered Surgical Solutions, Fort Worth, Texas. While Medtronic Powered Surgical Solutions guarantees complete compatibility among its products within a specific product line, the dissecting tools are designed for single-use only, and Medtronic disclaims any responsibility when reprocessed dissecting tools are used. If you would like more information about the patient and product risks associated with reprocessed tools, please contact the number or e-mail address listed above.

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

PTSC224

Preventative Maintenance

The *Midas Rex MR7 System Preventive Maintenance Manual* has been developed to assist you in getting the greatest ownership value from your MR7 System, while helping to maximize its performance, safety and reliability. The scheduled preventive maintenance/service program is in addition to the required routine cleaning after each use. Please refer to the preventive maintenance manual for the specific steps necessary to maintain the MR7 System.

Limited Warranty

A. This Limited Warranty provides the following assurance to the purchaser of a Medtronic Midas Rex® MR7 Pneumatic High Speed System. This Limited Warranty is extended only to the buyer purchasing the MR7 System directly from Medtronic or from its affiliate or its authorized distributor or representative. The Midas Rex® MR7 Pneumatic High Speed System includes the motor, foot control, instrumentation cases and trays (hereafter referred to as System Components), straight and angled 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 MR7 Pneumatic High Speed 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 thirty (30) days following discovery of a defect.

(4) The Product must be returned to Medtronic within thirty (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

C. This Limited Warranty is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the MR7 System, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

D. 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. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this Limited Warranty is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion 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.

Appendix A—Specialized Attachments

Angled Attachments

Installation:

1. Slide the attachment over the motor collet, aligning the triangular markers (Figure 27). You will feel and hear the attachment click into place when it is fully seated.
2. Turn the attachment to the 🔒 position on the motor case (Figure 28).
3. With the "tool lock" in the 🔓 position, insert the dissecting tool into the attachment with a slight rotational motion (Figure 29). You will feel and hear the tool click into place when it is fully seated.
4. Turn the tool lock to the 🔒 position (Figure 30). Gently pull on the shaft of the dissecting tool to verify proper installation.

NOTE: A dissecting tool may be installed in the attachment before the angled attachment is placed on the motor.

CAUTION: Hold the handpiece assembly by the attachment, so that the attachment does not inadvertently loosen from the handpiece.

Removal:

Removal is the reverse of installation.

Figure 27: Sliding the Attachment over the Motor Collet

Figure 28: Attachment in the Locked Position

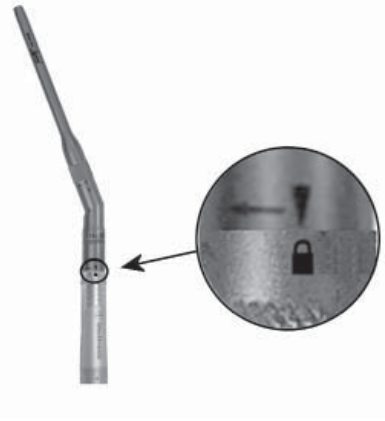


Figure 29: Inserting the Dissecting Tool into the Attachment

Figure 30: Tool Lock in the Locked Position

Angled Double Lock Attachments

Installation:

1. Slide the attachment over the motor collet, aligning the triangular markers.
2. Pull the attachment towards the motor and turn the attachment to the 🔒 position.
3. With the "tool lock" in the 🔓 position, insert the dissecting tool into the attachment with a slight rotational motion. You will feel the tool click into place when it is fully seated.
4. Turn the tool lock to the 🔒 position. Gently pull on the shaft of the dissecting tool to verify proper installation.
5. On Variable Exposure Attachments, use the TUBE adjustment ring to adjust the exposure of the dissecting tool. With the tool pointing away from you, turn the ring to the right to increase the length of the tube, thereby decreasing the exposure of the tool. Turn the ring to the left to decrease the length of the tube, thereby increasing the exposure of the tool.

Removal:

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 🔓 position.
2. Release the sleeve and remove the attachment.

Figure 31: Installing the attachment.

Figure 32: Inserting the Dissecting Tool into the Attachment

Figure 33: Removing the Attachment

Curved Bur Attachments

WARNINGS:

- Use adequate irrigation and keep the cooling sleeve soaked during dissection. Inadequate irrigation may cause thermal necrosis.
- Do not modify the bur. Bending or prying may break the bur, causing harm to the patient or operating room staff.
- Excessive pressure applied to the bur may cause bur damage. If this occurs, use extreme care to ensure that all fragments of the bur are removed from the patient.
- Disposable devices are for single-use only. Do not attempt to sterilize disposable devices. The disposables are packed sterile and are not intended for repeat use. To prevent contamination, use only once.
- Test for bur wobble (eccentricity) at the desired speed prior to use. Select a new bur or reduce speed if wobble is observed prior to use or during the procedure. Bur wobble may cause patient injury.

CAUTIONS:

- Curved burs are not designed for variable tool exposure. Do not attempt to adjust tool exposure, as this may damage the device.
- When operating or testing the motor, ensure the bur is properly inserted and locked into AT10 attachment.

Installation

1. Turn the tube locking ring and the tool locking ring on the AT10 (V01) Telescoping Attachment into the 🔓 position.
2. Slide the curved bur into the AT10 (V01), until the hub is fully seated.
3. Gently press on the head of the dissecting tool to lock it into place. You will hear a click when the curved bur is fully seated.
4. Turn both locking rings to the 🔒 position on the AT10 (V01).
5. Gently pull on the curved bur to verify proper installation.
6. Refer to your motor's *Instruction Manual* for information on setting up the AT10 (V01) attachment and motor.
7. Briefly run the motor with the curved bur installed, checking for bur wobble or excessive vibration. If either occurs, perform the corrective actions described in the *Troubleshooting* section of these instructions.

Cooling the Bur

1. Prior to initial use, soak the cooling sleeve by dipping it into a cup of saline or DI water, as shown below.

Wetting of the cooling sleeve prior to cutting

2. During use, maintain copious irrigation of the cooling sleeve and bur tip by dribbling saline or DI water along the entire length of the cooling sleeve and bur tip.

Operation

1. Activate the motor and gently press the curved bur against the bone to begin dissection.
2. Use a light sweeping motion to continue removing bone.

Removal

1. Turn both AT10 (V01) locking rings to the 🔓 position and pull the bur out of the attachment.
2. Discard the curved bur, according to hospital procedures.

Reuse and Cleaning

Do not reuse.

Sterility

Each bur is gamma-sterilized and is not intended for repeated use. Do not attempt to re-sterilize.

Cutting Time

Continuous cutting for extended periods may cause the device to heat to an uncomfortable temperature. To avoid this, limit cutting to the recommended times below:

	Maximum Continuous Cutting Time	Maximum Total Cutting Time
1 & 2 mm burs	2 minutes	12 minutes
3 & 4 mm burs	3 minutes	12 minutes

Variable Exposure Attachments

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

WARNINGS:

- Surgeons should familiarize themselves with the performance of dissecting tools before use, and should explore the effect of various levels of tool exposure on dissection stability. If the tool exhibits excessive chatter, vibration, or movement, decrease the tool exposure.
- Dissecting tool size and geometry may contribute to excessive vibration at certain speeds. Increase or decrease speed by adjusting the foot/finger control, or by changing the operating pressure or console speed setting. If necessary, use a different dissecting tool.

Installation:

1. Refer to the appropriate section of this manual on installing fixed or angled attachments.
2. After installation, use the TUBE adjustment ring to adjust the exposure of the dissecting tool (Figure 34). With the tool pointing away from you, turn the ring to the right to increase the length of the tube, thereby decreasing the exposure of the tool. Turn the ring to the left to decrease the length of the tube, thereby increasing the exposure of the tool.

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

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

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

Removal:

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

Figure 34: Adjusting Tool Exposure

Footed Attachments

Installation:

1. Insert the dissecting tool into the motor collet with a slight rotational motion (Figure 35). You will feel and hear the tool click into place when it is fully seated.
2. Slide the footed attachment over the dissecting tool, onto the motor, aligning the triangular markers (Figure 36).
3. Pull the footed attachment towards the motor and turn the attachment to the 🔒 position (Figure 37).

Removal:

1. To remove the Legend footed attachment, hold the motor in the palm of your hand, and push the sleeve on the attachment distally while turning the attachment to the 🔓 position (Figure 38).

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

2. Release the sleeve and remove the attachment.
3. Pull the dissecting tool out of the motor collet and discard the tool.

Figure 35: Inserting the Tool into the Collet

Figure 36: Sliding the Attachment onto the Motor

Figure 37: Attachment in the Locked Position

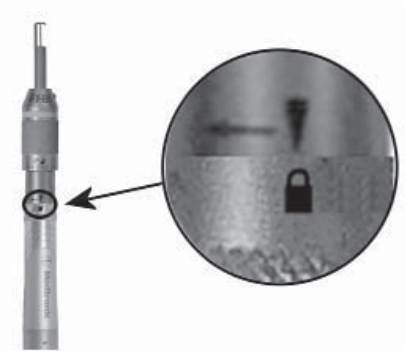


Figure 38: Removing the Attachment

Rotating Footed Attachments

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

Installation:

1. Insert the dissecting tool into the motor collet with a slight rotational motion (Figure 39). You will feel and hear the tool click into place when it is fully seated.
2. Slide the attachment over the dissecting tool and onto the motor, aligning the triangular markers (Figure 40). You will feel and hear the attachment click into place when it is fully seated.
3. Turn the attachment to the 🔒 position (Figure 41).

NOTE: The footed end of the attachment now has 360˚ of unrestricted rotation.

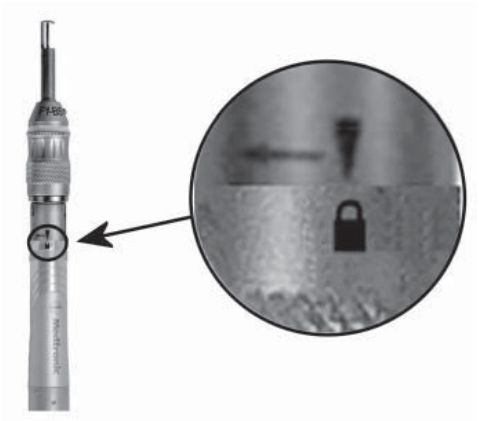
Removal:

Removal is the reverse of installation.

Figure 39: Inserting the Tool into the Collet

Figure 40: Sliding the Attachment onto the Motor

Figure 41: Attachment in the Locked Position



Contra-Angle Attachment (16-MF)

CAUTION: Do not run the 16-MF attachment with operating pressure above 80 psi (5.5 bar). This may cause over-heating and damage to internal gears of attachment.

Installation:

1. Decrease the pressure at the compressed gas source to 80 psi (5.5 bar).
2. Adjust the pressure as needed by lowering it at the gas source, then push down the pressure relief on the pneumatic control unit to exhaust the excess pressure in the hoses.
3. Slide the attachment over the motor collet, aligning the triangular markers (Figure 42). You will feel and hear the attachment click into place when it is fully seated.
4. Turn the attachment to the 🔒 position (Figure 43).
5. Turn the attachment head lever to the open position (Figure 44).
6. Insert the dissecting tool and return the lever to the closed position. Gently pull on the dissecting tool shaft to verify proper installation.

Removal:

1. Removal is the reverse of installation.
2. Discard the dissecting tool after removing it from the attachment.

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

Figure 42: Sliding the Attachment over the Motor Collet

Figure 43: Attachment in the Locked Position

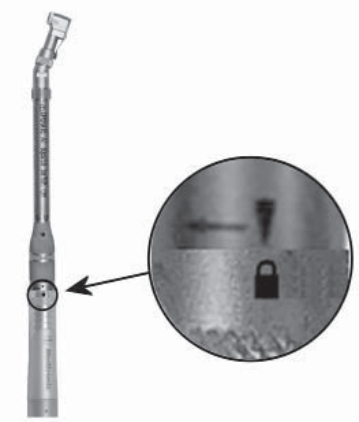


Figure 44: Opening the Attachment Head Lever

Metal Cutting Attachments

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

- Wear eye protection.
- Irrigate well to cool the cutting surfaces.
- Protect the wound site from metal debris.
- Use a clamp or grasping device to control loose fragments during transection of any metal component.

The Metal Cutting Attachment uses the tungsten carbide or diamond wheel dissecting tools.

Installation:

1. Slide the attachment over the motor collet aligning the triangular markers (Figure 45). You will feel and hear the attachment click into place when it is fully seated.
2. Turn the attachment to the 🔒 position.
3. Turn the tool lock towards the 🔓 icon, and insert the dissecting tool into the attachment with a slight rotational motion (Figure 46). You will feel and hear the tool click into place when it is fully seated.
4. Turn the tool lock to the 🔒 position (Figure 47). Gently pull on the shaft of the dissecting tool to verify proper installation.

NOTE: A dissecting tool may be installed and locked in the attachment before the metal cutting attachment is installed on the motor.

Removal:

Removal is the reverse of installation.

WARNING: Do not use metal cutting dissecting tools on bone.

Figure 45: Sliding the Attachment over the Motor Collet

Figure 46: Inserting the Tool into the Attachment

Figure 47: Turning the Tool Lock to the Locked Position

Telescoping Attachments

Installation:

1. Slide the attachment over the motor collet aligning the triangular markers (Figure 48). You will feel and hear the attachment click into place when it is fully seated.

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

2. Turn the attachment to the 🔒 position.
3. Turn the TUBE locking ring towards the 🔓 icon.
4. Insert the base of the telescoping tube into the attachment (Figure 49).
5. To lock the tube in place, turn the TUBE locking ring towards the 🔒 icon. Do not over tighten.
6. To insert the tool, make sure that the TOOL locking ring is in the 🔓 position, and insert the dissecting tool into the top of the tube (Figure 50). You will feel and hear the tool click into place when it is fully seated.
7. Turn the TOOL locking ring to the 🔒 position. Gently pull on the shaft of the dissecting tool to verify proper installation.
8. If the tube position needs to be changed, turn the TUBE locking ring towards the 🔓 icon, re-position the tube, then turn the TUBE locking ring towards the 🔒 icon.

Removal:

1. To remove the attachment, unlock both locking rings, and pull the telescoping tube and tool out of the attachment.
2. Turn the attachment to the 🔓 position and remove it from the motor.

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

Figure 48: Sliding the Attachment over the Motor Collet

Figure 49: Inserting the Telescoping Tube

Figure 50: Inserting the Dissecting Tool

Figure 51: Locking Rings

Perforator Driver Attachments

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

NOTE: MPSS does not provide cranial perforator devices.

Installation:

1. Slide the attachment over the motor collet aligning the triangular markers (Figure 52). You will feel and hear the attachment click into place when it is fully seated.
2. Turn the attachment to the 🔒 position (Figure 53).
3. To install a cranial perforator device with a Hudson shank, pull back on the collar of the attachment (Figure 54).
4. Insert the device and release the collar.

NOTE: A cranial perforator device may be installed in the attachment before the attachment is installed on the motor.

Removal:

1. To remove the cranial perforator device, pull back on the collar of the attachment.
2. To remove the attachment, turn it to the 🔓 position and slide it off of the motor.

WARNING: Consult the cranial perforator device labeling for the recommended speed specifications.

Maximum Speed of Perforator Attachments

Gas Pressure (Dynamic)	Model AD01 Output Speed (Max.)	Model AD03 Output Speed (Max.)
80 psi	660 rpm	850 rpm
100 psi	820 rpm	1050 rpm
120 psi	890 rpm	1140 rpm

Figure 52: Sliding the Attachment over the Motor Collet

Figure 53: Attachment in the Locked Position

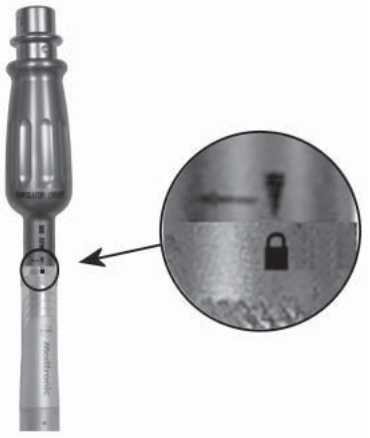


Figure 54: Pulling Back on the Collar

Jacobs® Chuck Attachments

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

Installation:

1. Slide the attachment over the motor collet aligning the triangular markers (Figure 55). You will feel and hear the attachment click into place when it is fully seated.
2. Turn the attachment to the 🔒 position (Figure 56).
3. To install a drill bit, turn the Jacobs key to open the collar.
4. Insert the drill bit and tighten the collar.

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

Removal:

Removal is the reverse of installation.

Figure 55: Sliding the Attachment over the Motor Collet

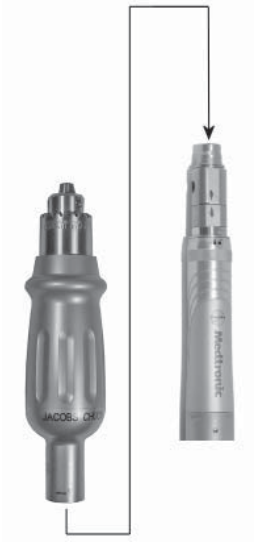
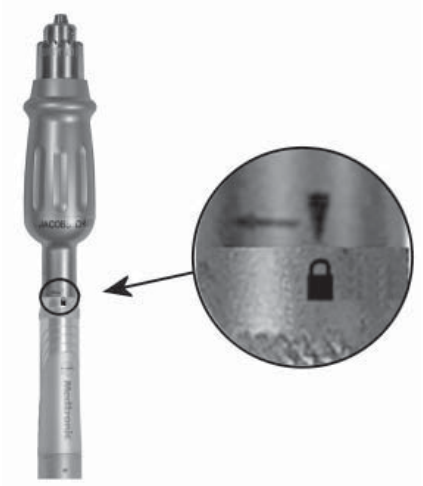


Figure 56: Attachment in the Locked Position

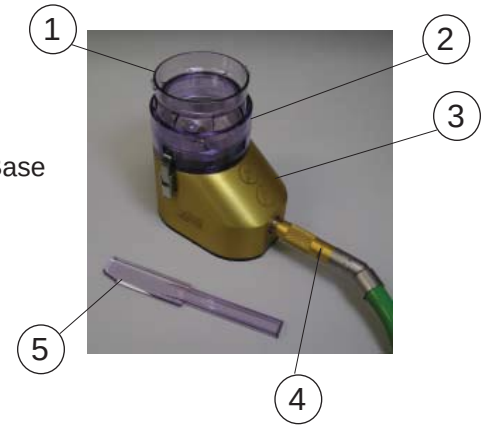


Bone Mill Attachment

The Legend Bone Mill attachment is composed of a non sterile base and gamma-sterilized, single use disposable components. The gamma-sterilized single use disposable components consist of one bowl, one cap (with LOW and HIGH settings), and one spatula. A Legend or MR7 motor provides the power to drive the Bone Mill attachment. The Bone Mill attachment is intended to mill bone into particles 1 to 5mm in size.

Figure 57: Bone Mill Attachment

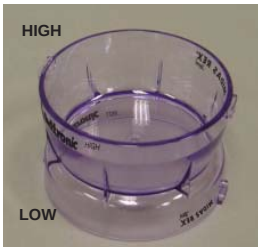
1. Cap
2. Bowl
3. Bone Mill Base
4. Motor
5. Spatula



WARNINGS:

- Do not operate the Bone Mill attachment without the bowl, and cap secured in place.
- Do not come in contact with the interior of the disposable bowl and cap during bone milling.
- Do not use the Bone Mill disposable components for more than one surgical procedure, as this may cause cross-contamination and affect patient safety.
- Use only Legend/MR7 motors and Legend Bone Mill disposables in combination with the Bone Mill attachment. Use of other devices will void the manufacturer's warranty.

Figure 58: Bone Mill Cap



Using the Bone Mill Attachment

1. Place the bowl onto Bone Mill base and secure the latches.
2. Lay harvested bone specimens into the bowl.

CAUTIONS:

- The addition of any liquid to the milling process should be administered in small volumes to prevent leakage.
- Do not use Bone Mill disposables to process more than 6 bone pieces approximately 1.5 cc in size at one time.
- Do not use Bone Mill disposables to process more than a total of 40 cc of bone during any one surgical procedure.

3. Secure the cap onto the bowl by rotating counterclockwise. Do not activate the Bone Mill Attachment without securing the cap.
4. Use the HIGH cap position when starting with large pieces of bone or large batch amounts. Use the LOW cap position to finish milling a batch or when starting with small pieces or batch amounts (Figure 58).
5. Insert the motor into the motor connection on the Bone Mill base and rotate the motor to the 🔒 position (Figure 59).
6. Activate the motor to mill bone. Continue to run the Bone Mill Attachment until desired bone particle size is achieved. Adjust motor speed to obtain desired particle size.

Figure 59: Inserting the Motor

NOTE: If bone does not process, deactivate the motor, rotate the motor to the 🔓 position, and remove the cap. Reinsert the cap in the HIGH position and activate the motor. If bone spins without milling or jams, divide bone chunks into two batches and process separately.

7. Process the bone for 5–15 seconds and visually check to gauge quality of milling before continuing.
8. Continue to process bone in 5–15 second batches until the majority of particles reach desired size.
9. To remove bone particles stop operation of the motor and rotate it to the 🔓 position. Remove the cap by rotating it clockwise. Use the spatula inside the bowl and cap to remove bone particles.

NOTES:

- Milling time is dependent on the density of the patient's bone, the ratio of cancellous and cortical bone, the size of the individual particles and the batch amount of the bone to be processed. Always check bone after 10–15 seconds to gauge quality of milling.
- If the blade becomes inoperable, stop operation of the motor and rotate the motor to the 🔓 position. Remove the cap and use the spatula to free bone and/or blades.
- After removing bone particles from the bowl, the milling process may be repeated with additional bone specimens, as needed. (Up to a total of 40 cc of bone may be processed by the Bone Mill Disposable during any one surgical procedure.)

After Use

1. Rotate the motor to the 🔓 position.
2. Unlatch the Bone Mill disposables from the base.
3. Discard the bowl, cap, and spatula per hospital procedure.
4. Clean the Bone Mill base according to the directions below.
5. Clean the motor according to its instruction manual.

② Bone Mill bowl, cap, and spatula are single use devices. Opened but unused Bone Mill disposables may not be re-sterilized under any sterilization method.

Preventative Maintenance

The Bone Mill Attachment should be returned for factory maintenance annually (approximately 100 procedures).

If the Bone Mill Attachment does not function according to these instructions, call your Medtronic Regional Distributor or Medtronic Neurologic Sales Representative. If necessary, return the Bone Mill Attachment base to your Distributor or Sales Representative to be repaired.