Integrated Power Console

Model EC 300

User's Guide

Rx Only

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Warnings and Precautions

It is important that the IPC® operator be familiar with this manual: it's Warnings, Precautions, procedures and safety issues. Three labels are used in this manual to identify important concerns, conditions, or procedures:

Warnings: Describes serious adverse reactions and potential safety hazards that can occur during the proper or improper use of a device.

Precautions: Any special care to be exercised by a practitioner or patient for the safe and effective use of the device.

Note: Identifies special information or to clarify/emphasize important instructions.

Warnings

System Warnings

W1	It is important that the IPC® operator be familiar with the system User's Guide, its precautions, procedures and safety issues.
W2	Do not use the IPC® System in the presence of flammable anesthetics. Avoid potential ignition or explosion of gases
W3	When not operating handpiece, eliminate accidental foot control activation. Control energy to and through the handpiece to prevent unintended tissue, bone, or nerve resection.
W4	Disconnect power to the IPC® before cleaning the unit to avoid electrical macro shock.
W5	Do not attach unapproved components to the IPC® to avoid electrical macro shock.
W6	To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the IPC® to hospital grade receptacles only.
W7	This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment 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. Diminished performance may lengthen operating time for anesthetized patient.
W8	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 Guide.
W9	Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
W10	Do not operate the IPC® System in the presence of Magnetic Resonance Imaging devices.
W11	Use of accessories and cables other than those specified and sold by Medtronic may result in increased emissions and decreased immunity of this unit.
W12	The IPC® should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the IPC® should be observed to verify normal operation in the configuration in which it will be used.
W13	Do not attempt to run the IPC® System handpiece immediately after autoclaving. Allow an adequate "cool down" period (Typically 1 hour).
W14	Consult the Legend® Bone Mill product insert before use with the Integrated Power Console™.
W15	For metal transection, observe the following safety precautions:
W	15a Eye wear protection is essential.
W	15b Irrigate well to cool the cutting surfaces.
W	15c Protect the wound site from metal debris.
W	15d Use a clamp or grasping device to control loose fragments during transection of any metal component.
W16	Do not operate the IPC® System without eye protection.
W17	All service must be performed by Medtronic qualified personnel only.
W18	Repair and/or modification to the IPC® by anyone other than qualified service personnel may significantly compromise the unit's ability to perform effectively and/or void the equipment warranty.

Component Warnings

W19	Do not use any parts other than Medtronic system components as damage or substandard performance could result.
W20	Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is repaired or replaced. Damaged parts may deposit metal shavings on surgical site.
W21	When precise location of blade tip is required, engage the rotation lock on the handpiece, then calibrate and verify the blade tip on Image Guided Surgery (IGS) system. Always lock M4 handpiece when driving non-rotatable blades to maintain their IGS calibration.
W22	Employ visualization, including use of imaging techniques (e.g., fluoroscopy, image guided surgery) when using rotating powered accessories. Discontinue powered application in the event of lack of visualization of surgical site.
W23	Midas Rex® Variable Exposure attachments 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.
W24	Motors and attachments may fail due to extended use and allow a component to detach and fall from the motor or attachment, causing patient injury.
W25	Electrical contacts must be dry prior to use.
W26	Heavy side loads and/or long operating periods may cause the device to overheat.
W27	Do not use an overheated device, as it may cause thermal injury to the patient or operator.
W28	Use adequate irrigation. The use of a tool without irrigation may cause an inordinate amount of heat buildup resulting in a thermal injury to tissue. Depending on the amount of irrigation used, the drill bits can achieve temperatures in excess of 50° C.
W29	Do not attempt to change a dissecting tool or attachment while the motor is running, or when the motor or attachment is in an overheated state.
W30	Do not immerse the system components.
W31	Do not place motor, attachment and tool on the patient or in an unsecured location during surgery.
W32	A system that is not functioning properly should not be used until all necessary repairs have been made and the unit is tested to ensure that it is functioning in accordance with Medtronic specifications.
W33	Match the nomenclature and color code on the tool packaging to the same nomenclature and color code on the Attachment.
W34	Make sure that the attachment is still in the locked position after each adjustment of the tool exposure, as attempting to increase the tool exposure too far, may result in the attachment accidentally being unlocked.
W35	Midas Rex® Legend EHS® Motor and Midas Rex® Legend EHS® Stylus Motor should only be operated when the attachment is in the locked position.
W36	Smoke may be generated if attachment is not in the locked position.
W37	The Legend EHS® motors will not run properly unless the attachment is in the locked position.
W38	DO NOT change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
W39	Remove Legend® Footed Attachments cautiously and slowly as per instructions to avoid injury to the operator.
W40	DO NOT modify accessories used with the handpiece. Performance could be diminished with modified accessories.
W41	The safe use of the Endo-Scrub® 2 System in procedures where surgical lasers are also employed has not been clinically demonstrated.
W42	In order to ensure compliance with requirements of IEC 60601-1, use a Medtronic approved power cable
W43	To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
W44	Keep NIM® Muting Probe cable away from IPC® system cables.

Disposable Warnings

W45	Verify reusable device was sterilized prior to use. If not sterilized, do not use.
W46	Tools are available for resection of soft tissue and bone for surgical procedures. Use of tools depends on the intended application and patient needs. Sharp-cutting powered tools induce bleeding and removal of significant tissue and bone.
W47	Use methods at the operative site to control bleeding that do not compromise patient safety during at-risk surgery.
W48	Always keep the cutting tip of the tool away from fingers and loose clothing. Prevent laceration of user and cross-contamination through compromised glove.

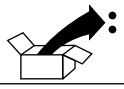
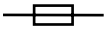
Warnings and Precautions

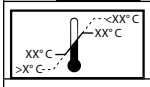
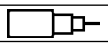
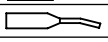
W49	Operate the tool only after the appropriate anatomical landmarks and the intended surgical site have been confirmed.
W50	Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using powered accessories.
W51	Insertion of metal objects in accessory tip may cause the accessory to break leaving fragments in the wound. The fragments may be difficult to remove, causing irritation, inflammation and foreign-body response at surgical site.
W52	Bending or prying may break the accessory, causing harm to patient or staff.
W53	Do not use excessive force to pry or push bone with the attachment or tool during dissection.
W54	A tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease speed on console. Change to a new tool to prevent unintended tissue removal from patient.
W55	Test for wobble at desired speed prior to use. Discontinue use of accessory if tip begins to wobble and replace accessory to prevent unintended tissue removal from patient.
W56	Eccentricity of the tool can cause tool vibration and may result in excess tissue and bone destruction and hearing damage.
W57	Excessive noise from the tool when drilling close to the cochlea or ossicular chain may cause hearing damage.
W58	CONSULT the cranial perforator device labeling for the recommended speed specifications.
W59	Tools with "L" identification are longer tools intended for light bone dissection. The increased tool head/stem configuration may affect dissection stability.
W60	Tool flutes are sharp and may perforate surgical gloves. Tools may be grasped with a hemostat to aid in installation and removal.
W61	DO NOT attempt to resharpen used tools. Worn tools should be replaced with new ones frequently to ensure effective cutting and control.
W62	Carefully inspect tool both prior to and following each use for signs of excessive wear, fragmentation, eccentricities or other defects. Replace any suspicious tools with a new one prior to use.
W63	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 retrieved and removed from the patient. Unremoved tool fragments may cause tissue damage to the patient.
W64	Do not use metal-cutting tools on bone.
W65	Use only rotary tools specifically designed for use with this drill system.
W66	When using non-rotatable tools, ensure rotation lock is engaged to prevent inadvertent rotation.
W67	The use of powered reciprocating instruments may result in vibration \ related injury.
W68	Powered blades should be operated in the oscillate mode only. Operating in the forward mode may cause damage to the blade.
W69	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.
W70	Any tubing or other tip protectors used during shipping must be removed prior to cleaning and sterilization.
W71	Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination.
W72	Properly dispose of single-use devices removed from sterile packages. Devices lose sterility upon removal from packaging.
W73	Do not use dull, damaged or bent tools. Use of dull tools can reduce handpiece effectiveness and cause the handpiece temperature to increase.
W74	T&A Blades: Gently remove the inner tube from the outer tube. The inner tube may elongate upon removal from the outer tube. If this occurs, the inner tube may not lock properly into the handpiece or the blade may not work properly.
W75	T&A Blades: Rotate the inner tube when removing and inserting it in the outer tubes to prevent damage to the internal seal. If the seal is damaged, the blade will leak at the handpiece.
W76	Always ensure that the drill is securely engaged into the handpiece prior to operating the system.
W77	Always examine operation of each tool in a handpiece before use.
W78	Powered burs and drills should be operated in the forward mode only.
W79	This system requires insulated connectors for the StraightShot® M4 Microdebrider, Straightshot® Magnum® II Microdebrider, Straightshot® III Microdebrider, Midas Rex® SC1, Visao®, or Skeeter® handpieces and the Multi Function Foot Control Unit.
W80	Sterilize and dry reusable device before storing the system. Decrease likelihood of cross-contamination with timely sterilization.
W81	After each procedure, properly clean all reusable system components.
W82	Auxiliary Power Outlet with protective cover is for use with the Hydrodebrider™, or Bone Mill consoles only.
W83	Place Stylus Touch™ in safe mode while not in use.
W84	Do not place Stylus Touch™ handpiece in the proximity of magnetic field, such as magnetic drape and MRI equipment, to avoid inadvertent handpiece activation.
W85	Do not apply excessive side loading. Excessive side loading could cause angled attachments to unlock accidentally from motor.

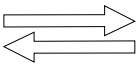
Precautions

P1	PRIME/FLUSH Priming is a feature designed to purge air out of the tubing set(s) during setup. The first time a Prime or Flush button is pressed it will turn on pump 1 and/or 2 long enough to purge air out of the tubing set(s). Turning power Off and On resets the PRIME feature. Once pressed all Prime buttons will change to Flush buttons.
P2	To prevent damage to curved tools, disconnect suction tube prior to changing tool during procedure.
P3	When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece.
P4	For Legend tools only: If a tool package is opened, but the tool is not used or contaminated, the tool can be re-sterilized. Remove tool from original packaging and place into an approved autoclave package. Steam sterilize as follows: High-Vacuum Steam 132°C for 5 minutes Gravity Displacement 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.
P5	DO NOT run the 16-MF attachment with operating speed above 62,000 rpm. This may cause over heating and damage to internal gears of attachment.
P6	DO NOT use twist drill or Contra-Angle tool at an operating speed over 62,000 rpm.
P7	Do not attempt to disconnect the cable from the Midas Rex® Legend EHS® Stylus Motor.
P8	Do not kink cables. Inspect cables and pins for cracks, tears or corrosion.
P9	Do not use anti-fog on scope or sheath, as weeping or leaking may result.
P10	Disconnect cable from Midas Rex® Legend EHS® motor prior to sterilization.
P11	The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.
P12	Remove devices from instrument case before placing into washer disinfector and allow devices to drain.
P13	Orient devices in the washer-disinfector by following manufacturer recommendations
P14	DO NOT use low-temperature hydrogen peroxide gas plasma sterilization due to the lumen internal diameter and length restrictions.
P15	DO NOT use low-temperature liquid peracetic acid sterilization due to immersion procedure.
P16	DO NOT steam or EO sterilize the Legend® Attachment Cleaning Nozzle.
P17	Remove and discard accessories following local regulations for proper disposal of contaminated materials.
P18	Disposable devices are for single-use only.
P19	Clean the motor and cable while still connected together. This will help to reduce ingress of debris.
P20	Use ONLY recommended cleaning agents
P21	Do not use excessive force to insert the endoscope into the Endo-Scrub® 2 sheath. This will damage the endoscope as well as the Endo-Scrub® 2 sheath.
P22	If the endoscope tip can be seen extending beyond the tip of the Endo-Scrub® 2 sheath, then the sheath has been damaged. Damaged product must be immediately discarded.

Symbols

SN	Serial Number
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://Recycling.Medtronic.Com for instructions on proper disposal of this product.
	Do not use if package is open or damaged
	Package Contents
1	Pump Head 1
2	Pump Head 2
	Use by Date
	Do not Reuse
LOT	Lot Number
	Fuse
ACC	Accessory
REF REF	Catalog Number
	AC power
	Output
	Is approximately equal to
STERILE R	Sterilized by Radiation. Do not use if package is open or damaged
~~STERILE~~	Non Sterile
STERILE EO	Sterilized by Ethylene Oxide. Do not use if package is open or damaged
EC REP	Authorized representative in the European Community
CE 0123 CE 0086	This device complies with Medical Device Directive 93/42/EEC
Rx Only	Caution: Federal law (U.S.A.) Restricts this device to sale by or on the order of a physician
! USA	USA Only
	Quantity
	Manufacturer

	Date of Manufacture
	ROHS - Environmental friendly use period - China (sj/t11364-2006.)
	Not greater than 120VAC
	Applied part duty cycle
	Recommended storage temperature and limits.
	Conforms to ANSI/AAMI ES 60601-1, IEC/EN 60601-1. Certified to CSA C22.2 No.601.1
	Handpiece
	Skeeter® handpiece
	EMC compliance mark
	Protective earth
	Equipotential
	Consult instructions for use
	Attention see instructions for use
IPX1	Protected against vertical water drops
IPX7	Protected against the effects of temporary immersion in water
	Type BF applied part
	Manual Start/Stop
	Rf transmitter (interference may occur)
	Precaution: pinch hazard. Keep fingers clear of rollers
BUR	STIM bur connector
NIM	NIM® console connector
EHS	Electrical high speed handpiece connector
	Foot pedal connector
Fr	World Wide Standard for medical tubing diameter.
	Fine irrigant adjustment
	Left foot control unit button

	Right foot control unit button
	Top foot control unit button
	Locked
	Unlocked
	On/Off (main power)
	Use with
Instrument Case	Instrument case
Lubricant/Diffuser	Lubricant/diffuser
Dissecting Tool	Dissecting tool
Attachment	Attachment
Control Unit	Control unit
Refurbished	Refurbished
Accessory	Accessory
Regulator	Regulator
Bone Mill	Bone mill
Motor	Motor
Brush	Brush
Adapter	Adapter
TOOL	Tool control
TUBE	Tube control
Multi-Use Disposable Attachment	Multi-use disposable attachment

Buttons and Indicators

Setting	Located on Splash Screen used to open Setting Screen.
	Direction indicator Direction is clockwise.
	Direction indicator Direction is counter-clockwise.
	Blade Rotating indicator Shows blade is in motion. Does NOT indicate blades orientation.
Cancel	Cancel Button Located on Setting Screen used to cancel any changes that were selected.
OK	OK Button Located on Setting Screen used to accept any changes that were selected.
+	**Large Increment / Decrement Buttons** **Increase / Decrease a given value with each depression.** Typically used for custom speed adjustment. Enables the operator to toggle (using FCU button) between OSC/FWD or REV/FWD (custom speed remains the same in all modes).
−	
+	Small Increment / Decrement Buttons Increase / Decrease a given value with each depression. Typically used for flow rate or size adjustment.
−	
	FCU Variable / On-Off Speed Select Changes foot pedal function on Foot Control Unit between variable control and On/Off.
5000	Speed Select (OCS) Buttons (Straightshot) M4 Screen Only. Preset OSC speeds. When selected the FCU Radio Button will be displayed to the right of the button. Using the FCU left button the operator can toggle between the pre-selected speeds.
3000	
1500	
300	
	FCU Radio Buttons Indicates option selectable via the FCU's left button (center is white when active).
	Radio Button for option selection (center is white when selected).
	Check Box used to show if an option is turned On or Off (green with check mark is On).
IPC	IPC/XPS® Toggle Button When IPC is selected (visible on the button), the microdebrider blades will stop, and then return to the original starting position. When XPS® is selected; the microdebrider blades will stop in a random position.
XPS 3000	
Default	Default Button Found on the Settings screen and used to open Default screens for handpieces.

60°	Toggle Button Sets left button on FCU so that each press will move the handpiece tool in increments of 60 or 180 degrees.
180°	
?	Help Button Opens help screen.
	Pumps Button Opens pump options panel.
	Prime Button See Precaution P1.
	Flush Button Depressing the Flush Button will turn on pump as long as button is held. See Precaution P1.
	Exit Button Exits or closes a screen or panel.
	Attention Icon Indicates a problem to the user.
Visao	Cycle Bar Cycles through, the default / help screens
English Français Italiano Deutsch Español	Language Buttons Located on setting screen and used to select language.
(Error Name)	Error Button Displays Handpiece Error Opens Error Message.
(Handpiece Name)	Inactive Handpiece Displays Inactive Handpiece Makes Inactive Handpiece Active.

List used in Manual

This manual contains two basic types of list, Alphabetic list (A. B. C. etc.) and Numeric list (1. 2. 3.). The alphabetic list contains general information about the part such as name or usages. Numeric list are instructions for completing a task.

Definitions

This section explains the essential meaning of a word or acronym as used in this manual.
Also explains changes in words or phrases variations from one product generation to the next.

FCU –	Foot Control Unit
IPC® -	Integrated Power Console
I.V. -	Intravenous
NIM® -	Nerve Integrity Monitor - One or all of the following units: NIM-Response® 2.0, NIM-Neuro® 2.0, NIM-Response® 3.0, and NIM-Neuro® 3.0
Nomenclature	The act or process or an instance of naming
XPS® -	Xomed Power System

When The System Arrives

Unpacking and Inspection

Check off the contents of the box against packing slip. If incomplete or damaged, notify Customer Care.
If container is damaged, or cushioning material shows stress, notify carrier and Customer Care. Keep shipping materials for carrier inspection.
After unpacking, save the cartons and packing material. If the instrument is to be shipped the shipping package will provide proper protection.

System Description

The IPC™ System is a powered microdebrider, drill and saw system that will remove soft tissue, hard tissue, and bone during surgical procedures. The system consists of a power control console, footswitch, connection cables, and assorted handpieces to drive various burs, blades, drills, rasps, cannulae, and saws. It includes integrated irrigation pumps for irrigation of blades, burs and for motor coolant.

The Nerve Integrity Monitor (NIM®) is a separate device that stimulates and monitors the nerve. This system has connections that allow the NIM® to be connected with the Visao® handpiece and Stimulating Bur Guard enabling the NIM® to stimulate and monitor the nerve at the surgical site.

The system can be used to clear the end of a rigid rod endoscope in order to maintain good visualization of endoscopic procedures without having to remove the scope from the surgical site.

This device is intended for use by physicians trained in the procedures described.

Intended Use / Indications for use

The IPC™ is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) Orthopedic, Arthroscopic, Spinal,Sternotomy, and General surgical procedures.

Contraindications

The IPC™ system is contraindicated for arthroscopic microdiscectomy in individuals with the following:

- Severe/progressive neurological deficits
- Cauda equine syndrome
- Active infection.

Arthroscopic microdiscectomy is not indicated for individuals with sequestered disc fragments, discogenic pain, internal disc destruction, or lumbago.

Sales And Customer Care

Medtronic Powered Surgical Solutions

4620 North Beach StreetFort Worth, TX 76137 USA

www.medtronic.com

U.S. Help Line

(800) 468-9710

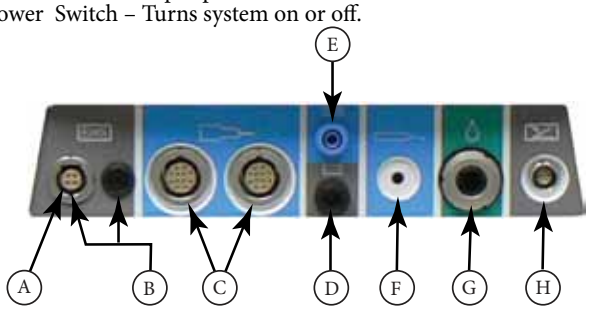
International Service

International customers should contact their Medtronic Neurologic Technologies representative.

Console

Console Front

A. Touchscreen – User interface.
B. Pump 1 – For coolant, lens cleaning, or irrigation.
C. Pump 2 – For Irrigation.
D. Connector Panel - peripheral devices.
E. Power Switch – Turns system on or off.



Connector Panel

Port #	Component	Quantity
A	Midas Rex® Legend EHS® motor	1
B	Midas Rex® Legend EHS® Stylus motor	1
C	StraightShot® M4 Microdebrider	2
	Midas Rex® Legend EHS® Stylus Touch™ motor	1
	Midas Rex® SC1	
	Straightshot® Magnum® II and Straightshot® III	
	Visao®	
D	Stimulus input from Patient Interface connection (NIM).	1
E	Stimulus output to STIM Bur Guard	1
F	Skeeter® Handpiece	1
G	Endo-Scrub® 2 Finger Switch	1
	Endo-Scrub® 2 Footpedal	
	IntelliFlow Irrigation Remote Control	
H	Foot Control Unit (FCU)	1

Console

Connector Panel Cable Connection

Cable to console connection red/silver dot

Red or silver dot connections are multi pin and must be correctly aligned (oriented).

Cable to console connection without dot

Connectors without the red or silver dot are single pin and may be inserted without regard to orientation.

Connector Panel Cable Disconnection (multi pin)

To remove Midas Rex® Legend EHS® Motor and Legend EHS Stylus® Motor, cable from motor or console:

1. Push the cable towards the motor or console.
2. Then pull out by locking ring (A).

To remove Midas Rex® Legend EHS Stylus® cable from console:

1. Push the cable towards the console, then pull by locking ring (A)

To remove cables (multi pin) with silicone insulating boots:

1. Silicone insulated connectors do not have a locking device (ring) and may be removed by pulling straight out on the connector.

Cable disconnection (single pin)

1. Single pin connectors do not have a locking device (ring) and may be removed by pulling straight out on the connector.

Console Rear

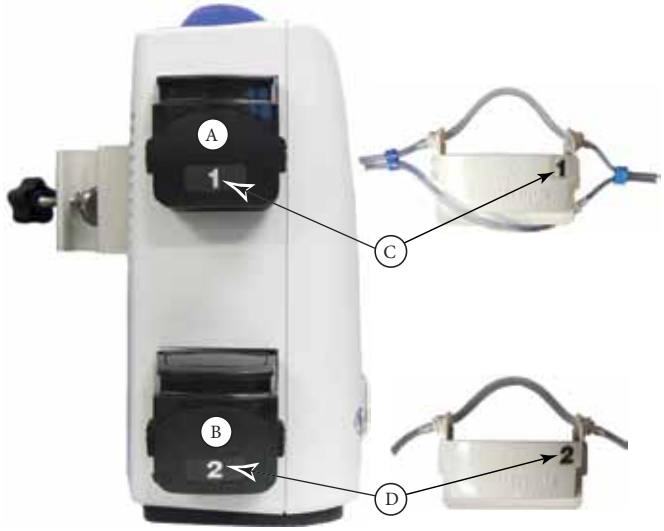
A. Pole Clamp
B. Compact Flash Card port (factory use only)
C. Manual Start Stop Button
D. Fuse Access – Replace only with 5 x 20 T. L. 5A, 250V fuse.
E. Auxiliary Power Outlet with protective cover:
   - For use at grid voltage < 120VAC only.
   - HydroDebrider™, or Bone Mill consoles only. See warning W80.
F. To remove cover, place small screwdriver in notch at bottom and pull/pry off.
G. Endo-Scrub® 2 - power connector.
H. Power Cord Connector:
   - Hospital grade power cord connects here.
   - Means of disconnecting device from Mains voltage by the power cord.
I. Equipotential:
   - Uniform potential.
   - Means for eliminating noise or interference with sensitive equipment by application of a POTENTIAL EQUALIZATION CONDUCTOR.

Power Cords

North America: USA, Barbados, Belize, Bolivia, Canada, Columbia, Ecuador, Venezuela Standard P/N EA600 or 1895820 6 meter P/N EA650 or 189721	United Kingdom, Ireland, Hong Kong, Malaysia, Singapore P/N EA606 or 1895821	Continental Europe: Austria, Belgium, Finland, France, Germany, Greece, Korea, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden P/N EA602 or 1895822
China P/N EA604	India, South Africa P/N EA607	Switzerland P/N EA601
Argentina P/N EA608	Israel P/N EA609	Denmark P/N EA610
Australia, New Zealand P/N EA605	Japan P/N EA603 or 1895823	Italy, Chile P/N EA611

Console Pump Basics

Console Pump Designator

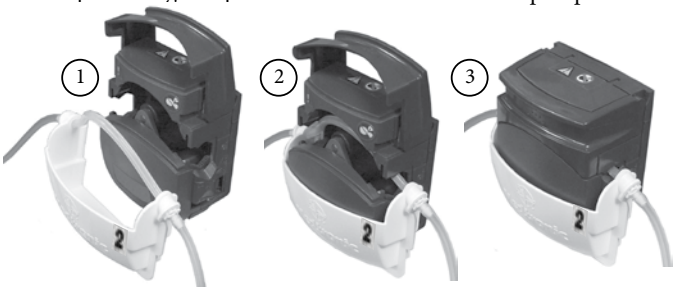


A. Pump 1: Coolant, lens cleaning, or irrigation.
B. Pump 2: Irrigation.
C. Pump 1 Designator – This designator number is used to coordinate the pump (by number) with the cartridge number and/or pump set-up screen number listed on the touch screen. When setting up the console these ***numbers must match***.
D. Pump 2 Designator.

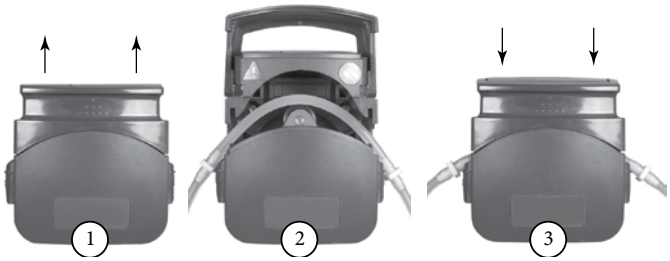
NOTE: Not all Pump Cartridges have pump designator numbers. For these cartridges the operator should view the Pump Setup Screen prior to installing the cartridge.

Pump Cartridge Set-Up

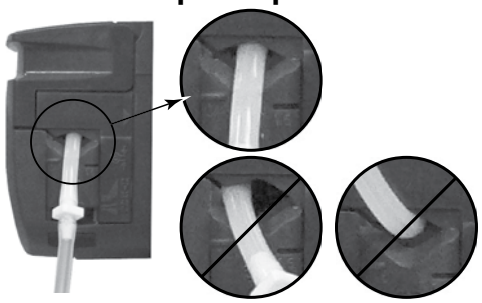
The Pump Cartridge snaps onto the lower section of the pump.



Standard Pump Set-Up



Tips on Standard Pump Set-Up



Pump Default Table

Pump configurations is very dependent upon handpiece being used. The following table shows the pump default settings (X) and default options (O).

Handpiece	Pump 1		Pump 2		Endo-Scrub® 2		Suction Irrigator	
	Cooling	Irrigation	Irrigation		Pumps		Pumps	
					1	2	1	2
Visao®	X		X			O		O
Midas Rex® SC1		O	X		O	O		
Straightshot® M4 All Microdebriders			*X		X	O		
Midas Rex® Legend EHS® Stylus motor		O	O	*X	O	O	O	O
Midas Rex® Legend EHS® motor		X	O		O	O	O	O
Midas Rex® Legend EHS® Stylus Touch		X	O		O	O	O	O
Skeeter® Handpiece					O	O	O	O
Endo-Scrub® 2					O	X		
Suction Irrigator							O	O

*X See pump sharing

Pump sharing M4 (1 or 2) and Stylus

When the IPC® detects both M4 (1 or 2) and Stylus handpiece, it will by default set pump 2 as a "Shared" irrigation pump. The operator is expected to manually move the irrigation tubing from the inactive to the active handpiece.

Tubing and Cable Management

A variety of clips exist for securing tubing. Refer to your tubing set for type included.

Console Supplement

Console Specifications

Functional Standards for Electric Systems		
ANSI / AAMI: - ES 60601-1	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	2005
IEC - 60601-1	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	2005
EN - 60601-1	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005))	2006
IEC - 60601-1-4	Medical Electrical Equipment – Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems	2000
EN - 60601-1-2	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	2001/ A1: 2006
CSA - C22.2 No. 601.1	Medical Electrical Equipment - Part 1: General Requirements for Safety.	2005

Physical Dimensions

Size: 277 mm W x 353 mm H x 267 mm D
Weight: 7.3 kg

Operational Environment

Temperature:	+10°C to +33°C
Humidity:	30% to 75% RH
Barometric Pressure:	700 - 1060 hPa

Transport and Storage Environment

Temperature:	-40°C to +70°C
Humidity:	10% to 95% RH
Barometric Pressure:	500 to 1060 hPa

Display / Touch Screen

Type:	High contrast, digital, graphic Color, visible in complete darkness.
Resolution:	Display 21 cm diagonal, resolution 480 X 640 pixels

Audio Output

Baseline Audio Sound Level	60 dBA minimum SPL (1 m)

Electrical

Input Voltage	100 V-240 V ± 10%
Frequency	50/60 Hz
Power Consumption:	500 VA
Auxiliary AC output:	200 VA Max.
Internal Fuse	5 x 20 mm T. L. 5 A, 250 V Medtronic Xomed P/N 11270066
Duty Cycle for Applied Part	Maximum on Time 120 Seconds Minimum off Time 180 Seconds

Audio – Understanding What You Hear

Audible Alarm

A sequence of three short beeps is issued when an error is detected and an error message is displayed on the screen.

Audible Tones

A confirmation beep is issued anytime a change button is depressed.

Three long beeps are issued when the active handpiece is in reverse mode and the foot pedal is depressed.

Error conditions see Troubleshooting for additional information.

IPC® Tone	Cause(s)
1 Beep	• (Tone) confirmation anytime a change button is depressed • Change from forward to oscillate • When changing handpiece to a microdebrider
2 Beeps	• Change from oscillate to forward
3 Beeps	• (Alarm) when an error is detected and an error message is displayed on the screen. • When the active handpiece is in reverse mode and the foot pedal is depressed • 1st time changing from Forward to Reverse
Long Beep	• When changing handpiece to a drill

Multifunction Foot Control Unit (FCU)

Part No. 1898430 or EF 200

The multifunction footswitch allows control of handpiece selection, handpiece speed, and mode selection.

Buttons and Pedal

NOTE: Each button must be depressed and held for a definable amount of time (100 mS by default).

Drills

A. Foot Pedal - Start-Stop/Variable speed.
   Aa. Non-Slip Foot Pad.
B. Right Button - Mode selection, (FWD/REV).
C. Top Button - Enable inactive handpiece selection
D. Left Button - Pedal function, (Start-Stop or Variable speed).

Microdebriders

A. Pedal, toggles from Start-Stop to Variable speed.
   Aa. Non-Slip Foot Pad.
B. Right Button, IF Mode is set to OSC this button will, rotate inner tube on blades 180º. IF Mode is set to FWD this button will, select Pedal function (Start/Stop, or Variable speed).
C. Top Button, Enable inactive handpiece.
D. Left Button, Mode/rpm selection.

SC1

A. Pedal, Start-Stop/Variable speed.
   Aa. Non-Slip Foot Pad.
B. Right Button - In OSC Mode this button will rotate inner blade 60°/180º (touchscreen selected). In FWD Mode this button will select Pedal function (Start/Stop, or Variable speed).
C. Top Button - Enable active handpiece.
D. Left Button - Mode selection -FWD/OSC.

Cleaning

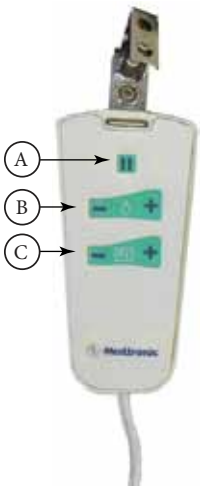
IPC™, Foot Control Unit, and Endo-Scrub® 2 Footswitch

DO NOT immerse or sterilize the units.
Do not use alcohol, other solvents, or abrasive cleaners.

1. Wipe down the IPC™, Foot Control Unit, and Endo-Scrub® 2 Footswitch with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0 or phenol based disinfectant.
   Slip Resistant Pad ONLY
   1a. Spray a neutral enzymatic detergent, pH 6.0 – 8.0, or a phenol based disinfectant, mixed to manufactures instructions, directly onto foot pad.
   1b. Allow the solution to remain in contact with the surface for approximately 10 minutes.
   1c. Wipe the solution or disinfectant off the foot pedal until visually clean.
2. Dry the units with a clean, non-abrasive cloth.

NOTE: If debris is found under the Foot Control Unit's boot, return for warranty service.

IntelliFlow Irrigation Remote Control



The IntelliFlow Irrigation Remote Control is designed to set and change the flow rates from the sterile field.

A. Pause/On-Off:
   - Pause if used with handpiece irrigation (Flow rate will flash yellow).
   - On-Off/Pause if used with Suction Irrigator.
B. Increase/Decrease:
   - Fine adjustment for handpiece irrigation rate.
   - Fine adjustment for suction Irrigator flow rate.
C. Increase/Decrease:
   - Used for coarse adjustment for handpiece irrigation rate.
   - Selects stainless steel (Fr) tubing size for the suction Irrigator.

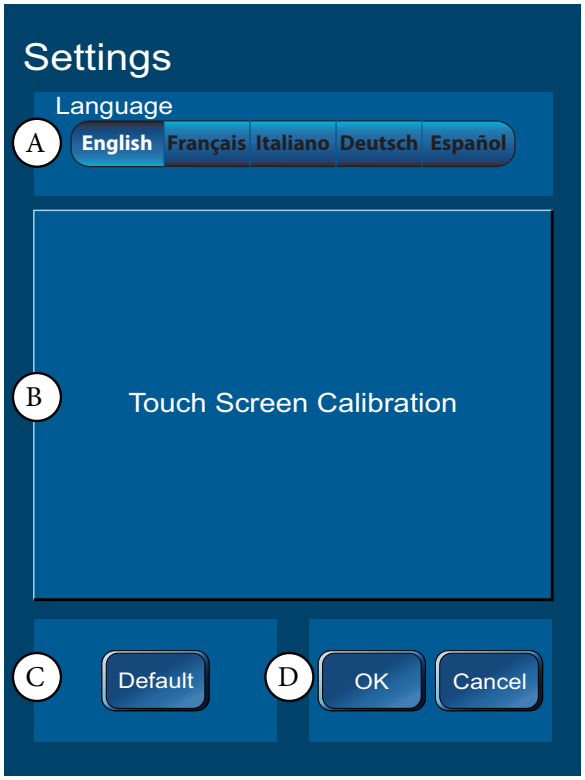
Console Screen

Splash Screen

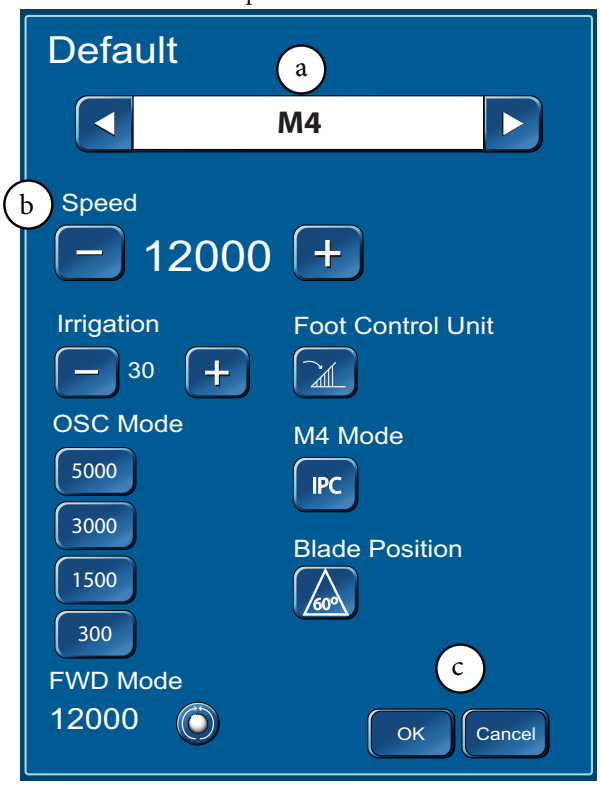
The Splash Screen is displayed while the system is starting up and executing its self tests.

Settings Screen

During the boot up/self-test operation the Splash Screen will display the Setting button for about 5 seconds. To change language, default settings, or calibrate the touch screen you must depress this button while it is displayed.



A. This area is used to select desired language.
B. "Touch Screen Calibration" button will open the calibration screen. To calibrate follow the on screen instructions
C. The "Default" button will open the default screens.



a. The operator can cycle through handpieces to locate desired handpiece.
b. The operator may change any of the default settings to those most frequently used or view default settings.
c. OK / Cancel button will accept or void changes and return to previous screen.

D. OK / Cancel button will accept or void changes and return to previous screen.

NOTE: Changing the default setting of any handpiece in no way affects the operator's ability to change settings during surgery.

Handpiece Default Settings Table

Handpiece		Mode		Pumps	
	Speed Setting	Fwd	Osc	Pump 1	Pump 2
Visao®	80000	X		Coolant	Irrigant
Midas Rex® SC1	3400		X		Irrigant
Straightshot® M4,	12000	X		Endo-Scrub® 2	Irrigant
Straightshot® III, Magnum® II	5000		X	Endo-Scrub® 2	Irrigant
Midas Rex® Legend EHS® motor.	70000	X		Irrigant	
Midas Rex® Legend EHS® Stylus motor	60000	X		Irrigant	
Midas Rex® Legend EHS® Stylus Touch™	60000	X		Irrigant	
Skeeter® Handpiece	16000	X			
Endo-Scrub® 2				X	
Suction Irrigator				Optional	Optional

Device	Setting
FCU Delay	100 mS
Endo-Scrub® 2 Pump	Pump 2
Endo-Scrub® 2 Setting	1

Console Set-Up

Connect Handpiece/Footswitch Screen

When the IPC® detects no handpiece the Connect Handpiece screen will open.

By pressing the OK button in the Connect Footswitch panel the handpiece function will be allowed without the use of a footswitch.

By pressing the OK button in the Endo-Scrub® 2 panel the Endo-Scrub® 2 function will be allowed without the use of a hand piece.

Console Set-Up Instructions

General instructions: for set-up and use of the Integrated Power Console. See "Accessories" for instructions specific to the peripheral being used.
NOTE: Use sterile water or saline for irrigation and cooling.

1. Locate cart and lock wheels.
2. Inspect components for damage and determine if system is ready to use.
3. On IV pole, mount IPC® and irrigation/coolant bag(s).
   NOTE: Irrigant and coolant bags should be placed above the console to ensure adequate flow.
4. Position the IPC® in a manner that does not obstruct the power inlet for the purpose of disconnecting the Mains voltage by the power cord. Plug unit into power source.
5. Connect footswitch.
6. Connect the sterilized accessories to console.
7. Tubing
   - Connect tubing as needed (suction, cooling, irrigation).
8. Turn power switch ON and verify:
   - System passes self test
   - Default screen opens. If "Attach Handpiece / Attach Footpedal" screen opens, return to steps 4 and 5.
9. Prime irrigation and cooling: See Precaution P1.
   a. Adjust clamp on the irrigation tubing to OPEN.
   b. Manually prime the clear drip chamber (if used).
   c. Depress and release the prime button on the touch screen panel.
      Verify:
      - Pump(s) run until all air has been purged out of the tubing.
      - A small amount of irrigant is observed flowing at the tip of irrigation device(s).
      - Pump(s) turns off.
10. Confirm system operation.
    Verify:
    - Pedal (Coolant) Starts handpiece and coolant flow (coolant pump continues to run for 1 minute after pedal is released).
    - Pedal (Irrigation) Starts and stops the handpiece and irrigation flow (At this step you should also verify that the characters on the SPEED display changed from white to yellow.
    - Pedal Buttons: Please refer to "Multifunction Foot Control Unit".
11. Depress the intraoperative button on the back of the console.
    Verify:
    - Starts and stops the handpiece, irrigation and/or coolant flow.
12. Touch Screen
    Verify:
    - Speed can be adjusted.
    - Mode can be changed.
      - In oscillate and cut modes check:
        - The "Blade Position" panel opens.
        - The clockwise and counterclockwise buttons move the position indicator and blade in the appropriate direction.
        - Depressing the 180° button moves the position indicator and blade 180°.
    - Flow rate for irrigation is adjustable.

Special Function Panel - Endo-Scrub® 2

Endo-Scrub® 2

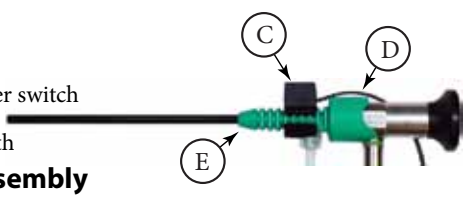
The IPC® System incorporates Endo-Scrub® 2 functionality by using irrigation pump number one (1) and controlling operation with the touch screen and an external footswitch or finger switch.

It is not to be used for infusion, for disinfection or sterilization of an endoscope, or for suction removal of blood and debris.
NOTE: Use the Endo-Scrub® 2 sheath only with an endoscope listed on the sheath product label, as malfunction or poor performance could result.

A. By default the Endo-Scrub® 2 uses pump 1. See "Standard Pump Set-Up" for loading the tubing.
B. Flow panel:
   - Enable/disable pump 1 using the check button.
   - Adjust the flow rate (Setting).
   - Prime button see "Push Buttons and Indicators".
C. Pump number 1 panel:
   - Attachments listed for this pump.
   - Prime button (See Push Buttons and Indicators).
   - Pump panel may be closed by pressing the X-button.
D. Pump number 2 panel:
   - Attachments listed for this pump.
   - Prime button (See Push Buttons and Indicators).

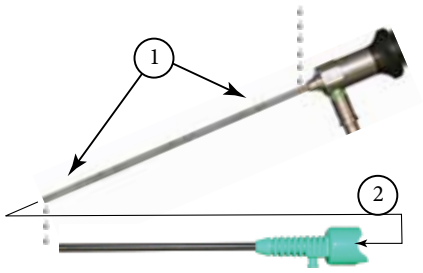
Endo-Scrub® 2 Footswitch / Finger Switch

A. Endo-Scrub® 2 Footswitch
B. Endo-Scrub® 2 Footswitch cable

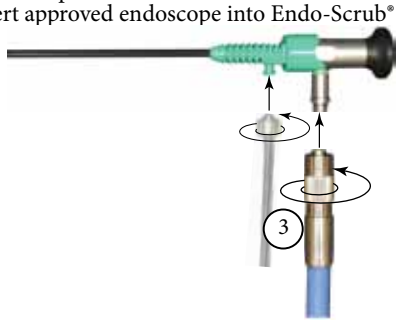


C. Endo-Scrub® 2 Finger switch
D. Finger switch cable
E. Endo-Scrub® 2 Sheath

Endo-Scrub® 2 Assembly



1. Wet the Endoscope.
2. Slowly insert approved endoscope into Endo-Scrub® 2 Sheath.



3. Attach irrigation and light source.

NOTE: For cleaning instructions see Multifunction Foot Control Unit (FCU)

Reprocessing Instructions Finger Switch

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

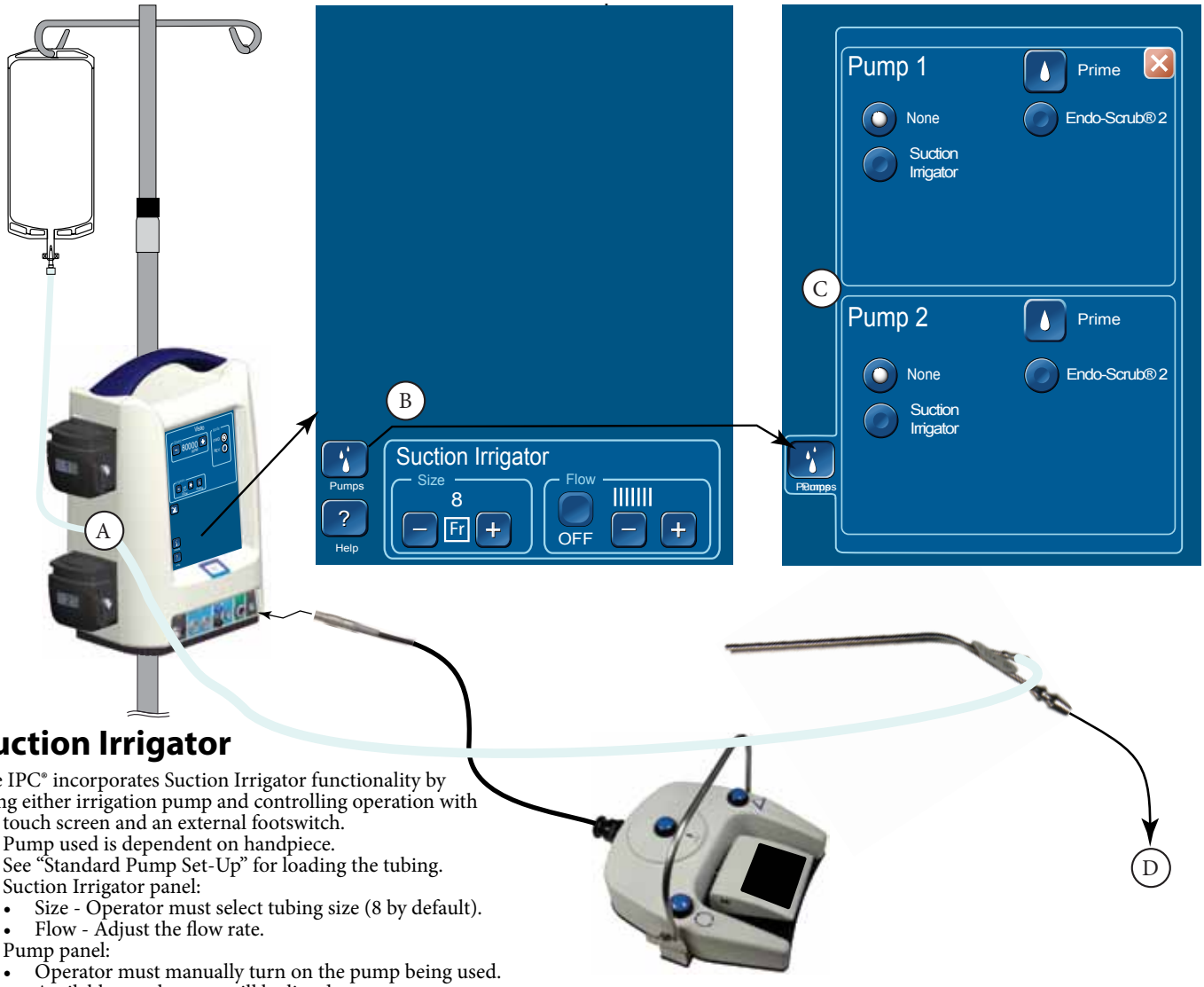
Endo-Scrub® 2 Finger Switch

Warnings / Precautions	Disconnect the finger switch from the Endo-Scrub® 2 pump before cleaning.		
Limitations	After cleaning and sterilization, verify functionality prior to re-use.		
Instructions			
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. After use, remove the finger switch from the sheath and disconnect the plug from the pump. Thoroughly rinse with water following use.		
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.		
Preparation for decontamination	Promptly and thoroughly rinse with deionized water after each use.		
Cleaning: Automated	**Not validated**		
Cleaning: Manual	Dip the finger switch housing in a diluted mixture of mild (pH 7.0 - 8.5) enzymatic detergent. (Follow detergent manufacturer's instructions for proper dilution.) Thoroughly clean the housing with a soft instrument brush to remove any blood and tissue. Rinse the housing thoroughly with tap water and wipe dry. NOTE: If wiping the cord dry, be sure to hold the cord and not the housing to avoid stressing or breaking the electrical connections located inside the housing.		
Disinfection	NOTE: Do not cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilize, as damage to the instrument finish may occur.		
Packaging	A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instruments trays or general purpose sterilization trays. Ensure that cutting edges are protected. Wrap trays using appropriate method.		
Sterilization	**Check the cleanliness and operation of the instrument. Clean again if debris is present and remove from use any damaged instrument. Close instruments with catches and racks on the first notch. Arrange the instruments in sterilization containers with perforations on the top and bottom, and on supports such as those used in microsurgery. Follow the appropriate cycle listed in the table below.** **All steam cycles have been validated in the wrapped configuration and can be sterilized wrapped or unwrapped. These devices have only been validated for steam sterilization methods.** **The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instruments.**		
(Temperatures are minimum required, times are minimum required)	**Cycle:**	**Gravity**	**Pre-vac**
	Temperature:	132 °C	132 °C
	Time:	10 min	10 min
	Drying:	15-30 minutes, or until visibly dry	
Maintenance, Inspection and Testing	Inspect finger switch for any damage before and after each use. If damage is observed do not use the finger switch until it is repaired or replaced. After cleaning and sterilization, verify functionality prior to re-use.		
Storage	Store in a clean, dry area.		
Additional Information	None.		

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 is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

NOTE: All validations performed per AAMI TIR 12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers. Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.

Special Function Panel - Suction Irrigator



Suction Irrigator

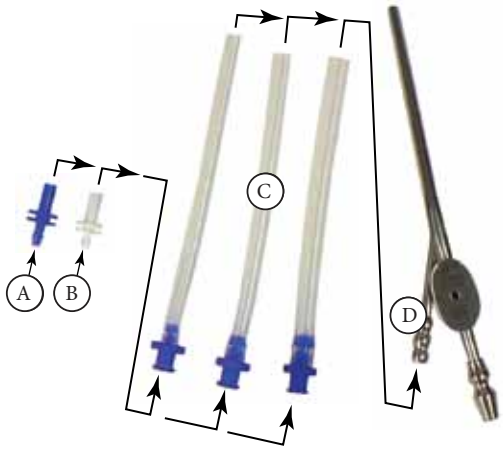
The IPC® incorporates Suction Irrigator functionality by using either irrigation pump and controlling operation with the touch screen and an external footswitch.

A. Pump used is dependent on handpiece.
   See "Standard Pump Set-Up" for loading the tubing.
B. Suction Irrigator panel:
   - Size - Operator must select tubing size (8 by default).
   - Flow - Adjust the flow rate.
C. Pump panel:
   - Operator must manually turn on the pump being used.
   - Available attachments will be listed.
   - Pump panel may be closed by pressing the X-button.
D. Suction Source

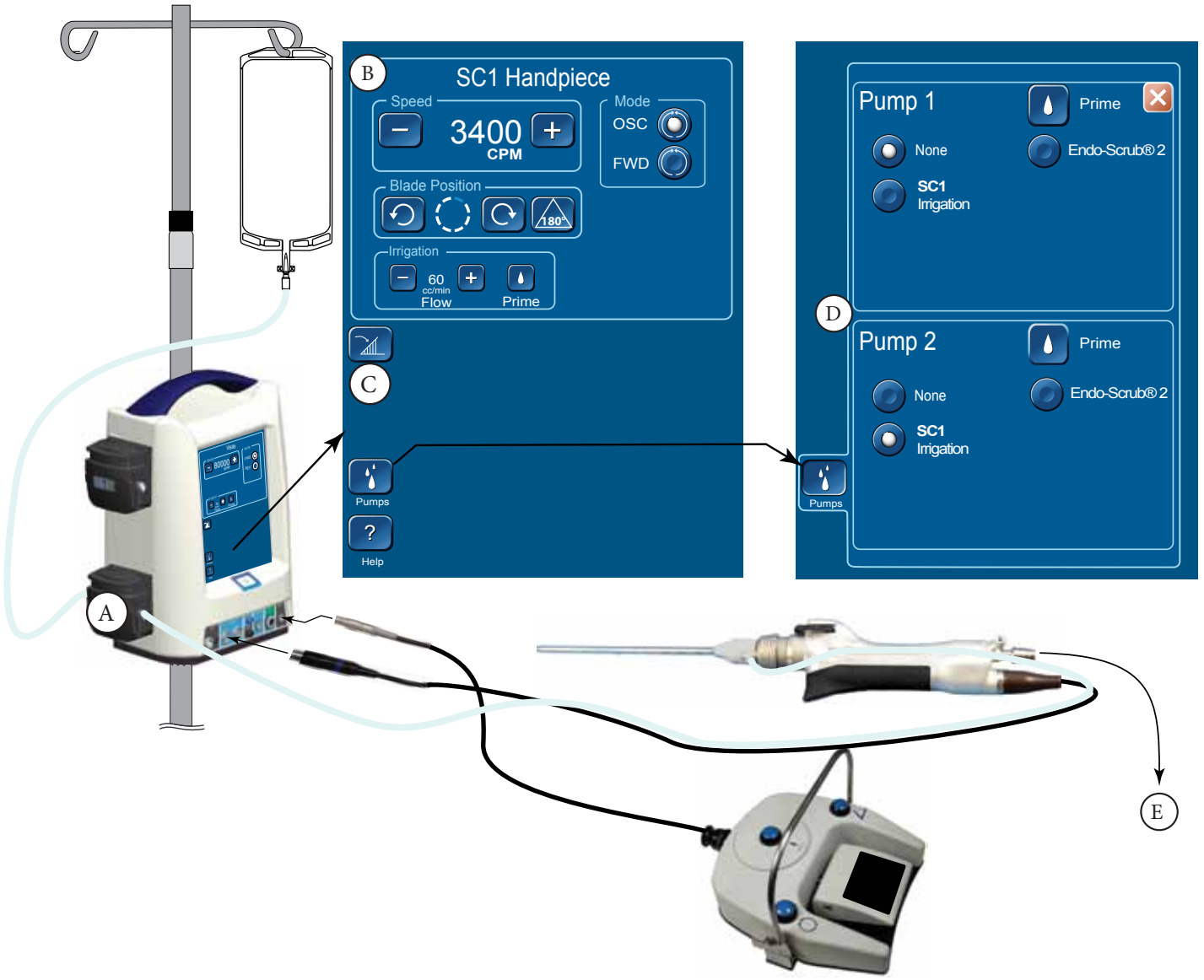
Suction irrigator handpiece.

A. Suction Tube
B. Irrigation tube
C. Suction Fitting
D. Irrigation Fitting
E. Tube Size

Suction Irrigator Adapter Kit



A. Blue Irrigation Tube Adapter fits high speed irrigation tubing - 3318503.
B. White Irrigation Tube Adapter fits IPC® Visao® irrigation tubing - 3318603.
C. Irrigation Connector Set is used to adjust the Blue or White Adapter to the stainless steel Irrigation Fitting.
D. Irrigation Fitting



SC1 Set-Up

A. Irrigation pump

SC1 Touch Screen

B. SC1 Touch Screen:

- Speed Panel:
  - In Fwd Mode, allows variable adjustment from 50 to 12000 rpm with a default speed of 12000 rpm.
  - In Osc Mode, allows variable adjustment from 50 to 5000 cpm with a default speed of 3400 cpm.
- Blade position Panel (Osc Mode ONLY):
  - Delta button (right side of panel) rotates the inner blade 180° via the foot pedal right button or Theta button.
  - The rotation buttons are for manual adjustment and rotates the blade, in small increments, in a clockwise or counter-clockwise direction.
  - Between the rotation buttons is the motion indicator. This does not indicate blade position only blade motion.
- *NOTE: For positioning the outer blade see Blade Position and Finger Wheel.*
- Irrigation Panel - Used to adjust the flow rate for in-blade irrigation. Default is 30 cc per minute in Fwd Mode and 60 cc per minute in Osc Mode.
  Flow rate is adjustable with the touchscreen or the irrigation remote control. See Precaution P1 for Prime/Flush button.
- Mode Panel - For selection of Fwd or Osc mode.

C. Main Screen subsection buttons:

- Foot Control Unit (FCU) Button - changes foot pedal from variable speed control to On/Off.
- Augment Area - (blank area) Shows supplemental information, such as, inactive handpiece(s), or the special function panel (Suction Irrigator or Endo-Scrub® 2).
- Pumps - Opens pump panel.
- Help - Opens help screens.

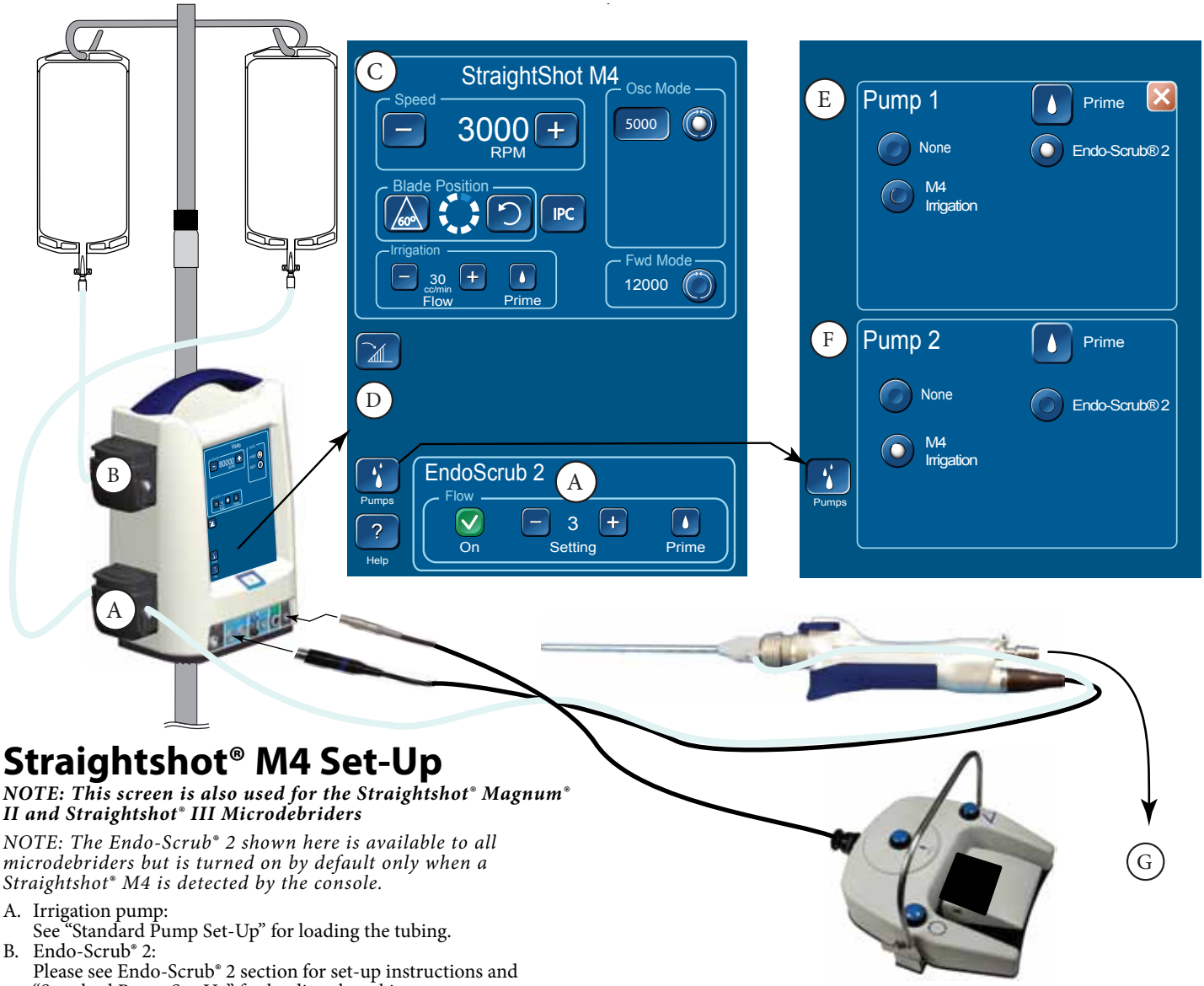
SC1 Pump Screen

D. Pump number 1 panel:

- Attachments listed for this pump.
- Pump 1 is none, and pump 2 irrigation, by default when using the SC1.
- Pump panel may be closed by pressing the X-button.
- See Precaution P1 for Prime/Flush button.

E. Suction source

Strightshot® Microdebriders Set-Up



Straightshot® M4 Set-Up

NOTE: This screen is also used for the Straightshot® Magnum® II and Straightshot® III Microdebriders

NOTE: The Endo-Scrub® 2 shown here is available to all microdebriders but is turned on by default only when a Straightshot® M4 is detected by the console.

A. Irrigation pump:
See "Standard Pump Set-Up" for loading the tubing.

B. Endo-Scrub® 2:
Please see Endo-Scrub® 2 section for set-up instructions and "Standard Pump Set-Up" for loading the tubing.

Straightshot® M4 Touch Screen

C. Straightshot® M4 Handpiece Touch Screen:
- Speed Panel:
  - In Fwd Mode, allows variable adjustment from 50 to 12000 rpm with a default speed of 12000 rpm
  - In Osc Mode, allows variable adjustment from a minimum or 50 rpm to 5000, 3000, 1500, or 300, dependent on buttons selected.
- Blade position Panel:
  - Delta button (1st button on left) sets the inner blade rotation via the foot pedal right (delta symbol) to 60º or 180º.
  - Next to the theta is the motion indicator. This does not indicate blade position only blade motion.
  - The rotation button is for manual adjustment and rotates the blades, in small increments, in a counter-clockwise direction.
- *NOTE: For positioning the outer blade see Blade Position and Finger Wheel.*
- IPC/XPS® button:
  - When the IPC is visible on the button the inner blade will stop in the same position as it started in.
  - When XPS® is visible on the button the inner blades stopping position is random.
- Irrigation Panel - Used to adjust the flow rate for in-blade irrigation. Default is 30 cc per minute. Flow rate is adjustable with the touchscreen or the irrigation remote control. See Precaution P1 for Prime/Flush button.
- Osc Mode Panel - Four selectable oscillation speeds. Each speed is adjustable via the touch screen. The foot pedal (left button) steps through each selected speed including forward.
- Forward Mode Panel is on by default.

D. Main Screen subsection buttons:
- Foot Control Unit (FCU) Button - changes foot pedal from variable speed control to On/Off.
- Augment Area (blank area) - Shows supplemental information, such as, inactive handpiece(s), or the special function panel (Suction Irrigator or Endo-Scrub® 2).
- Pumps - Opens pump panel.
- Help - Opens help screens.

Straightshot® M4 Pump Screen

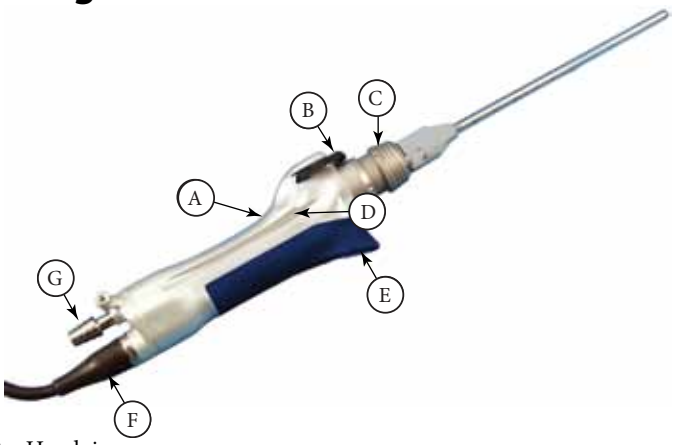
E. Pump number 1 panel:
- Attachments listed for this pump.
- *NOTE: If the Straightshot® M4 has been detected by the console Pump 1 will default to Endo-Scrub® 2.*
- Pump panel may be closed by pressing the X-button.
- See Precaution P1 for Prime/Flush button.

F. Pump number 2 panel:
- Attachments listed for this pump.
- *NOTE: If the Straightshot® M4 has been detected by the console Pump 2 will default to irrigation, with optional attachments listed.*
- See Precaution P1 for Prime/Flush button.

G. Suction Source

Handpiece Set-Up Microdebriders

Midas Rex® SC1, Straightshot® M4, Straightshot® Magnum® II, and Straightshot® III



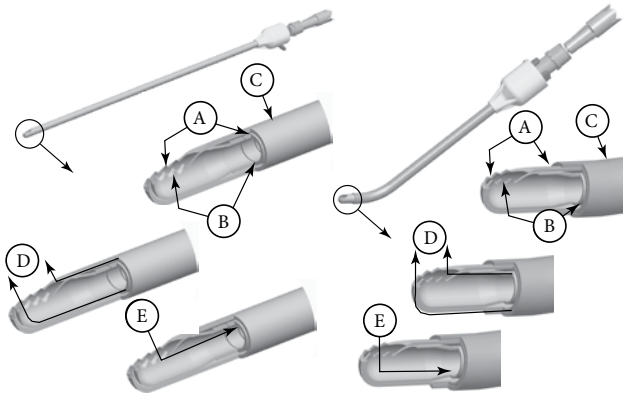
A. Handpiece
B. Finger wheel
C. Locking collar
D. Irrigation-tubing groove
E. Finger-wheel lock
F. Cable
G. Suction barb

Blade Position and Finger Wheel, Straightshot® M4 and SC1

Blades

NOTE: On keeping blades clear:
During the procedure, it is recommended to periodically submerse the blade tip in sterile water with suction connected to the handpiece.

NOTE: For Airway Blades:
Should the blade become clogged during use, risk assessment has determined 1-5 cc of irrigant could be aspirated by the patient before detection by the user.



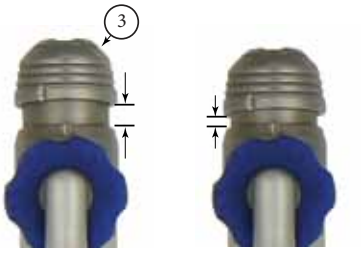
A. Outer blade - rotated by Finger Wheel (Straightshot® M4 and Midas Rex® SC1).
B. Inner blade - rotated by the Blade Position panel (Straightshot® M4, Straightshot® Magnum® II, Straightshot® III, and the Midas Rex® SC1).
C. Outer Sleeve.
D. Irrigation flow is between the inner and outer blades.
E. Suction flow is through the inner blade.

StraightShot® M4 and Midas Rex® SC1 Blade or bur installation

NOTE: The Straightshot® M4 uses cutting tools with a four (4) tab alignment system where the Midas Rex® SC1 uses cutting tools with a three- (3) tab alignment system.

1. Insert tool aligning the tabs with the notches (1) and orientate the irrigation barb (2) to the left or right side.

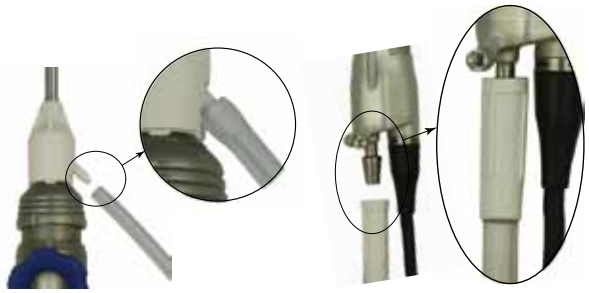
2. Depress the locking collar (3).



3. Release the locking collar. (If collar does not return to full out position adjust the finger wheel with small back-and-forth motions until collar pops out).

4. Pull on the blade or bur to ensure engagement and visually check to make sure distal tip of inner blade is in contact with the distal tip of the outer cannula.

Tubing (Straightshot® M4, and the Midas Rex® SC1).



1. Push the free end of the irrigation tubing onto the irrigation barb on the blade until fully seated.
2. Attach suction tubing securely to the suction port on the handpiece.

Strightshot® Midas Rex® Handpiece Set-Up

3. Secure the irrigation tubing.
4. Secure the suction and irrigation tubing (see Tubing Management).

Technical Specifications

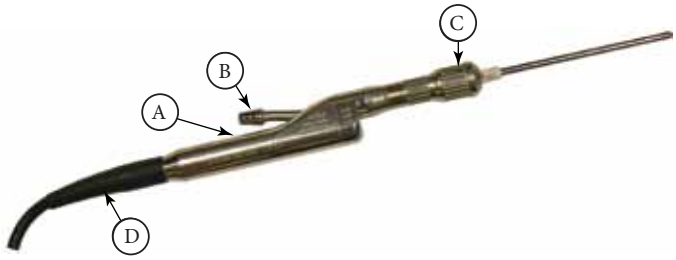
StraightShot® M4 Microdebrider Part No. 1898200T

Midas Rex® SC1 Part No. ED100

Speed	50-5,000 rpm oscillate	
	50-12,000 rpm forward	
Size	14.3 cm length x 1.8 cm width (1898200T)	
Weight	228 g	1898200T
	240 g	1897200
	254 g	1897200T
	240 g	1897201
Duty Cycle	The StraightShot® M4 Handpiece under full load is rated for intermittent operation per the following:	
	Maximum On Time 60 seconds	
	Minimum Off Time 30 seconds	

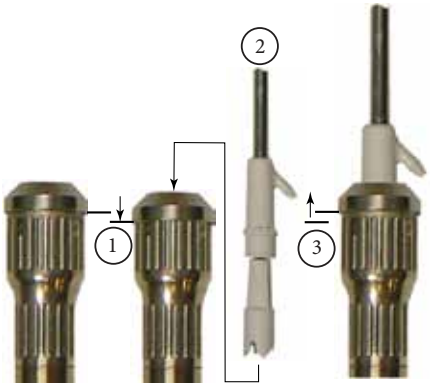
Straightshot® Magnum® II and Straightshot® III

NOTE: Straightshot® Magnum® II and Straightshot® III both use the Straightshot® M4 touch screen interface.



A. Basic handpiece
B. Suction barb
C. Locking collar
D. Cable

Blade installation



1. Depress collet (1).
2. Insert blade in collet and release collet (2 and 3).
3. Pull on the tool to ensure engagement and check distal tip of inner blade is in contact with the distal tip of the outer cannula.

Tubing

4. Attach suction tubing.
5. Push irrigation tubing onto the irrigation barb.
6. Secure the suction and irrigation tubing (see Tubing Management).

Technical Specifications

Straightshot® Magnum® II, Part No. 1897200
Straightshot® III Part No. 1897201

Size	17 cm length x 1.6 cm diameter (1897200)
Speed	500-5,000 rpm oscillate
	500-12,000 rpm forward
Size	17 cm length x 1.6 cm diameter (1897201)
Weight	240 g
Duty Cycle	Under full load is rated for intermittent operation per the following:
	Maximum on time 60 seconds
	Minimum off time 30 seconds

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Magnum®, Straightshot®, M4, SC1 Handpieces

Warnings/ Precautions	• Disconnect the power before cleaning. • Do not fully immerse, or ultrasonically clean, this instrument. • Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty. • Do not use organic solvents to clean the bur chuck. • For drill handpiece cleaning, cover handpiece cable connector end with Handpiece Cable Cap, Small, catalog no. 3318510 or Handpiece Cleaning Cap, Universal, catalog no. 3318520. (Note: Use 3318520 for Straightshot® M4, Visao®, and Xcalibur® Hi-Speed with angled cable. Use 3318510 for other handpieces.) • After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning.
Limitations	After cleaning and sterilization, verify functionality prior to re-use.
Instructions	
Point of Use	• This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. • To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.
Preparation for Decontamination	Remove the bur from the handpiece, otherwise disassembly is not required.
Cleaning: Automated (Do NOT use ultrasonic washer)	• Remove instruments and equipment from any sterilization trays before placing into washer baskets. • Orient devices following recommendations of washer/disinfector manufacturers. • Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. • These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.
Cleaning: Manual	 • Do not immerse the handpiece. • Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth. • Gently clean the handpiece with a moistened soft bristle brush or pipe cleaner, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit. • Hold the handpiece with the front end pointed downward during rinsing.* *Additional Cleaning Instructions for XPS® Straightshot® M4/SC1 Microdebrider: - During the normal cleaning cycle, run a gentle stream of warm water into the collet (front end), and into the lock lever of the Straightshot® M4/SC1 handpiece. - While warm water is running into the collet, rotate the mechanism for several revolutions (rotate the wheel); and while water is running into the lock lever, actuate the lock lever several times (locking and unlocking). - Shake excess water from the handpiece. - PRECAUTION: Ensure the use of a very gentle stream of warm clean water during this additional cleaning step. • Dry the handpiece and cable with a lint-free towel. Make sure to dry off the electrical conection on the cable ends. • Apply a small amount of silicone spray into the front-end collet and outside of the handpiece. • Sterilize the handpiece immediately after cleaning.
Disinfection	Do not cold soak in gluteraldehyde.
Packaging	• A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. • In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.
Sterilization (Temperatures are minimum required, times are minimum required)	• The sterlization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). • All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.

Cycle	**Gravity**	**Pre-vac**	**Pre-vac (FR/WHO)**	**Pre-vac (UK)**	
Temperature	121°C	132°C	134°C	134°C	
Time	40 min	4 min	18 min	3 min	
Drying	8 minutes, or until visibly dry.				
STERRAD Sterilization	100S Compatible				
100% EtO Sterilization Parameters		**Temperature**	54-55°C	**Relative Humidity**	60 +/- 5%
		Ethylene oxide concentration	600 +/- 25 mg/L	**Gas Exposure (full cycle)**	120 min
		Aeration at	48-52°C, 8 hr		

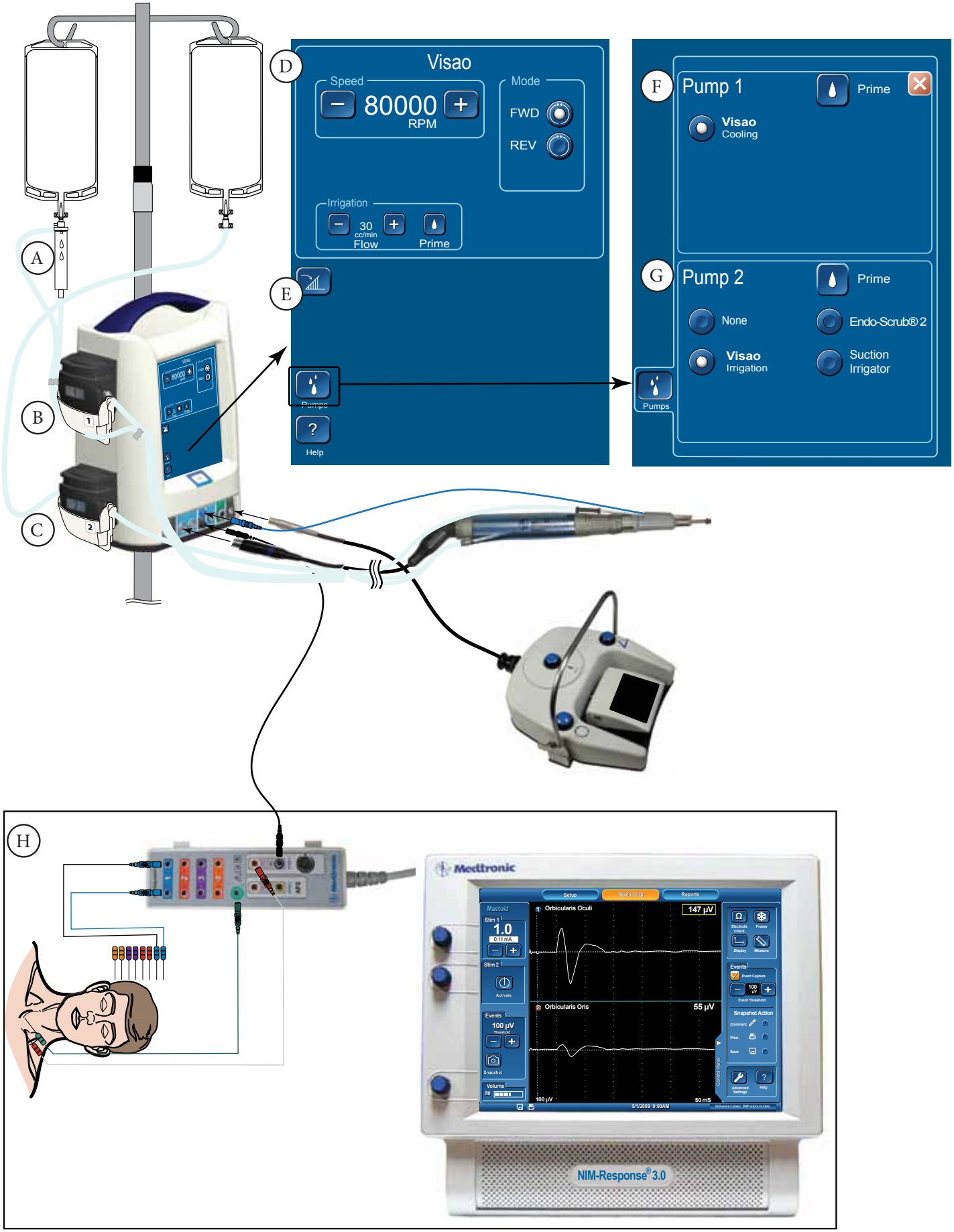
Maintenance, Inspection, and Testing	• Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. • After cleaning and sterilization, verify functionality prior to re-use.
Storage	It is extremely important that the handpiece be rapidly and completely vacuum dried before storage to prevent corrosion and residue deposits in the bearing and motor.
Additional Information	Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149° C (300° F). Heating above 149° C (300° F) may damage the handpiece and will void the warranty.

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 is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.

Visao® Set-Up


A
B
C
D
Visao
Speed
80000
RPM
Mode
FWD
REV
Irrigation
30
cc/min
Flow
Prime
E
Pumps
Help
F
Pump 1
Prime
Visao
Cooling
G
Pump 2
Prime
None
Endo-Scrub® 2
Visao
Irrigation
Suction
Irrigator
Pumps
H
Medtronic
Setup
Monitoring
Reports
Mastoid
Orbicularis Oculi
147 µV
Stim 1
1.0
0.11 mA
Stim 2
Activate
Orbicularis Oris
55 µV
Events
100 µV
Threshold
Snapshot
Volume
100 µV
50 mS
NIM-Response® 3.0

Visao® Set-Up

This is the default set-up for the Visao® drill: Pump 1 will default to coolant and Pump 2 will default to irrigation.

A. Visao® Clear Drip Chamber:
The clear drip chamber must be filled with coolant before priming the coolant system. To fill, squeeze and release the chamber until full. Visao® Coolant Pump (1) Cartridge

B. The Visao® Coolant Pump Cartridge:
The Cartridge has both a pump tube and a return tube (returns to the drip chamber). Used for cooling. Pump and cartridge are numbered (1).

C. The Irrigation Pump Cartridge:
The Cartridge (single tube) snaps onto the lower section of the pump. Normally used for irrigation. Pump and cartridge are numbered (2).

Visao® Touch Screen

D. Visao® Handpiece Touch Screen:
- Speed Panel - Variable adjustment from 200 to 80,000 rpm (FWD and REV) with a default speed of 80,000 rpm in FWD Mode.
- Mode Panel - Enables forward or reverse tool rotation. Direction is selectable with the touchscreen or foot pedal (left button).
- Irrigation Panel - Used to adjust the flow rate for on-drill irrigation. Default is 30 cc per minute. Flow rate is adjustable with the touchscreen or the irrigation remote control.
- Special Function Panel - Shows Suction Irrigator or Endo-Scrub® 2 panel.

E. Main Screen subsection buttons:
- Foot Control Unit (FCU) Button - changes foot pedal from variable speed control to On/Off.
- Augment Area - (blank area) Shows supplemental information, such as, inactive handpiece(s), or the special function panel.
- Pumps - Opens pump panel.
- Help - Opens help screens.

Visao® Pump Screen

F. Pump number 1 panel:
- Attachments listed for this pump.
- *NOTE: If the Visao® drill has been detected by the console Pump 1 will default to coolant and Pump 2 will default to irrigation, with optional attachments listed.*
- Pump panel may be closed by pressing the X-button.
- See Precaution P1 for Prime/Flush button.

G. Pump number 2 panel:
- Attachments listed for this pump.
- If no irrigation is used the operator should select the pump 2 "None" radio button or the suction irrigator/other handpiece radio button.
- See Precaution P1 for Prime/Flush button.

STIM Bur Guard

H. The STIM bur guard is equipped with a cable that connects to the BUR jack on the Integrated Power Console™. A separate cable, supplied with the bur guard, then connects the IPC® (NIM® Jack) to the Medtronic Nerve Integrity Monitor (NIM®) Patient Interface Box. Wires within the STIM Bur Guard make contact with the uncoated tool and carry the stimulating current to the tool's tip.

For more information related to the STIM Bur Guard system contact your local Medtronic ENT representative.

Visao® Bur Guards

	Visao® Reusable Bur Guards with and without irrigation.
	Visao® Single use bur guard with irrigation
	Visao® Single use STIM bur guard with and without irrigation The STIM bur guard also provides nerve stimulation to standard burs in static and dynamic modes when used with both the Medtronic Nerve Integrity Monitor (NIM®) and the IPC® or XPS® 3000 (REF 1897102BF only) Drill System.

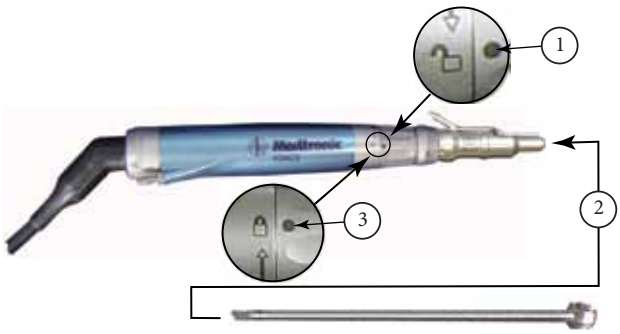
Visao® Bur Guard Installation

NOTE: Bur Guard is required for use with all burs.

NOTE: Multi-use bur guard with irrigation shown. Single-use and STIM bur guard, installs in the same fashion. See also, Notch alignment.

1. To install, simply slide the guard down over the front end fully seated.

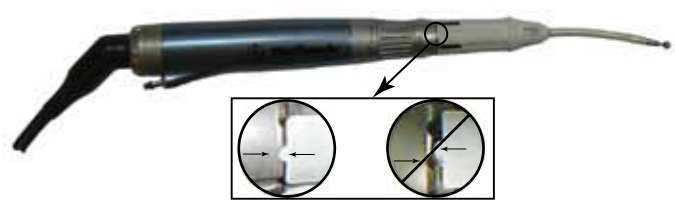
Visao® Straight Tool Installation



1. Align the dot on with the unlock symbol.
2. Insert tool until fully seated.
3. Align the dot on with the lock symbol.
4. Gently pull on tool to ensure it is locked.
5. Remove in the reverse order.

Visao® Notch Alignment and Curved Tool Installation

1. Align the dot on with the unlock symbol as previously described.



2. Align the notch on the tool with the notch on the base.
3. Gently press on the tool until fully seated.
4. Align the dot with the lock symbol.
5. Gently pull on tool to ensure it is locked.
6. Remove in the reverse order.

Visao® Tubing

Visao® Motor Coolant Tubing

The Visao® utilizes saline or DI water to cool the motor. The coolant may flow in the left or right port as long as return tubing is connected to the opposite port.
NOTE: Be careful not to confuse the coolant with irrigation.

1. Connect one tube to each port (numbers 1 & 2 in diagram).

Visao® Bur Guard Irrigation Tubing Instructions

Includes:

- Visao® multi-use Bur Guard with irrigation
- Visao® single-use Bur Guard with irrigation
- Visao® STIM Bur with irrigation

1. Push the free end of the irrigation tubing (number 3 in diagram) onto the irrigation barb until fully seated.

See Precaution P1 for Prime/Flush button.

Visao® Curved Tool Irrigation

1. Prior to initial use, soak the cooling sleeve by dipping it into a cup of saline or DI water, as shown.
2. During use, maintain copious irrigation of the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

Visao® Technical Specifications

Visao® High-Speed Drill Part No. 3334800

Speed	200-80,000 rpm forward/reverse, Visao® High-Speed Drill, Water-Cooled
Size	16.0 cm length x 2.0 cm diameter
Weight	148 g
Duty Cycle	The Visao® High-Speed Drill under full load is rated for intermittent operation per the following: Maximum On Time: 60 seconds Minimum Off Time: 30 seconds

Reprocessing Instructions Visao®

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Visao®

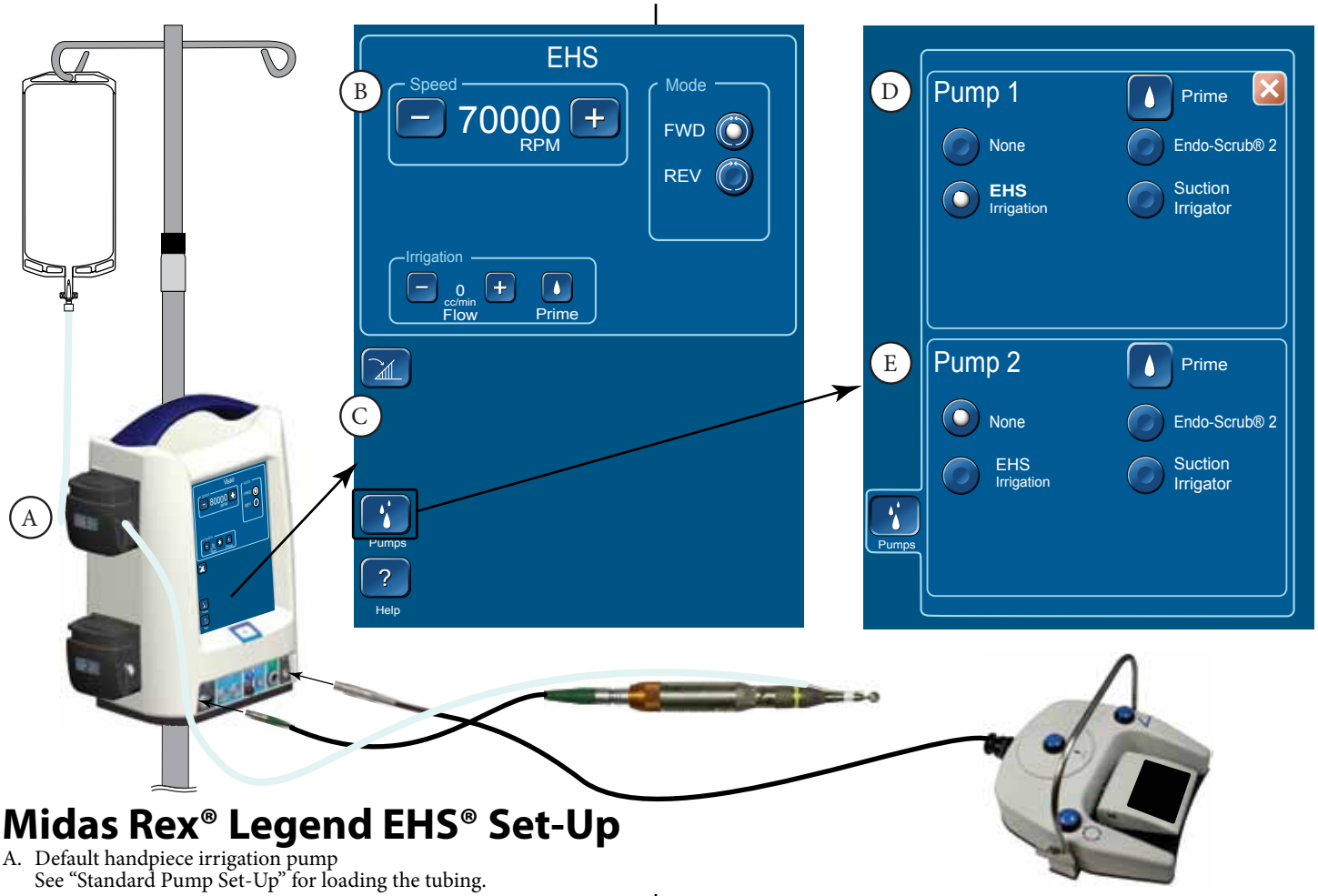
Warnings / Precautions	• Disconnect the power before cleaning. • Do not fully immerse, or ultrasonically clean, this instrument. • Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty. • Do not use organic solvents to clean the bur chuck. • For drill handpiece cleaning, cover handpiece cable connector end with Handpiece Cable Cap, Small, catalog no. 3318510 or Handpiece Cleaning Cap, Universal, catalog no. 3318520. (Note: Use 3318520 for Straightshot® M4, Visao®, and Xcalibur® Hi-Speed with angled cable. Use 3318510 for other handpieces.) • After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning.				
Limitations	After cleaning and sterilization, verify functionality prior to re-use.				
Instructions					
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.				
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.				
Preparation for decontamination	Remove the bur from the handpiece, otherwise disassembly is not required.				
Cleaning: Automated	Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.				
Cleaning: Manual	• Do not immerse the handpiece. • After surgery, clean the irrigation sleeves and bur guards with an enzymatic detergent solution. Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth. • A chuck brush cleaner (REF# 3112500) or an appropriately sized small (plastic bristle) bore brush may be inserted into the distal end of the Visao® handpiece, irrigation sleeves and bur guards to assist in removing fluids, tissue, or bone fragments, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit. • Rinse out the distal end of the handpiece. Shake excess water from the handpiece. • Ensure all water is drained from the cooling housing. If saline was used for cooling during surgery, use distilled water to rinse the housing prior to draining. • Using distilled water, rinse saline from the irrigation nozzles. Drain the nozzle of all water. • Sterilize the handpiece immediately after cleaning.				
Disinfection	Do not cold soak in gluteraldehyde.				
Packaging	A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.				
Sterilization (Temperatures are minimum required, times are minimum required)	The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.				
	Cycle: **Temperature:** **Time:**	**Gravity** **121°C** **40 min**	**Pre-vac** **132°C** **4 min**	**Pre-vac (FR/WHO)** **134°C** **18 min**	**Pre-vac (UK)** **134°C** **3 min**
	Drying:	**8 minutes, or until visibly dry**			
	STERRAD Sterilization: 100S Compatible (Handpiece Only)				
	100% EtO SterilizationParameters: **Temperature** **Ethylene oxide concentration** **Aeration at: 48-52°C, 8 hr.**	**54 - 55°C** **600 +/- 25 mg/L**	**Relative Humidity:** **Gas exposure time (full-cycle):**	**60 +/-5%** **120 minutes**	
Maintenance, Inspection and Testing	Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use.				
Storage	It is extremely important that the handpiece be rapidly and completely vacuum dried before storage to prevent corrosion and residue deposits in the bearing and motor.				
Additional Information	Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149° C (300° F). Heating above 149° C (300° F) may damage the handpiece and will void the warranty.				

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 is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.

Midas Rex® Legend EHS® and Midas Rex® Legend EHS® Stylus Set-Up



Midas Rex® Legend EHS® Set-Up

A. Default handpiece irrigation pump
See "Standard Pump Set-Up" for loading the tubing.

Legend EHS® Touch Screen

B. EHS® Touch Screen:
- Speed Panel:
  - In FWD Mode, allows variable adjustment from 200 to 75000 rpm with a default speed of 70000 rpm.
  - In REV Mode, allows variable adjustment from 200 to 75000 cpm with a default speed of 70000 rpm.
- Irrigation Panel - Used to adjust the flow rate for optional in-blade irrigation. Default is 0 cc per minute in FWD Mode and 0 cc per minute in REV Mode.
  Flow rate is adjustable with the touchscreen or the irrigation remote control. See Precaution P1 for Prime/Flush button.
- Mode Panel - Enables selection of FWD or REV mode.

C. Main Screen subsection buttons:
- Foot Control Unit (FCU) Button - changes foot pedal from variable speed control to On/Off.
- Augment Area - (blank area) Shows supplemental information, such as, inactive handpiece(s), or the special function panel (Suction Irrigator or Endo-Scrub® 2).
- Pumps - Opens pump panel.
- Help - Opens help screens.

Legend EHS® Pump Screen

D. Pump number 1 panel:
- Attachments listed for this pump.
- Pump 1 is EHS® irrigation by default. If not using irrigation operator should change to none.
- Pump panel may be closed by pressing the X-button.
- See Precaution P1 for Prime/Flush button.

E. Pump number 2 panel:
- Attachments listed for this pump.

NOTE: When the Legend EHS® is detected by the console, Pump 2 will default to none, with optional attachments listed.

- See Precaution P1 for Prime/Flush button. Legend EHS® Motors

Midas Rex® Legend EHS® Motor

High speed, high torque, reversible electric motor used to dissect bone and biomaterial at selectable speeds from 200 to 75,000 rpm.

A. Midas Rex® Legend EHS® Motor
B. 4-pin cable connection
C. Stationary collet
D. Rotational collet

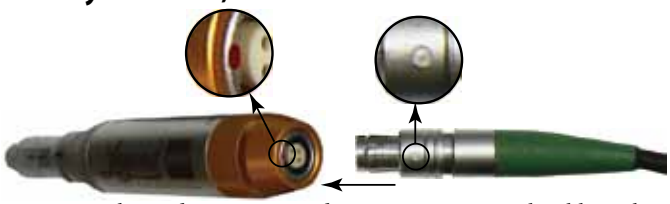
Legend EHS® Motor Cable

EHS® motor to console connection.

A. 4-pin connector
B. Locking sleeve
C. Green boot
D. Cable

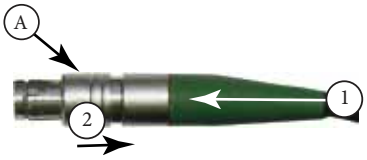
Midas Rex® Legend EHS® and Midas Rex® Legend EHS® Stylus Set-Up

Connect Midas Rex® Legend EHS® Motor and Legend EHS® Stylus Motor, Cable



1. Connect the Midas Rex® Legend EHS® Motor Control Cable to the Midas Rex® Legend EHS® Motor.
   - Take care to align the cable dot to the handpiece's red dot. See illustration.

To Remove Cable:



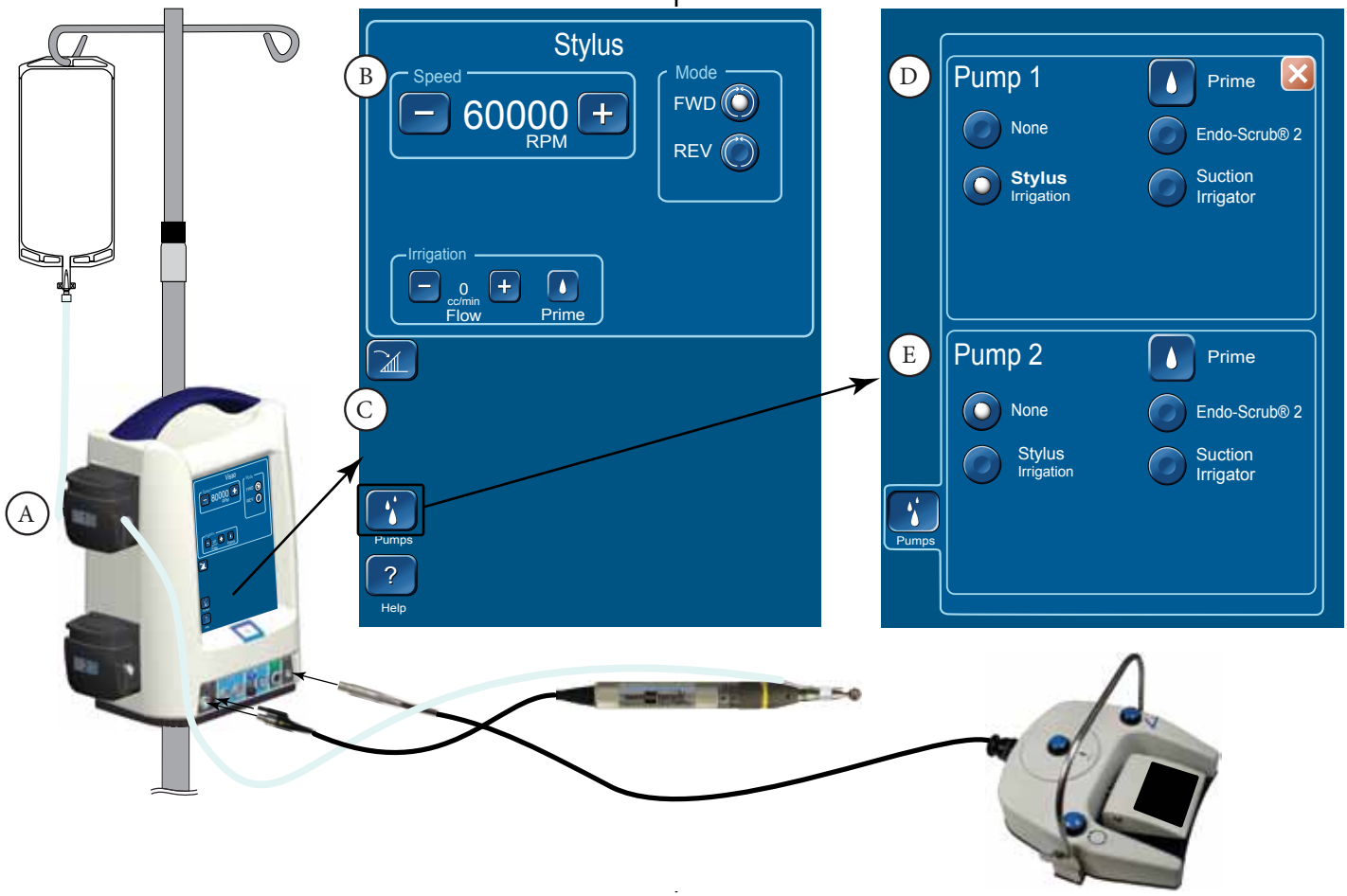
1. Push the cable towards the motor or console.
2. Then pull out by locking ring (A) ONLY.

Technical Specifications

Legend EHS® Motor Part No. EM100-A

Speed 75000 rpm forward/reverse
Size 9.02 cm length x 2.03 cm diameter
Weight 180 g
Duty Cycle (To avoid overheating):

- For continuous use in operating room temperatures up to 40°C (104°F), the Legend EHS® 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 Legend EHS® Motor is rated for a continuous cutting time of 10 minutes followed by 25 minutes of rest.
- The Legend EHS® Motor is rated for intermittent use of 20 seconds ON / 20 seconds OFF, indefinitely at 70,000 rpm.



Legend EHS® Stylus Set-Up

A. Default handpiece irrigation pump
See "Standard Pump Set-Up" for loading the tubing.

Stylus, Touch Screen

B. Touch Screen:
- Speed Panel:
  - In FWD Mode, allows variable adjustment from 200 to 75000 rpm with a default speed of 70000 rpm.
  - In REV Mode, allows variable adjustment from 200 to 75000 rpm with a default speed of 70000 rpm.
- Irrigation Panel - Used to adjust the flow rate for optional in-blade irrigation. Default is 0 cc per minute in FWD Mode and 0 cc per minute in REV Mode.
  Flow rate is adjustable with the touchscreen or the irrigation remote control. See Precaution P1 for Prime/Flush button.
- Mode Panel - Enables selection of FWD or REV mode.

C. Main Screen subsection buttons:
- Foot Control Unit (FCU) Button - changes foot pedal from variable speed control to On/Off.
- Augment Area - (blank area) Shows supplemental information, such as, inactive handpiece(s), or the special function panel (Suction Irrigator or Endo-Scrub® 2).
- Pumps - Opens pump panel.
- Help - Opens help screens.

Stylus, Pump Screen

D. Pump number 1 panel:
- Attachments listed for this pump.
- Pump 1 is Stylus irrigation by default. If not using irrigation operator should change to none.
- Pump panel may be closed by pressing the X-button.
- See Precaution P1 for Prime/Flush button.

E. Pump number 2 panel:
- Panel is Pump is set to none by default.
- Attachments listed for this pump.
- See Precaution P1 for Prime/Flush button. Midas Rex® Legend EHS® Stylus Motor

A smaller compact high speed, high torque, reversible electric motor used to dissect bone and biomaterials at selectable speeds from 200 to 75,000 rpm. The Midas Rex® Legend EHS® Stylus Motor cable is integral with the Handpiece and is not removable from the motor.

A. Midas Rex® Legend EHS® Stylus Motor
B. Cable
C. Rotational collet
D. Stationary collet
E. Ground connector
F. 4-pin connector
G. Locking sleeve
H. Black boot

Technical Specifications

Legend EHS Stylus® Motor Part No. EM200

Speed	75000 rpm forward/reverse
Size	7.77 cm length x 1.65 cm diameter
Weight	90 g

Duty Cycle (To avoid overheating):
- For continuous use in operating room temperatures up to 40°C, the Legend EHS® Stylus Motor is rated for 3 minutes at 60,000 rpm, followed by 25 minutes of rest.
- For normal operating room temperatures (typically 20°C) the Legend EHS® Stylus Motor is rated for continuous cutting indefinitely at 60,000 rpm.

Reprocessing Instructions Midas Rex® Legend EHS® and Midas Rex® Legend EHS Stylus®

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

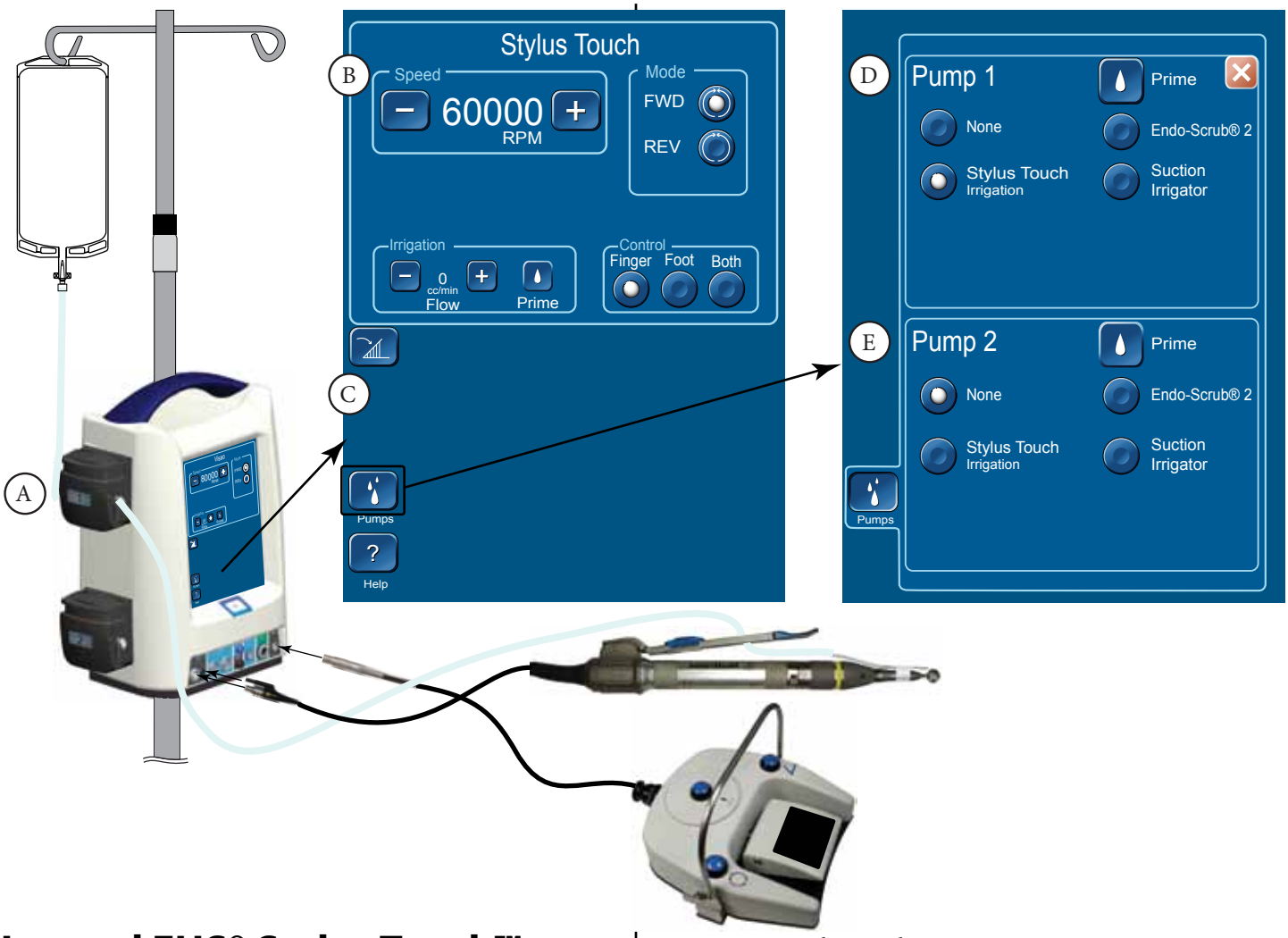
Midas Rex® Legend® Electric High-Speed EHS System Motors

Warnings and Precautions	Do not soak Midas Rex® Legend EHS® equipment. Do not use ultrasound to clean Midas Rex Legend EHS® equipment. 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. Clean the Legend EHS® motor and cable while still connected to each other. This will help reduce ingress of debris.			
Limitations	After cleaning and sterilization, verify functionality prior to re-use.			
Instructions				
Point of Use	This product is provided non-sterile nd must be cleaned and sterilized before the first use and any reuse			
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.			
Preparation for decontamination	Disassembly of Equipment: Turn off power. Disconnect Legend EHS® Motor Cable from Legend EHS® Console. Disconnect Legend EHS® Foot Control Cable from the Legend EHS® Console.			
Cleaning: Automated (Do NOT use ultrasonic washer)	Remove instruments and equipment from any instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. Recommended Washer/Disinfector Cycle Pre-Wash: 35°C, 5 min. Main Wash: 93°C, 30 min. Neutralize: 2 min. Final Rinse: 65°C, 10 min.			
Cleaning: Manual	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 handpiece and cable thoroughly under running water, collet end pointing down. Dry collet and motor with a lint free towel			
Disinfection	No particular requirements			
Packaging	No particular requirements			
Sterilization (Temperatures are minimum required, times are minimum required)	**Steam Sterilization:**			
	Cycle: **Temperature:** **Time:**	**Gravity** 132°C 25 min	**Pre-vac** 132°C 4 min.	**Pre-vac (FR/WHO)** 134-137°C 18 min.
	Drying: 8 minutes			
	STERRAD Sterilization: Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.			
	100% EtO Sterilization Parameters: Temperature: 53-57oC Relative humidity: 70 ±5% Ethylene oxide concentration: 725 ± 25mg/L Gas exposure time (full-cycle): 4 hours (Wrapped) Aeration: 18 hours at 53-57oC			
	Steris: Do not use liquid peracetic acid sterilization due to immersion procedure.			
Maintenance, Inspection and Testing	Inspect components for any damage before and after each use. If damage is observed, do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use.			
Storage	Store with other sterile devices			
Additional Information	None			

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 is actually performed, using equipment, materials and personnel in the reprocessing facility, achieve the desired result. This normally requires validation and routine monitoring of the process.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.
NOTE: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Midas Rex® Legend EHS® Stylus Touch™ Set-Up



Legend EHS® Stylus Touch™ Set-Up

A. Default handpiece irrigation pump
See "Standard Pump Set-Up" for loading the tubing.

Stylus Touch™, Touch Screen

B. Touch Screen:
- Speed Panel:
  - In FWD Mode, allows variable adjustment from 200 to 75000 rpm with a default speed of 60000 rpm.
  - In REV Mode, allows variable adjustment from 200 to 75000 cpm with a default speed of 60000 cpm.
  - In Safe Mode, (when finger lever safe mode switch is on) will not display rpm but will display the word "SAFE" in yellow letters. Handpiece will not operate in safe mode.

- Irrigation Panel - Used to adjust the flow rate for optional irrigation. Default is 0 cc per minute in FWD Mode and 0 cc per minute in REV Mode.
  Flow rate is adjustable with the touchscreen or the irrigation remote control. See Precaution P1 for Prime/Flush button.
- Mode Panel - Enables selection of FWD or REV mode.

C. Main Screen subsection buttons:
- Foot Control Unit (FCU) Button - toggles foot pedal and/or finger lever from variable speed control to On/Off.
- Augment Area - (blank area) Shows supplemental information, such as, inactive handpiece(s), or the special function panel (Suction Irrigator or Endo-Scrub® 2).
- Pumps - Opens pump panel.
- Help - Opens help screens.

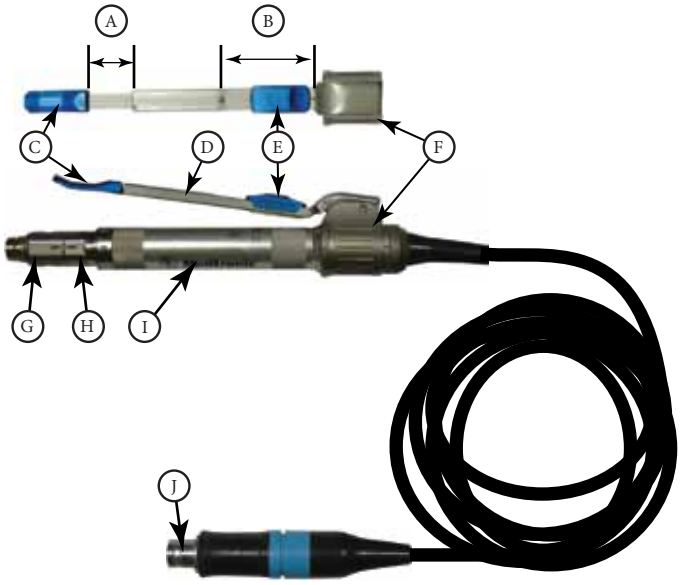
Stylus Touch™, Pump Screen

D. Pump number 1 panel:
- Attachments listed for this pump.
- Pump 1 is Stylus Touch™ irrigation by default. If not using irrigation operator should change to none.
- Pump panel may be closed by pressing the X-button.
- See Precaution P1 for Prime/Flush button.

E. Pump number 2 panel:
- Attachments listed for this pump.
- Panel is Pump is set to none by default.
- See Precaution P1 for Prime/Flush button.

Midas Rex® Legend EHS® Stylus Touch™ Motor

The Midas Rex® Legend EHS® Stylus Touch™ Motor is a small, compact, high-speed, high-torque, reversible electric motor used to dissect bone and biomaterials at selectable speeds from 200 to 75,000 rpm. The Midas Rex® Legend EHS® Stylus Touch™ Motor includes a rotating finger lever that emulates the functions of the multifunction foot switch (on, off, variable speed)



A. Range of motion
B. Range of motion
C. Telescoping Finger Rest (pull out/push in).
D. Finger Lever
E. Finger Lever Safe Mode Switch
F. Control Lever Ring
G. Stationary Collet
H. Rotational Collet
I. Midas Rex® Legend EHS® Stylus Motor
J. 12-pin Connector and Boot

To Rotate the Finger Lever

1. Firmly push the "Control Lever Ring" forward and rotate slightly in a clockwise or counter-clockwise direction as shown in figure below.
2. Continue rotating the finger lever until lever locks in new position.

Technical Specifications

Legend EHS® Stylus Touch™ Part No. EM210

Speed: 75,000 rpm forward/reverse

Size: 15.26 cm length x 1.65 cm diameter

Weight 130 g

Duty Cycle (To avoid overheating):

- For continuous use in operating room temperatures up to 40°C, the Legend EHS® Stylus Motor is rated for 3 minutes at 60,000 rpm, followed by 25 minutes of rest.
- For normal operating room temperatures (typically 20°C) the Legend EHS® Stylus Motor is rated for continuous cutting indefinitely at 60,000 rpm.

Reprocessing Instructions Midas Rex® Legend EHS Stylus® Touch

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Midas Rex® Legend EHS® Stylus Touch™ Motor

Warnings/ Precautions	• Do not soak/submerge Midas Rex® Legend EHS® Stylus Touch® Motor devices. • Do not use ultrasound to clean Midas Rex® Legend EHS® Stylus Touch® Motor devices. • Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium • hydroxide, formic acid, or solutions containing glutaraldehyde. • The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. • Allow an adequate cooling period after steam sterilization.					
Limitations	Verify functionality prior to re-use.					
Instructions						
Point of Use	No particular requirements.					
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.					
Preparation for Decontamination	No particular requirements.					
Cleaning: Automated (Do NOT use ultra-sonic 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: 66°C, 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 aneutral enzymatic detergent, pH 6.0-8.0. • Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent, 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					
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)	**Cycle**	**Gravity**	**Pre-vac**	**Pre-vac (FR/ WHO)**	**Pre-vac (UK)**	**Flash (Pre-Vac, Unwrapped)**
	Temperature	132°C	132°C	134°C	134°C	132°C
	Time	25 min	4 min	18 min	3 min	4 min
	Drying	15 min	15 min	20 min	10 min	N/A
	STERRAD Sterilization: Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.					
	100% EtO SterilizationParameters		Preconditioning: 51-59°C, 70 ±5% relative humidity, 30 min Temperature: 51-59°C Ethylene oxide concentration: 725 ± 25mg/L Aeration at: 12 hours at 51-59°C			Relative humidity: 70 ±5% Gas exposure time (full cycle): 4 hours
	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.					
Additional Information	None					

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 is actually performed, using equipment, materials and personnel in the reprocessing facility, achieve the desired result. This normally requires validation and routine monitoring of the process.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.
NOTE: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Attachments, Midas Rex® Legend EHS® , Midas Rex® Legend EHS Stylus® , and Midas Rex® Legend EHS® Stylus Touch™

Midas Rex® Attachments

Motor Collet

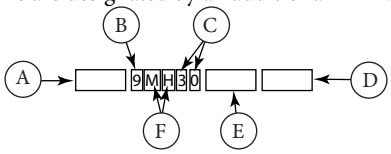
Prior to installing an attachment, ensure that arrows on the motor collet are in proper alignment.

1. Collet improperly aligned.
1. Collet properly aligned.
2. Alignment arrows properly aligned.

If the arrows are not aligned, use the Motor Wrench to turn the rotational collet until its arrow is aligned with the arrow on the stationary collet.

Medtronic Powered Surgical Solutions 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 five characters, representing 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.



A	Optional Prefix
B	Associated Attachment Length
C	Tool Head Diameter (x.x millimeters)
D	Optional "-MN" Suffix for Mednext Tool Designs
E	Optional Suffix
F	Tool Head Shape

Tool Number Prefixes

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

Tool Head Shapes

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		
F	Fine	DC	Diamond Coarse
C	Carbide	DX	Diamond Extra Coarse

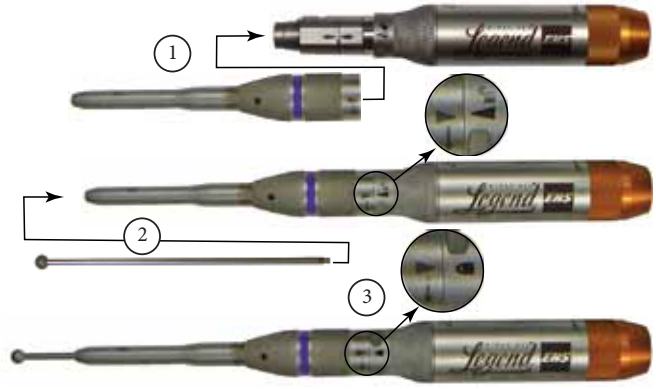
Nomenclature and color-code example

NOTE: In the example shown, the tool can also be used in attachments with a red color code and nomenclature 8-B.

Installing Attachments

Straight Attachment

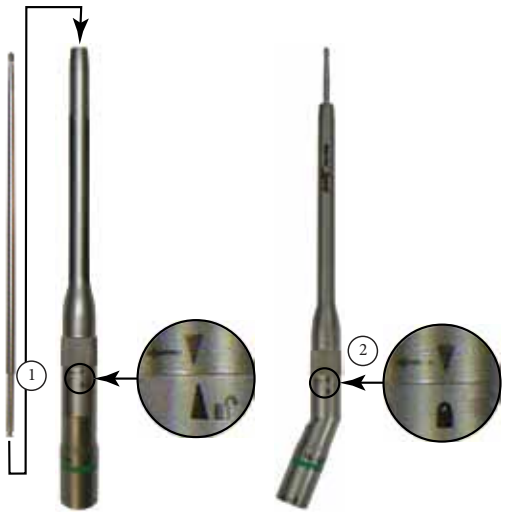
Please see Warning W36 and W54



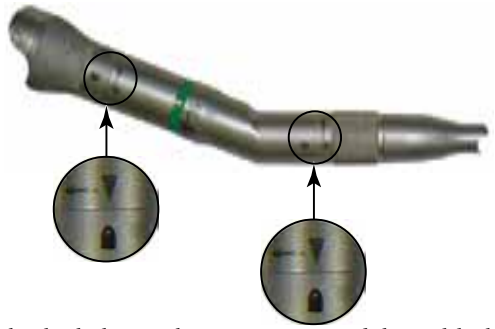
1. Slide straight attachment over motor collet
   Verify:
   - Alignment marks match up at the unlocked symbol.
   - An audible click is heard as the attachment is seated.
2. Insert the tool into the attachment with a slight rotational motion. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
3. Rotate attachment in direction indicated by arrow until attachment alignment mark is directly in line with the locked symbol (you will hear two clicks as the attachment is rotated).
   Verify:
   - Pull on the tool to ensure that it is locked into the handpiece.
   - Tool should rotates freely, if not, unlock the attachment, re-seat the tool, and re-lock the attachment.
4. Removal is in the reverse order of installation.

Angled Attachments

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



1. Insert the tool into the attachment with a slight rotational motion. An audible click, perceptible by touch, confirms that the tool is fully seated.
2. Rotate the tool lock in direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol.
   Verify:
   - Pull on the tool to ensure that it is locked into the handpiece.
   - Tool should rotates freely, if not, unlock the attachment, re-seat the tool, and re-lock the attachment.
3. Install the angled attachment in the same manner as the straight attachment.

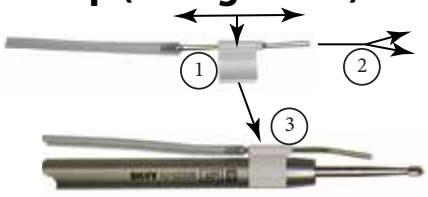


4. Verify that both the attachment to motor and the tool-lock alignment mark is directly in line with the locked symbol.

To Install Angled Attachment:

1. The Angled Attachment installs onto the motor using the standard method (see Straight Attachment for instructions).
2. Removal is in the reverse order of installation.

Irrigation Clip (Straight Bur)



1. Adjust the plastic clip onto the stainless-steel irrigation tube.
2. Bend irrigation tube to a desirable angle.
3. Snap the clip onto the handpiece near the tool.

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

NOTE:

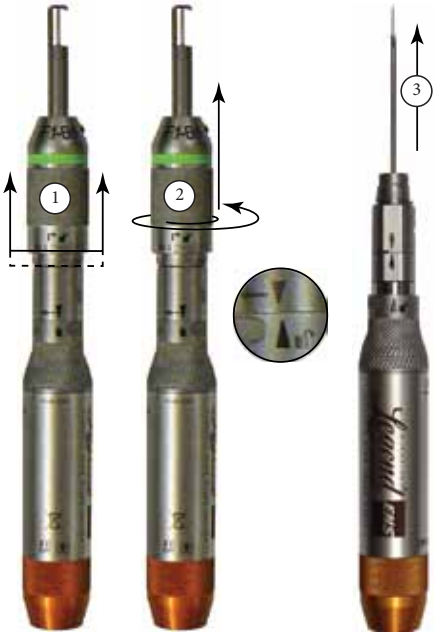
- *A dissecting tool may be installed and locked in the angled attachment before it is installed onto the motor.*
- *Angled and straight attachments with the same length, marking and color band share the same dissecting tools.*
- *The Midas Rex® Legend EHS® Motors will not run properly unless the attachment is in the locked position.*

Fixed Footed Attachment

To Install:

1. Insert the tool into the attachment with a slight rotational motion. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Slide attachment over tool and motor collet.
   Verify:
   - Alignment marks match up at the unlocked symbol.
   - An audible click confirms that the attachment is seated.
3. Rotate attachment in direction indicated by arrow until attachment-alignment mark is directly in line with the locked symbol, there will be two (2) audible clicks observed as the attachment is rotated.

Please see Warning W37



To Remove:

1. Move the sleeve on attachment distally (away from motor).
2. While holding sleeve away from motor rotate attachment toward the unlock position until there is one (1) audible click.
3. Release outward pressure on sleeve.
4. Continue to rotate attachment to the unlock position. There will be one (1) additional audible click as the marks line up.
5. Carefully slide attachment off tool.
6. Pull tool out of motor collet and discard.

Rotating Footed Attachment

Please see Warning W20 & W52

A. Rotating (360°) section
B. Motor-mount section

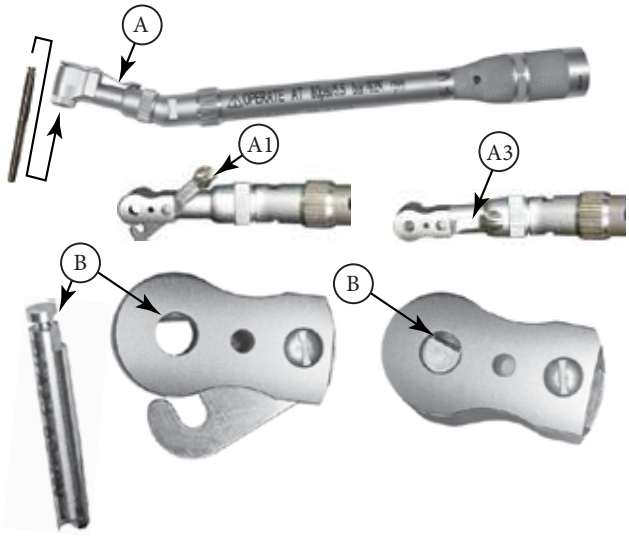
The Rotating and Fixed Footed Attachments use the same tools and are installed and removed from the motor in the same way.
NOTE: When mounting to motor hold by section B.

Contra-Angle Attachment 16-MF

Operating Speed: 62,000 rpm

Before installing the motor or tool, adjust the no-load speed setting to 62,000 rpm using the speed control buttons on the console.

To Install Tool:



1. Lock lever open (see detail A1).
2. Align flat keyway in drill head (see detail B).
3. Lock lever closed (see detail A3).
4. Pull on the tool to ensure that it is locked.
5. Removal is the reverse order.

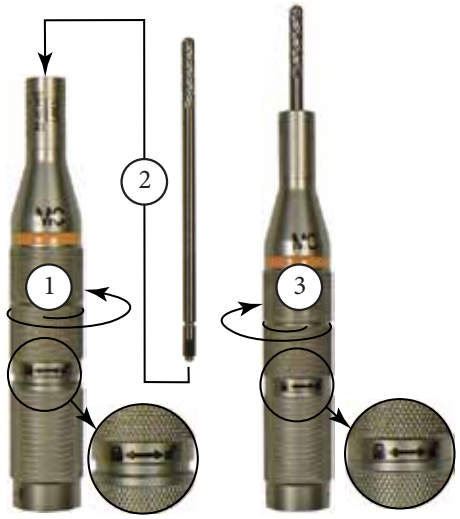
To Install Contra-Angle Attachment:

1. See Straight Attachment.
2. Removal is the reverse order.

Metal-cutting Attachment

The Metal-cutting Attachment uses the tungsten-carbide or diamond-wheel tool. All metal-cutting tools have an "MC" attachment prefix in their nomenclature (example, MC254, MC30). Metal-cutting tools cannot be installed into any other attachment.

Please see Warning W15



To Install Tool:

1. Hold lower section of the attachment, rotate the upper section in the direction of the unlock symbol until it stops.
2. Insert the tool.
3. Rotate the upper section in the direction of the lock symbol until it stops.
4. Gently pull on tool shaft to ensure proper installation.
5. Removal is the reverse order.

To Install Metal-cutting Attachment to motor:

See the Straight Attachment.

Variable-Exposure attachment

The Legend® Variable-Exposure attachments can be distinguished from standard attachments by the dual color bands on the shaft of the attachment.

To Install Variable-Exposure Attachment to motor

1. The Variable-Exposure attachment installs onto the motor using the standard method (see the Straight Attachment for instructions).
2. Removal is in the reverse order of installation.

To Adjust the Variable-Exposure Attachment

Use the Tube adjustment ring to adjust the exposure of the tool. With the tool pointing away from you, turn the Tube adjustment 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.

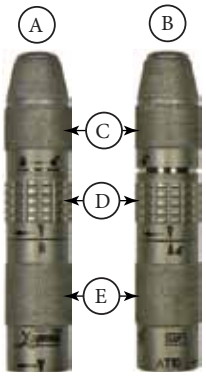
Please see Warning W23, W34, W53, and W57

Cleaning

When cleaning, clean the attachment completely, first without adjusting the tube length, then with the tube fully extended, and with the tube fully retracted.

Telescoping Attachment AT10

Telescoping-Base Attachment



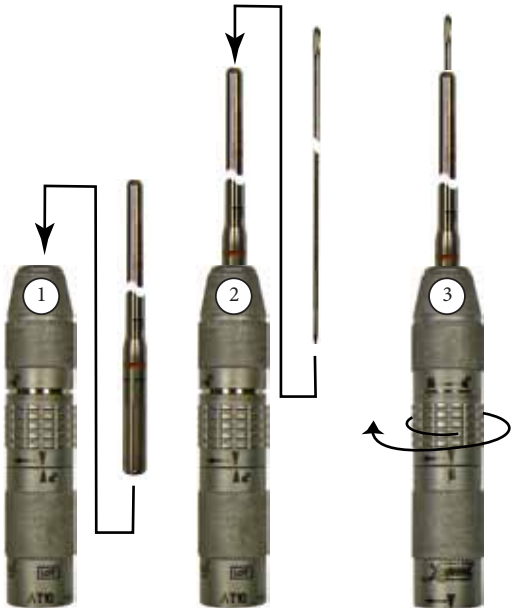
A. Locked
B. Unlocked

C. Tube Locking Ring
D. Tool Locking Ring
E. Base

To Install Base to Motor

See Straight Attachment for instructions.

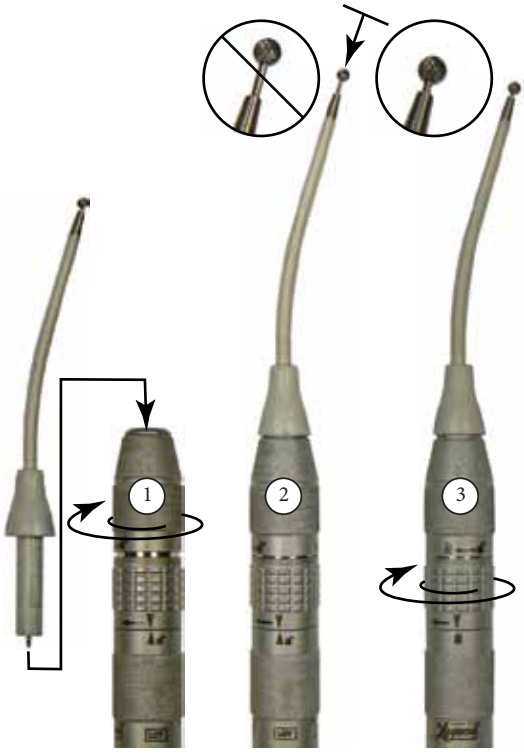
To Install Straight Telescoping Tube and Tool to Base Attachment



The locking rings in the unlocked position.

1. Insert base end of selected telescoping tube into attachment.
   - Turn the Tube Locking Ring until finger tight.
   - DO NOT over tighten.
   - Verify that the tube is in place by gently pulling on the tube.
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.
3. Rotate the Tool Locking Ring lock in direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol.
   - Verify that the tool is in place by gently pulling on the tool.
4. If using a curved tube and position needs to be changed, rotate Tube Locking Ring to the unlocked position, re-position tube, then rotate Tube Locking Ring to the locked position. Gently pull on tool, then the tube, to ensure proper installation.
5. Removal is in the reverse order of installation.

Install Curved Bur into Base Attachment

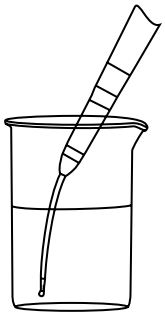


The locking rings in the unlocked position.

1. Insert base end of curved bur into attachment until the hub is fully seated.
   - Turn the Tube Locking Ring until finger tight.
   - DO NOT over tighten.
   - Verify that the hub is in place by gently pulling on the tool.
2. Seat the tool into the tool Locking Ring by applying a slight amount of inward pressure on the bur.
   An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
3. Rotate the Tool Locking Ring until the tool lock alignment mark is directly in line with the locked symbol.
   - Verify that the bur is in place by gently pulling on the bur.
4. Removal is in the reverse order of installation.

Curved Bur Cooling

1. Prior to initial use, soak the cooling sleeve by dipping it into a cup of saline or DI water, as shown.
2. During use, maintain copious irrigation of the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.



Perforator Attachments (AD01 & AD03)

Maximum Speed

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

To Install Perforator-Driver Attachment to Motor:

See the Straight Attachment for instructions.

To Install a Cranial Perforator Device with a Hudson shank

3. Pull back on the collar.
4. Insert device.
5. Release collar to its original position.

Please see Warning W56

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

To Remove:

1. Removal is in the reverse order of installation.

Jacobs® Chuck Attachment

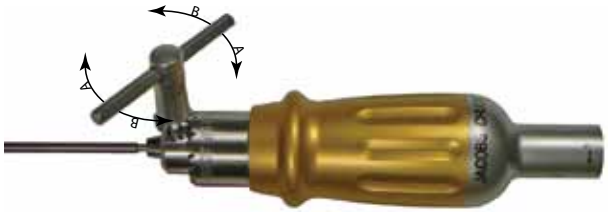
To install Jacobs® Chuck Attachment to motor:

See the Straight Attachment for instructions.
To install drill bit in Jacobs® Chuck

1. Turn chuck-key counter-clockwise (B) to open ridged collar.
2. Insert drill bit and turn chuck-key clockwise (A) to tighten collar.

NOTE: A drill bit may be installed in the attachment before the Jacobs® Chuck attachment is installed on the motor.
Medtronic Powered Surgical Solutions does not provide drill bits.

To Remove:



1. Removal is in the reverse order of installation.

Reprocessing Instructions Attachments

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Midas Rex® Legend® Attachments and Telescoping Tubes

<table>
<tr><td>Warnings and Precautions</td><td>Do not soak/submerge Legend® devices.
Do not use ultrasound to clean Legend® devices.
Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.
The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.
Allow an adequate cooling period after steam sterilization.
Do not steam or EO sterilize the Legend® attachment cleaning nozzle.
Do not use Pana Spray on variable exposure attachments, as it may cause the attachment to overheat.</td></tr>
<tr><td>Limitations</td><td>Verify functionality prior to re-use.</td></tr>
<tr><td colspan="2">Instructions</td></tr>
<tr><td>Point of Use</td><td>No particular requirements.</td></tr>
<tr><td>Containment and Transportation</td><td>It is recommended that devices are reprocessed as soon as is practical following use.</td></tr>
<tr><td>Preparation for decontamination</td><td>No particular requirements.</td></tr>
<tr><td>Cleaning: Automated (Do NOT use ultrasonic washer)</td><td>Review the washer-disinfector warning above, before using this cleaning method. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers.
Recommended Washer/Disinfector Cycle
Pre-Wash: 35°C, 5 min.
Main Wash: 93°C, 30 min.
Neutralize: 2 min.
Final Rinse: 65°C, 10 min.</td></tr>
<tr><td>Cleaning: Manual</td><td>1 Wipe all attachments and telescoping tubes with a cloth, dampened with a surgical instrument cleaning solution.
2 Immerse the head of Contra-Angle attachments in surgical instrument cleaning solution and run the motor for 1 minute.
3 Other attachments and tubes may be mechanically agitated in cleaning solution, but not soaked or immersed.
4 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.
5 Move any moveable parts back and forth to allow solution to thoroughly clean attachment, e.g., sleeve on footed attachment, perforator attachment.
6 Rinse thoroughly with tap water.
7 Thoroughly dry attachments. An air gun may be used to blow moisture out from rear to front of attachment.
8 Attach the Legend attachment cleaning nozzle to the recommended aerosol spray lubricant (Pana Spray®), and perform the following steps to lubricate attachments (except for variable exposure attachments):
a Attach the nozzle to the aerosol spray can and push the attachment onto the nozzle by aligning the arrows on the attachment and on the cleaning nozzle.
b Rotate the attachment slightly to ensure a tight fit.
c Cover the attachment with a paper towel.
d Spray in one 3-second squirt to remove debris and lubricate the attachment.
e Rotate the attachment back to the arrow on the nozzle and pull the attachment off of the nozzle.
f Clean the nozzle for re-use.</td></tr>
<tr><td>Disinfection</td><td>No particular requirements</td></tr>
<tr><td>Packaging</td><td>Place devices in instrument tray, and double wrap instrument case with 1-ply polypropylene wrap.</td></tr>
<tr><td>Sterilization (Temperatures are minimum required, times are minimum required)</td><td>Steam Sterilization:
<table>
<tr><td>Cycle:</td><td>Gravity</td><td>Pre-vac</td><td>Pre-vac*</td></tr>
<tr><td>Temperature:</td><td>132°C</td><td>132°C</td><td>134°C</td></tr>
<tr><td>Time:</td><td>25 min.</td><td>4 min.</td><td>3 min.</td></tr>
<tr><td>Drying</td><td>10 minutes</td><td>15 minutes</td><td>10 minutes</td></tr>
</table>
*Items contaminated with TSE agents may be decontaminated using steam autoclave at a temperature of 134–137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles as referenced in NHS Estates HTM 2010 parts 4 & 6: Appendix 2, Items Contaminated With TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. Medtronic recommends that all products used on a patient suspected or confirmed with a TSE diagnosis be incinerated.
STERRAD Sterilization: Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.
100% EtO Sterilization Parameters:
Preconditioning: 51-59°C, 70 ±5% relative humidity, 60 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.</td></tr>
<tr><td>Maintenance, Inspection and Testing</td><td>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>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 is actually performed, using equipment, materials and personnel in the reprocessing facility, achieve the desired result. This normally requires validation and routine monitoring of the process.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.

NOTE: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Reprocessing Instructions Surgical Burs

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Medtronic Xomed Surgical Burs

Warnings / Precautions	Remove burs from the handpiece before cleaning and sterilizing. Before sterilization, carefully inspect the bur tips, bur flutes, under a microscope or magnifying glass for any irregularities or eccentricities. Discard any burs that show signs of damage or wear. Cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilization is not recommended as damage to the bur may occur.
Limitations	Discard any burs that show signs of damage or wear.
Instructions	
Point of Use	Remove burs from the handpiece before cleaning and sterilizing. Promptly and thoroughly rinse instruments with deionized water after each use.
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.
Preparation for decontamination	Promptly and thoroughly rinse instruments with deionized water after each use.
Cleaning: Automated (Do NOT use ultrasonic washer)	Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.
Cleaning: Manual	Soak in lukewarm*, mild* enzymatic detergent, and deionized water for a minimum of two minutes. Then clean ultrasonically in lukewarm* solution of mild* detergent and deionized water for at least 30 seconds. Rinse thoroughly with deionized water and wipe dry. *less than 43°C; pH 7.0 - 8.5 NOTE: When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations, particularly with regard to articulated instruments and positioning of instruments.
Disinfection	Do not cold soak in gluteraldehyde.
Packaging	A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.
Sterilization (Temperatures are minimum required, times are minimum required)	The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.

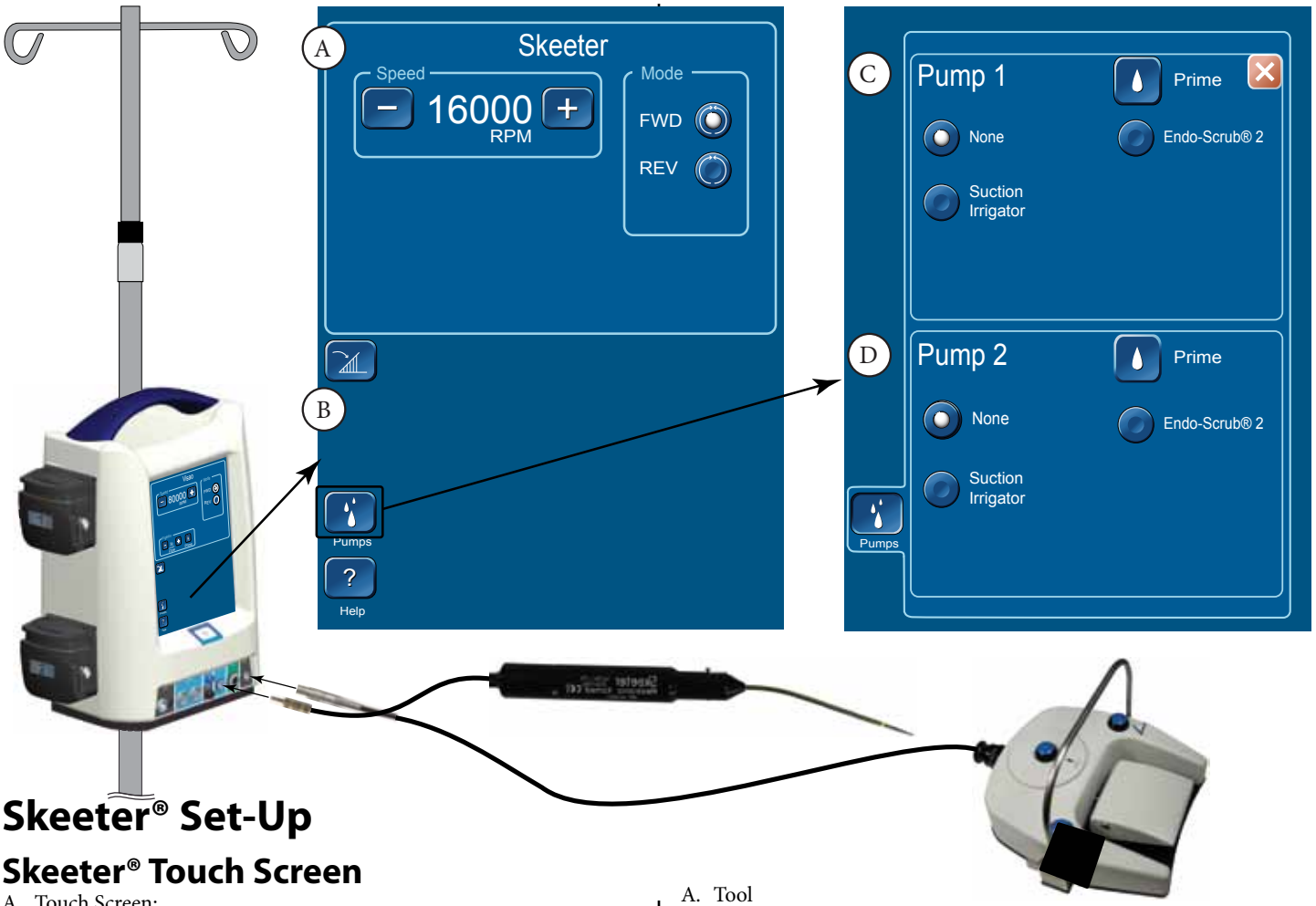
Cycle: **Temperature:** **Time:**	**Gravity:** **121°C** **30 min**	**Gravity:** **132°C** **10 min**	**Pre-Vac: (FR/ WHO)** **134°C** **18 min**	**Pre-vac : (UK)** **134°C** **3 min**	**Pre-vac:** **132°C** **4 min**
Drying:	**8 minutes, or until visibly dry**				
100% EtO **Not validated**				**STERRAD Sterilization** **Not validated**	

Maintenance, Inspection and Testing	Discard any burs that show signs of damage or wear.
Storage	Store in a clean dry place.
Additional Information	None

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 is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.

NOTE: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.



Skeeter® Set-Up

Skeeter® Touch Screen

A. Touch Screen:
- Speed Panel:
  - In FWD Mode, allows variable adjustment from 1000 to 16000 rpm with a default speed of 16000 rpm.
  - In REV Mode, allows variable adjustment from 1000 to 16000 cpm with a default speed of 16000 rpm.
- Mode Panel - Enables selection of FWD or REV mode.

B. Main Screen subsection buttons:
- Foot Control Unit (FCU) Button - changes foot pedal from variable speed control to On/Off.
- Augment Area - (blank area) Shows supplemental information, such as, inactive handpiece(s), or the special function panel (Suction Irrigator or Endo-Scrub® 2).
- Pumps - Opens pump panel.
- Help - Opens help screens.

Skeeter® Pump Screen

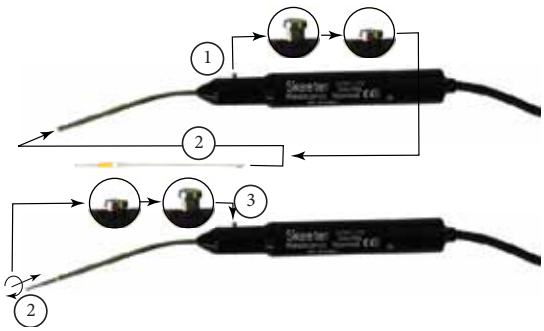
C. Pump number 1 panel:
- Attachments listed for this pump.
- Pump is set to Pump is set to none by default.
- Pump panel may be closed by pressing the X-button.
- See Precaution P1 for Prime/Flush button.

D. Pump number 2 panel:
- Attachments listed for this pump.
- Pump is set to none by default.
- See Precaution P1 for Prime/Flush button.

Skeeter® Ultra-Lite Oto-Tool Set-Up

A. Tool
B. Tool's color code
C. Tool lock/release button
D. Cannulated shaft
E. PTFE Bearing

Instructions for use



1. Press the bur release button.
2. Insert the bur shaft using a slight twisting motion.
3. When a "click" is noted release the bur release button.
4. Gently pull on bur to ensure it is locked.
5. Remove in the reverse order.

Technical Specifications

Skeeter® Ultra-Lite Oto-Tool Part No. 3055601

Speed	1,000-16,000 rpm forward/reverse
Size	17 cm length x 1.6 cm diameter
Weight	57 g
Duty Cycle	Continuous run
Storage Temperature:	-40°C to +70°C
Humidity:	10% to 100% RH
Barometric Pressure:	500 to 1060 hPa

Reprocessing Instructions Skeeter® Oto-flex Burs

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Skeeter® - Oto-flex Burs

Warnings / Precautions	Before sterilization, carefully inspect the bur tips. Burs exhibiting the following conditions should be replaced: 1) nicks on cutting surfaces, 2) noticeable wear on PTFE bearings, 3) severe bends or crimps on bur shaft Cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilization is not recommended as damage to the bur may occur.					
Limitations	Discard any burs that show signs of damage or wear.					
Instructions						
Point of Use	Remove burs from the handpiece before cleaning and sterilizing. Promptly and thoroughly rinse instruments with deionized water after each use.					
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.					
Preparation for decontamination	Promptly and thoroughly rinse instruments with deionized water after each use.					
Cleaning: Automated (Do NOT use ultrasonic washer)	Remove burs from any sterilization trays before placing into washer baskets. Orient burs following recommendations of washer/disinfector manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C. Following cleaning, apply a light coating of silicone spray in the following manner: grasp the PTFE bearing and rotate the bur to assure application of the silicone spray inside the bearing.					
Cleaning: Manual	Soak in lukewarm*, mild* enzymatic detergent, and deionized water for a minimum of two minutes. Then clean ultrasonically in lukewarm* solution of mild* detergent and deionized water for at least 30 seconds. Rinse thoroughly with deionized water and wipe dry. *less than 43°C; pH 7.0 - 8.5 Following cleaning, apply a light coating of silicone spray in the following manner: grasp the PTFE bearing and rotate the bur to assure application of the silicone spray inside the bearing. NOTE: When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations, particularly with regard to articulated instruments and positioning of instruments.					
Disinfection	Do not cold soak in gluteraldehyde.					
Packaging	A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.					
Sterilization (Temperatures are minimum required, times are minimum required)	The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.					
	Cycle: **Temperature:** **Time:**	**Gravity:** **121°C** **30 min**	**Gravity:** **132°C** **10 min**	**Pre-Vac:** **132°C** **4 min**	**Pre-Vac: (FR/WHO)** **134°C** **18 min**	**Pre-Vac: (UK)** **134°C** **3 min**
	Drying:	**8 minutes, or until visibly dry**				
	STERRAD Sterilization: Not validated					
	100% EtO Sterilization Parameters:					
	Temperature Ethylene oxide concentration Aeration at 48-52°C for 8 hrs.	54 +/- 2°C 600 +/- 25 mg/L	Relative Humidity: Gas exposure time (full-cycle):	60 +/- 5% 120 minutes		
Maintenance, Inspection and Testing	Discard any burs that show signs of damage or wear.					
Storage	Store in a clean, dry area.					
Additional Information	None					

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 is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

NOTE: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.

Reprocessing Instructions Skeeter® - Handpiece

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Skeeter® Handpiece

Warnings / Precautions	Disconnect the power before cleaning. Do not fully immerse, or ultrasonically clean, this instrument Do not use any cleaning instruments in the cannulated shaft of the handpiece. Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty. Do not use organic solvents to clean the bur chuck.
Limitations	After cleaning and sterilization, verify functionality prior to re-use.
Instructions	
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.
Preparation for decontamination	Disassembly not required, other than removal of the bur.
Cleaning: Automated (Do NOT use ultrasonic washer)	Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.
Cleaning: Manual	Carefully clean with an enzymatic detergent. Do not fully immerse. The cannulated needle nose should be cleaned by immersing in the detergent solution up to the level of the Bur Release button. Do not use any cleaning instruments in the cannulated shaft of the handpiece. Rinse by immersing the distal end of the handpiece (up to the Bur Release button) in distilled water, using a gentle swirling motion to flush away residual cleaning solution. Avoid water accumulation in the motor housing by shaking excess water out with a downward motion. Silicone spray should be sprayed into the cannulated shaft of the handpiece prior to sterilization. Apply silicone spray until surplus silicone lubricant is noted on the outside of the Bur Release Button. Wipe away excess lubricant from the handpiece. Following this procedure will insure that the bur release mechanism is well lubricated for proper functioning. Sterilize the handpieces immediately after cleaning.
Disinfection	Do not cold soak in gluteraldehyde.
Packaging	A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.
Sterilization (Temperatures are minimum required, times are minimum required)	The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.

Cycle:	**Gravity**	**Gravity**	**Pre-vac**	**Pre-Vac (FR/ WHO)**	**Pre-vac (UK)**
Temperature:	121°C	132°C	132°C	134°C	134°C
Time:	30 min	10 min	4 min	18 min	3 min

Drying: 8 minutes, or until visibly dry

STERRAD Sterilization: 100S Compatible

100% EtO Sterilization Parameters:

Temperature	54 +/- 2°C	Relative Humidity:	60 +/- 5%
Ethylene oxide concentration	600 +/- 25 mg/L	Gas exposure time (full-cycle):	120 minutes
Aeration at 48-52°C for 8 hrs.			

Maintenance, Inspection and Testing	Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use.
Storage	It is extremely important that the handpiece be rapidly and completely dried before storage to prevent corrosion and residue deposits in the bearing and motor.
Additional Information.	None

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 is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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.

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

Manual Surgical Instruments

Warnings / Precautions	To prevent stains, use distilled or demineralized water, and use a neutral detergent, to reprocess these instruments. Do not cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilize, as damage to the instrument finish may occur.
Limitations	After cleaning and sterilization, verify functionality prior to re-use.
Instructions	
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. Rinse instrument immediately after use in distilled or demineralized water. Keep instrument moist (for example, cover with a wet drape or saturate with tap water - do not use saline) after use and prior to decontamination, cleaning and sterilization to ensure adequate cleaning.
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.
Preparation for decontamination	Fully disassemble modular designed instruments for effective cleaning. Remove any cap covering the cleaning port, if applicable. For instruments with lumens, and instruments equipped with cleaning ports, inject cleaning solution through the instrument with an irrigation syringe. When cleaning suction tubes with holes to control suction, place gloved finger over the control hole to flush through the tube. Open any articulated instruments before positioning in the soaking solution. Place instruments so they do not touch each other. NOTE: Flushing in running water is essential between decontamination and cleaning to prevent any risk of reaction between the two solutions.
Cleaning: Automated	Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C. Thoroughly examine instruments for any residual soil.
Cleaning: Manual	Soak in lukewarm (less than 43°C), mild (pH 7.0 - 8.5), enzymatic detergent and deionized water for a minimum of 2 minutes. For instruments with lumens, and instruments equipped with cleaning ports, inject cleaning solution through the instrument with an irrigation syringe and allow to soak for a minimum of 2 minutes. Use a soft instrument brush to scrub instruments while submerged in cleaning solution to remove organic matter. Rinse with deionized water, then clean ultrasonically in a lukewarm (less than 43°C), mild (pH 7.0 - 8.5), detergent and deionized water for 10 minutes. Rinse thoroughly with deionized water, utilizing a syringe to thoroughly rinse cleaning solution from lumens and cleaning ports. Clean in this manner until no visible soil remains on the instrument. Dry with compressed air, or wipe dry with a lint-free cloth. Examine instruments for any staining or deterioration; remove from use as appropriate. NOTE: When using an ultrasonic cleaner or a spray washing machine, follow the manufacturers recommendations, particularly with regard to articulated instruments and positioning of instruments. Following cleaning, lightly lubricate instruments with movable parts. Use a lubricant intended for sterilizable instruments such as a water-soluble instrument milk. Do not use silicone spray.
Disinfection	NOTE: Do not cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilize, as damage to the instrument finish may occur.
Packaging	A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Ensure that cutting edges are protected. Wrap trays using appropriate method.
Sterilization	Check the cleanliness and operation of the instrument. Clean again if debris is present and remove from use any damaged instrument. Close instruments with catches and racks on the first notch. Arrange the instruments in sterilization containers with perforations on the top and bottom, and on supports such as those used in microsurgery. Follow the appropriate cycle listed in the table below. All steam cycles have been validated in the wrapped configuration and can be sterilized wrapped or unwrapped. These devices have only been validated for steam sterilization methods. The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s).

(Temperatures are minimum required; times are minimum required)						
	Cycle:	**Gravity**	**Gravity**	**Pre-vac**	**Pre-vac (FR/WHO)**	**Pre-vac (UK)**
	Temperature:	**121°C**	**132°C**	**132°C**	**134°C**	**134°C**
	Time:	**30 min**	**10 min**	**4 min**	**18 min**	**3 min**
	Drying:	**15 – 30 minutes, or until visibly dry**				

Maintenance, Inspection and Testing	Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use.
Storage	Store instruments in a clean, dry area.
Additional Information	NOTE: Additional cleaning methods may be warranted, including presoaking in 3% hydrogen peroxide.

NOTE: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. They are NOT APPLICABLE to single use devices or single use accessories, which must be destroyed after use in accordance with applicable local regulations. It remains the responsibility of the processor to ensure that the reprocessing is performed using validated equipment to achieve the desired result. This normally requires validation and routine monitoring of the process. Some devices have specific assembly instructions. In this case, refer to the assembly insert provided with the device for additional instructions.

NOTE: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

NOTE: In France, soaking the device in one mole of Soda (NaOH) per liter of solution is the recommendation of French Circular 138 in order to prevent Creutzfeld-Jakob Disease transmission.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a 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

Reprocessing Instructions (Per ISO17664:2004)

Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at www.medtronicENT-TechComms.com

TECHNICAL BULLETIN

CLEANING AND STERILIZATION FOR UNITED KINGDOM & EUROPE

REFERENCE: U.K. Health Technical Memorandum 2030 Washers-disinfectors
U.K. Health Technical Memorandum 2010 Sterilization

EQUIPMENT: MPS/POWERFORMA® Drill Handpieces; Visao®; Xcalibur® Drill Handpieces, Handpiece Attachments, Motor Assembly, Irrigation Sleeve and Extended Bur Guards; Straightshot® , Straightshot® Magnum®, and Straightshot® M4 Drill Handpieces; Skeeter® Otologic Drill Handpiece, and Legend EHS® Stylus Touch™ Motor.

ACCESSORIES: POWERFORMA/MICRO-CRAFT®, HELIX® or Skeeter® Oto-Flex Reusable Drill Burs, Bur Racks, Handpiece Cable Clips and Sterilization Trays.

The following guidelines have been validated for effective cleaning and sterilization with the listed surgical equipment and accessories referenced above. These guidelines serve as an addendum to the sterilization and re-use instructions originally provided with the particular device and are intended to provide compliance to HTM 2030 and HTM 2010 cleaning and sterilization recommendations set in the United Kingdom.

CLEANING: (Do NOT use ultrasonic washer)

1. Treat all devices presented for cleaning, disinfection, and sterilization as contaminated with infectious material.
2. Remove instruments and equipment from any sterilization trays before placing into washer baskets.
3. For drill handpiece cleaning, cover handpiece cable connector end with a Universal Cleaning Cap catalog no. 3318520 or Handpiece Cable Cap, Small, catalog no. 3318510 or Handpiece Cable Cap, Large, catalog no. 3318515. (Note: Use 3318515 for Straightshot® M4, Visao®, and Xcalibur® Hi-Speed with angled cable. Use 3318510 for other handpieces.) (Note: the Skeeter® Handpiece does not require a Handpiece Cable Cap during cleaning).
4. Orient devices in washer baskets or racks following recommendations of washer/disinfector manufacturers.
5. Use low foaming, alkaline or neutral pH, detergent recommended by washer/disinfector or detergent manufacturers.
6. These products have been validated for effective cleaning using automatic washers/disinfectors.

STERILIZATION:

7. After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning.
8. Return instruments and equipment to appropriate sterilization trays.
9. Sterilize using the following Porous Load Cycle for Autoclave conforming to local practices within the limits set below:

POROUS LOAD CYCLE

Cycle:	Porous Load (Pre-vacuum)
Temperature:	134oC to 137oC
Time:	3.5 minutes
Drying:	3 minutes minimum vacuum drying

Troubleshooting Guide

IPC® and Foot Control Unit		
Symptom	**Issue**	**Action**
Pumps don't run.	Failed internal components.	Contact Customer Care.
	Moisture ingress in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing, If problem persists, contact Customer Care.
Little or no irrigation flow.	Tubing Set improperly seated in pump.	Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right.
	Tubing is pinched or kinked.	Check tubing at side of pump, see Irrigation/Coolant Pumps Check remaining tubing for pinched or kinked areas, if necessary replace tubing.
	Tubing clamps are restricting flow.	Set tubing clamps in "open" position.
	Irrigation flow rate setting low.	Adjust irrigation flow rate
	Irrigator obstructed.	Replace irrigator
Pump stall error.	Tubing Set improperly seated in pump.	Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right. If problem persists, contact Customer Care.
	Tubing is pinched or kinked.	Check tubing is not pinched or kinked on side of pump (see section on "Irrigation/Coolant Pumps"). If problem persists, contact Customer Care.
Console default parameters incorrect.	Moisture ingress in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing, If problem persists, contact Customer Care.
Handpiece connected but console reads "Connect Handpiece"		
Handpiece connected but console displays incorrect handpiece.		
Console doesn't power up.	Power cord not properly connected.	Connect power cord.
	No power.	Check power available (i.e. power strip is on, circuit breaker is closed etc.)
	Power Inlet Fuses blown.	Replace fuses with 5.00 A, 250V, time delayed fuses (P/N 11270066)
	Failed internal components.	Contact Customer Care.
Power switch light is on but Touch Screen doesn't come on.	Failed internal components.	Contact Customer Care.
Console doesn't power down.	Power switch failure.	Unplug power cord, contact Customer Care.
Touch Screen doesn't respond.	Screen gasket displaced or failed internal components.	Contact Customer Care.
Touch Screen doesn't work properly.	Touch Screen not calibrated.	Calibrate Touch Screen. If problem persists, contact Customer Care.
Console displays wrong handpiece / motor type.	Console misidentified the handpiece / motor.	Disconnect and reconnect the motor cable.
		Turn console off then on.
		Change motor, motor cable, or console to isolate the problem.
	Moisture ingress in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing, if problem persists, contact Customer Care.
Foot control unit buttons or pedal doesn't respond.	Incorrect use.	Press and hold buttons for at least 1 second, wait for console confirmation beep.
	Top button doesn't respond.	One (1) handpiece connected (top button has no function with 1 handpiece connected).
	Connector not fully inserted.	Disconnect and reconnect the fcu cable connector.
		Try different fcu or console to isolate the problem.
		Contact Customer Care.
	Internal component failure.	Contact Customer Care.
Handpiece fails to rotate	Failed footswitch.	Disconnect footswitch, use manual start/stop rocker switch on rear of console.
	Failed handpiece motor or motor driver.	Contact Customer Care.

Troubleshooting Guide

Non EHS Blades or Burs

Symptom	Issue	Action
Appears to be damaged or defective.	Damaged or defective.	Remove and replace.
Tool Vibrates Excessively, Abnormal Noise movement.	Tool is not firmly seated.	Microdebriders, pull back locking collet and re-seat the tool.
		Visao®, unlock collar, check/re-seat notch, lock collar.
No suction.	Blade opening is obstructed.	Use stylet to clear blade.
		Remove blade from surgical site and submerse the blade tip in sterile water with suction connected to the handpiece to evacuate the obstruction.
	Tubing obstructed.	Remove and inspect suction tubing, and if obstructed, remove obstruction, reconnect tubing.
Tool is leaking irrigant.	Tool not seated correctly in collet.	Check for proper tool insertion by pulling back locking collet, and re-seating tool.
	Low or no suction.	See SYMPTOM, no suction.
Tool wobble in Handpiece.	Tool wobbles in Handpiece.	Reduce handpiece operating speeds.
		Use tools that are rated for the console speed selected
		If necessary, use bur guard with burs medium, long and X-long.
		Operate handpiece at 50% of full speed for medium, long and X-long burs.
		Select a new tool.
		Contact Customer Care.

Midas Rex® Legend EHS® motors

Symptom	Issue	Action
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.
		Contact Customer Care.
	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, contact Customer Care.
	Inadequate irrigation.	Ensure adequate irrigation to surgical site during bone dissection.
Tool is difficult to remove from attachment	Aging of attachment	Contact Customer Care.
	Use of reprocessed tools	
	Use of an unauthorized refurbisher	
	Improper cleaning	Clean the attachment thoroughly according to the instructions in this manual.
		Change tool.
Attachment will not seat properly on the motor	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.	Cables not properly connected.	Ensure motor and foot control cables are properly connected.
	Speed setting is too low.	Ensure that a speed greater than 10,000rpm (EHS) or 3,000rpm (Stylus) is selected.
	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 console.	Change motor or console to isolate the problem.
		Contact Customer Care.
	Foot control not properly functioning.	Check for obstruction under the foot pedal.
		If problem persists, contact Customer Care.
	Cables damaged	Check cables for cracks, splits, or bent connector pins.
Motor with attachment rotates, but an abnormal noise is heard	Bearings are worn.	Change the attachment to isolate the location of the problem.
		Contact Customer Care.
	Poor electrical Connection	Check all connections from electrical source to console.
		Ensure motor and foot control cables are properly connected.
	Internal failure of motor, console, or cable.	Change motor, console, or cable to isolate the failing component.
		Contact Customer Care.
	Attachment not properly installed	Remove and reinstall the attachment and dissecting tool

Midas Rex® Legend EHS® Stylus Touch™ motors

Symptom	Issue	Action
Motor does not run.	Finger switch not reaching maximum speed	Check that the control lever ring is properly seated in one of the four possible positions.
	Finger switch not responding. Safety switch in safe mode	Place switch in run mode.
	Finger control damaged.	Contact Customer Service.

Troubleshooting Guide

Midas Rex® Legend EHS® Attachments or Telescoping Tubes

Symptom	Issue	Action
Attachment or Telescoping Tube has uncomfortable temperature to touch/hold	Heat from worn attachment/tube bearings	DO NOT use. Try another attachment/tube. Contact Customer Care.
		Telescoping Tubes are multi-use disposable. If problem is resolved with a new Telescoping Tube, discard the over-heated tube.
	Attachment/tube 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 Customer Care.
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. Contact Customer Care.
		Dispose of telescoping tube. Telescoping Tubes are multi-use disposable.
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 Customer Care.
	Use of chlorine based or corrosive agents	
	Aging	Telescoping Tubes are multi-use disposable.
Attachment has excess lubrication	Over lubrication during cleaning process	Visually inspect and wipe excess 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 Customer Care.
	Bend caused by incorrect use.	
16-Mf 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 Customer Care.
Smoke is generated by the attachment or motor	Attachment is not in the locked position.	Make sure the attachment is in the locked position.

Midas Rex® Legend EHS® Tools

Symptom	Issue	Action
Tool fails	A non-Legend tool is being used.	Replace with a Legend tool.
	Worn attachment or tube bearings.	Try another attachment or tube to isolate the location of the problem.
		If the attachment is failing, contact Customer Care.
		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 tool packaging to the color code on the attachment/tube.
	Motor is damaged.	Contact Customer Care.
	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 tool.
Tool vibrates excessively	Tool's size and geometry may create excessive vibration at certain speeds.	Adjust the speed.
		Change tools.
Tool dull	Extended use	Change to a new tool
	Reprocessed tool was used	
	Incorrect geometry	Contact Customer Care.
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 Customer Care.
	A non-Legend tool is being used.	Replace with a Legend tool.

Error Codes

Error Code	Cause	Error Message Title	Error Message Description
1	MCB does not report that it is booted within 5 seconds of AI telling it to start and subsequent reattempts fail.	System Error	Power off. Wait 10 seconds. Power on. If error persists, call Technical Services.
2	Not Used	N/A	N/A
3	UI-MCB Com Failure - Max resends exceeded	System Error	Power off. Wait 10 seconds. Power on. If error persists, call Technical Services.
4	UI-MCB Com Failure - Get answer failed		
5	UI-MCB Com Failure - No status message received		
6	UI-MCB Com Failure - Serialization ID error		
7	UI-MCB Com Failure - Timeout exception		
8	Not Used	N/A	N/A
9	Pump 1 stalled (no transitions on opto sensor)	Pump #1 Stalled	Check tubing connection.
10	Pump 2 stalled (no transitions on opto sensor)	Pump #2 Stalled	
11	Unrecogonized/damaged handpiece plugged in on port 1 (first 12 pin)	Handpiece	Unplug handpiece and plug back in. If error persists, replace handpiece.
12	Unrecogonized/damaged handpiece plugged in on port 2 (second 12 pin)		
13	Unrecogonized/damaged handpiece plugged in on port 3 (4 pin)		
14	Unrecogonized/damaged handpiece plugged in on port 4 (Skeeter)		
15	Handpiece Stalled	Handpiece Stalled	Check accessory.
16	MCB motor overcurrent detected	Motor Overcurrent	Unplug handpiece and plug back in. If error persists, replace handpiece.
17	Unrecognized/damaged FCU plugged in	Foot Control Connection Error	Unplug Foot Control and plug back in. If error persists, replace Foot Control or switch to manual control.
18	Damaged handpiece or finger lever base out of position.	Finger Control Error	A finger control error has been detected. Check that the control lever ring is properly seated in one of the four possible positions. If error persists contact Medtronic support. Press OK to use alternate control method.
19	UI self test failure - culture (language) registry entry	Self Test Failed	Power off. Wait 10 seconds. Power on. If error persists, call Technical Services.
20	UI self test failure - sector configuration registry entry		
21	UI self test failure - corrupt usage data file or unable to create usage data file		
22	Not Used	N/A	N/A
23	MCB non-specific self test failure	Self Test Failed	Power off. Wait 10 seconds. Power on. If error persists, call Technical Services.
24	MCB self test failure - Port 1		
25	MCB self test failure - Port 2		
26	MCB self test failure - Port 3		
27	MCB self test failure - Port 4		
28	MCB self test failure - bridge transistor 1 shorted		
29	MCB self test failure - bridge transistor 2 shorted		
30	MCB self test failure - bridge transistor 3 shorted		
31	MCB self test failure - bridge transistor 4 shorted		
32	MCB self test failure - bridge transistor 5 shorted		
33	MCB self test failure - bridge transistor 6 shorted		
34	MCB self test failure - A/D converter		
35	MCB self test failure - motor error		
36	MCB self test failure - 3.3 volt supply		
37	MCB self test failure - 12 volt supply		
38	MCB self test failure - 48 volt supply		
39	MCB self test failure - FCU port		

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Part I

Guidance and manufacturer's declaration – electromagnetic immunity – Part I			
The NIM-Pulse® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM-Pulse® 3.0 should assure that it is used in such an environment.			
Immunity test	**IEC/EN60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 %UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NIM-Pulse® 3.0 requires continuous operation during power mains interruptions, it is recommended that the NIM-Pulse® 3.0 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic emissions		
The NIM-Pulse® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM-Pulse® 3.0 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The NIM-Pulse® 3.0 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The NIM-Pulse® 3.0 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 IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the NIM-Pulse® 3.0			
The NIM-Pulse® 3.0 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIM-Pulse® 3.0 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIM-Pulse® 3.0 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum power of transmitter W	**Separation distance according to frequency of transmitter meters**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz $d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Part II

The NIM-Pulse® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM-Pulse® 3.0 should assure that it is used in such an environment.			
Immunity test	**IEC/EN60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the NIM-Pulse® 3.0, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF	3 Vrms	3 Vrms	$d = 1.2 \sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	3 V / m	3 V / m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz		$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE 3 When operating the IPC with Stylus Touch, the compliance level is 3 V/m except from 88 MHz to 91 MHz where it is 1 V/m. The formula for separation distance for the IPC with Stylus Touch will be $d = 3.5 \sqrt{P}$ in that frequency range

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NIM-Pulse® 3.0 is used exceeds the applicable RF compliance level above, the NIM-Pulse® 3.0 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NIM-Pulse® 3.0.

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

Medtronic IPC® System
Limited Warranty

A. This Limited Warranty provides the following assurance for the customer who purchases a Medtronic IPC® System. This Limited Warranty is extended only to the buyer purchasing the IPC® System directly from Medtronic or from its affiliate or its authorized distributor or representative. The IPC® System includes the console, motor or handpiece, foot control, motor cables, instrumentation cases and trays (hereafter referred to as System Components), straight and angled motor attachments (hereinafter referred to as "Attachments"), bur guards and telescoping tubes (hereinafter referred to as Semi-reusable Components) and dissecting tools, irrigation and coolant tubing, and Intelliflow™ remote control (hereinafter referred to as Single Use Components) and jointly referred to as the IPC® 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, the following 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 IPC® 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.

For Items Contaminated With TSE Agents

MEDTRONIC ENT/NT

Transmissible Spongiform Encephalopathy (TSE) Return Policy

Medtronic will not authorize or accept the return of products that directly contact patients or is contaminated with a patient's body fluids suspected or confirmed with a Transmissible Spongiform Encephalopathy / Creutzfeldt-Jakob Disease (TSE/CJD) diagnosis.

The following are recommended guidelines and may vary according to specific policy and procedures among hospitals. Hospital personnel should contact their infection control personnel for current procedures and policy for reusable equipment processing when suspected of contamination with Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathy (TSE) agent.

Medtronic dissecting tools, burs, or blades used on a patient suspected of a TSE/CJD diagnosis should be incinerated. Reusable equipment that has been used on patients with suspected Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathy (TSE) should be quarantined and not reused until diagnosis is confirmed or excluded. Reusable equipment should be quarantined after having been cleaned, decontaminated, sterilized and packed in a rigid sealed container until final diagnosis. If TSE/CJD is excluded as a diagnosis, the quarantined reusable equipment may be returned for use after appropriate cleaning, decontamination and sterilization.

Medtronic recommends that all Medtronic products used directly on a patient confirmed with a TSE diagnosis be incinerated. Contact your Sales Representative to purchase replacement products or secure loaner equipment.

For additional information contact your Customer Service Representative.

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