 HEALTHCARE PROFESSIONALS

Indications, Safety, and Warnings

Integrated Power Console, Handpieces, and Accessories

## **INTEGRATED POWER CONSOLE (IPC SYSTEM)**

### **INDICATIONS**

The IPC® System is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone in Head & Neck / ENT (Otologic, Neurologic, Neurotologic, Sinus, Rhinologic, Nasopharyngeal / Laryngeal), Oral / Maxillofacial, and Plastic / Reconstructive / Aesthetic surgical procedures.

### **CONTRAINDICATIONS**

None.

### **WARNINGS**

| **System Warnings** |  |
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| W1 | It is important that the IPC™ system 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 | To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. |
| W4 | To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the IPC™ system to hospital grade receptacles only. |
| W5 | Do not attach any system component or accessory other than Medtronic approved components to the IPC™ system as this may result in electrical shock, component damage, substandard performance, increased emissions, or decreased immunity. |
| W6 | Disconnect power to the IPC™ system before cleaning the unit to avoid electrical shock. |
| 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 the anesthetized patient. |
| W8 | Do not operate the IPC™ system in the presence of Magnetic Resonance Imaging devices. |
| W9 | 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 User’s Guide. |
| W10 | The IPC™ system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the IPC™ system should be observed to verify normal operation in the configuration in which it will be used. |
| W11 | Portable and mobile RF communications equipment can affect Medical Electrical Equipment. |
| W12 | Keep NIM™ Muting Probe cable away from IPC™ system cables to prevent unintended EMG interference or muting. |
| W13 | After each procedure, properly clean all reusable system components. |
| W14 | All service must be performed by Medtronic qualified personnel only. Repair and/or modification to the IPC™ system by anyone other than qualified service personnel may significantly compromise the unit’s ability to perform effectively and/or void the equipment warranty. |
| W15 | Auxiliary Power Outlet with protective cover is for use with the Hydrodebrider or Bone Mill only. Consult Hydrodebrider and Bone Mill instructions prior to use. |

| **Component Warnings** |  |
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| W16 | Always inspect the components before and after use for any damage or malfunction. If damage or malfunction is observed, do not use damaged part until it is repaired or replaced. Use of damaged or malfunctioning parts can increase risk of injury. |
| W17 | 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. |
| W18 | Do not use an overheated device as it may cause thermal injury. Smoke and/or excessive heat may be caused by:* Applying excessive force while cutting (e.g. side loading)
* Long operating periods (exceeding handpiece duty cycle)
* Attachment not fully locked in handpiece
* Inadequate or loss of irrigation
* Component failure or wear
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| W19 | The handpieces will not run properly unless the attachment is in the locked or secured position. |
| W20 | Do not change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove. |
| W21 | Do not place motor, attachment and tool on the patient or in an unsecured location during surgery. |
| W22 | Do not activate foot pedal without confirming the safe position and handling of the handpiece. Accidental handpiece activation could result in unintended tissue, bone, or nerve resection. |
| W23 | Verify reusable device was cleaned and sterilized prior to use. If not sterilized, do not use. |
| W24 | For warnings & precautions related to reprocessing, refer to **Cleaning and sterilization** instructions. |
| W25 | This system requires insulated connectors for the StraightShot™ M4 Microdebrider, StraightShot™ Magnum™ II Microdebrider, StraightShot™ III Microdebrider, Midas Rex™ Spine Shaver (SC1), Visao™, or Skeeter™ handpieces and the multifunction foot pedal. |
| W26 | When using StraightShot™ microdebrider handpieces with non-rotatable tools, ensure rotation lock is engaged to prevent inadvertent rotation. When using with optical Image Guided Surgery (IGS), engage the rotation lock prior to calibration and verification of the tip. |

| **Disposable Warnings** |  |
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| W27 | 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. |
| W28 | Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination. |
| W29 | Operate the tool only after the appropriate anatomical landmarks and the intended surgical site have been confirmed. Ensure adequate visualization when using powered accessories. Discontinue powered application in the event of lack of visualization of the surgical site. |
| W30 | Use methods at the operative site to control bleeding that do not compromise patient safety during at-risk surgery. |
| W31 | Always keep the cutting area of the tool away from fingers and loose clothing to prevent laceration of user and cross-contamination through compromised glove. |
| W32 | Excessive noise from the tool when drilling close to the cochlea or ossicular chain may cause hearing damage. |
| W33 | Improper use of high speed burs can result in damage to the eye and/or orbit, vascular damage, nerve damage, and/or cerebral damage. Use appropriate caution when operating this device in the vicinity of critical anatomy. |
| W34 | Excessive pressure applied to tool may cause tool 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. |
| W35 | Do not use excessive force to pry or push bone with the attachment, tool or blade during dissection. |
| W36 | Do not apply excessive side loading. Excessive side loading could cause angled attachments to unlock accidentally from motor. |
| W37 | Do not modify any system components or accessories. Use of modified components or accessories may increase risk of injury or diminish performance of the system. |
| W38 | 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. |
| W39 | Bending or prying may break the accessory, causing harm to patient or staff. |
| W40 | Inspect tools prior to and during use for signs of wear, fragmentation, eccentricities, or other defects. Replace and discard damaged tools. Do not attempt to re-sharpen tools. |
| W41 | Test attachments for excessive vibration at desired speed before use. Vibration may be caused by eccentricity of the tool or worn components. Replace tool, attachment, or handpiece, or change handpiece speed. |
| W42 | 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. |
| W43 | Powered blades should be operated in the Oscillate mode only. Operating in the Forward mode may cause damage to the blade. |
| W44 | Do not use the burs above the speed indicated on the bur label. |
| W45 | If an airway blade becomes clogged during use, 1-5 cc of irrigant could be aspirated by the patient before detection by the user. |
| W46 | Do not attempt to sterilize disposable devices. The disposables are packed sterile and are intended for single use. Devices lose sterility upon removal from packaging. |

### **PRECAUTIONS**

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| P1 | Do not kink cables. Inspect cables and pins for cracks, tears or corrosion. |
| P2 | When using a Y-Splitter, only one multifunction foot pedal shall be active at a time. |
| P3 | Do not connect multiple Y-Splitters. |
| P4 | StraightShot™ handpieces are intended to operate at speeds greater than 6,000 rpm only when used with the high speed bur line. |
| P5 | Do not use anti-fog on scope or sheath, as weeping or leaking may result. |
| P6 | 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. |
| P7 | 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. |
| P8 | Remove and discard accessories following local regulations for proper disposal of contaminated materials. |
| P9 | When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece. |
| P10 | Always examine operation of each tool in a handpiece before use. |
| P11 | Powered burs and drills should be operated in the Forward mode only. |
| P12 | To prevent damage to tools, disconnect suction tube prior to changing tool during procedure. |
| P13 | Ensure the blade or bur is fully engaged in the microdebrider. For blades, verify the tip is fully engaged with the outer cannula prior to use. |
| P14 | 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. |
| P15 | 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. |

## **STRAIGHTSHOT BLADES AND BURS**

### **DEVICE DESCRIPTION**

The Straightshot® Microdebrider is designed to accommodate a number of otorhinolaryngology procedures, including functional endoscopic sinus surgery (FESS), adenoidectomy, removal of laryngeal and vocal cord lesions, rhinoplasty, dermabrasion, and submental lipectomy. A variety of disposable blades and burs are available for this purpose.

### **INDICATIONS**

Sinus indications include septoplasty, removal of septal spurs, polypectomy, antrostomy, ethmoidectomy/sphenoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR, trans-sphenoidal procedures, maxillary sinus polypectomy, circumferential maxillary antrostomy, choanal atresia, sphenoidectomy, and medial, lateral, and posterior frontal sinusotomy.

Nasopharyngeal/laryngeal indications include adenoidectomy, tracheal procedures, laryngeal polypectomy, laryngeal lesion debulking, tonsillectomy, tonsillotomy for obstructive tonsillar disease, removal of endobronchial lesions and surgical management of recurrent respiratory papillomatosis (RRP).

Head and neck (ENT) indications include soft tissue shaving, rhinoplasty (narrowing of the bony vault and revision of the bony pyramid), removal and shaping of bone during rhinoplasty procedures, removal of adipose tissue (lipo debridement) in the maxillary and mandibular regions of the face, removal of acoustic neuroma, and incision and removal of soft tissue during plastic, reconstructive, and/or aesthetic surgery.

### **CONTRAINDICATIONS**

None are known.

### **WARNINGS**

* DO NOT change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
* 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.
* DO NOT modify accessories used with the handpiece. Performance could be diminished with modified accessories.
* DO NOT use burs above the speed indicated on the bur label.
* For high speed drilling (greater than 6,000 rpm) ensure that an XPS High Speed Bur is used.
* Use adequate irrigation from a separate user-provided irrigating source. The use of an accessory without irrigation may cause an inordinate amount of heat buildup resulting in thermal injury to tissue.
* Disposable devices are for single-use only. Do not attempt to sterilize disposable devices. The disposables are packed sterile and not intended for repeat use. To prevent contamination, use only once.
* Insertion of metal objects in blade or bur tip may cause the blade or bur to break leaving fragments in the wound. The fragments may be difficult to remove, causing irritation, inflammation and foreign-body response at surgical site.
* Always keep the cutting tip of the accessory away from fingers and loose clothing. Prevent laceration of user and cross-contamination through compromised glove.
* Bending or prying may break the blade or bur, causing harm to patient or staff.
* Operate the blade or bur only after the appropriate anatomical landmarks and the intended surgical site have been confirmed.
* Blades, burs and irrigation tubing are disposable and intended for single-use only, UNLESS OTHERWISE MARKED.
* 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.
* Blade and bur accessories are available for resection of soft tissue and bone for surgical procedures. Use of accessories depends on the intended application and patient needs. Sharp-cutting powered accessories induce bleeding and removal of significant tissue and bone.
* Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using XPS accessories. The use of powered reciprocating/rotating instruments may result in vibration-related injury. Use appropriate precautions.
* Employ visualization when using rotating XPS accessories, including use of image guided surgery system if needed. Discontinue powered application in the event of lack of visualization of the surgical site.
* Use methods at the operative site to control bleeding that do not compromise patient safety during at-risk surgery.
* Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is replaced. Damaged parts may deposit metal shavings on surgical site.
* Do not use any parts other than Medtronic system components as damage or substandard performance could result.
* Remove and discard accessories following local regulations for proper disposal of contaminated materials.
* Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination.
* Use lock on Straightshot M4 and M5 handpieces to prevent inadvertent rotation of blade or bur during use.
* It is important that the XPS 3000 operator be familiar with the system User’s Guide, its precautions, procedures, and safety issues.
* Properly dispose of single-use devices removed from sterile packages. Devices lose sterility upon removal from packaging.
* Excessive pressure applied to bur may cause bur fracture. Should a bur fracture occur during use, extreme care must be exercised to ensure that all fragments of the bur are retrieved and removed from the patient. Unremoved bur fragments may cause tissue damage to the patient.

### **SURGICAL PRECAUTIONS**

* The Straightshot Magnum® II and Straightshot M4 and M5 High-Speed Microdebriders are intended to operate at speeds greater than 6,000 rpm ONLY when used with the XPS high-speed bur line.
* XPS Blades should be operated in the oscillate mode only. Operating in the forward mode may cause damage to the blade. XPS burs should be operated in the forward mode only.
* To prevent damage to curved blades and burs, disconnect suction tube prior to changing blade or bur during procedure.
* Be sure the blade is fully engaged in the microdebrider and verify the tip is fully engaged with the outer cannula prior to use.

## **CURVED BURS**

### **INDICATIONS**

The XPS® Curved Bur is intended for use in an ear, nose, and throat electric or
pneumatic surgical drill for incising or removing bone in the ear, nose, or throat
area, and is an accessory to the XPS® 3000 and IPC® System.

### **CONTRAINDICATIONS**

None are known.

### **WARNINGS**

* Use adequate irrigation from a separate user-provided irrigating source. The use of a bur without irrigation may cause an inordinate amount of heat buildup resulting in thermal injury to tissue.
* Keep the cooling sleeve irrigated to minimize thermal injury to tissue.
* Excessive noise from the drill or eccentricity of the drill may cause hearing damage when drilling close to the cochlea or ossicular chain.
* During procedures near nerves, keep bur and bur cannula away from tissue to minimize the potential for thermal injury.
* For procedures near nerves, nerve monitoring should be used to alert the user of the potential for injury.
* Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using XPS accessories.
* The use of powered reciprocating/rotating instruments may result in vibration-related injury. Use appropriate precautions.
* Employ visualization when using rotating XPS accessories. Discontinue powered application in the event of lack of visualization of the surgical site.
* Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is replaced. Damaged parts may deposit metal shavings on surgical site.
* When not operating handpiece, ensure that handpiece rests on a non-conductive surface that provides containment for handpiece and blade/bur. Avoid unintended thermal injury by an uncontained handpiece.
* When not operating handpiece, eliminate accidental foot control activation. Control energy to and through handpiece to prevent unintended tissue, bone or nerve resection.
* Always keep the cutting tip of the accessory away from fingers and loose clothing. Prevent laceration of user and cross-contamination through compromised glove.
* Do not change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
* Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination.
* Bending or prying may break the blade or bur, causing harm to patient or staff.
* Excessive pressure applied to bur may cause bur fracture. Should a bur fracture during use, extreme care must be exercised to ensure that all fragments of the bur are retrieved and removed from the patient. Unremoved bur fragments may cause tissue damage to the patient.
* Test for bur wobble (eccentricity) at the desired speed prior to use. Select a new bur or reduce speed if wobble is observed. Eccentricity of the bur can cause bur vibration and may result in excessive tissue and bone destruction and hearing damage. Always examine the operation of each bur in the handpiece before each use. Operating certain burs at high speed can cause vibration of the bur.
* Discontinue use of curved bur if tip begins to wobble and replace bur to prevent unintended tissue removal from patient.
* Blade and bur accessories are available for resection of soft tissue and bone for surgical procedures. Use of accessories depends on the intended application and patient needs. Sharp-cutting powered accessories induce bleeding and removal of significant tissue and bone.
* Do not modify accessories used with the handpiece. Performance could be diminished with modified accessories.
* Do not attempt to resharpen used burs. Worn burs should be replaced with new ones frequently to ensure effective cutting and control of the drill.
* Do not use any parts other than Medtronic Xomed, Inc. system components as damage or substandard performance could result.
* Disposable devices are for single-use only. Do not attempt to sterilize disposable devices. The disposables are packed sterile and not intended for repeat use. To prevent contamination use only once.
* Do not use burs above the speed indicated on the bur label. Exceeding speed may cause the burs to break.

### **SURGICAL PRECAUTIONS**

* Ensure the bur is properly secured in the handpiece prior to activation.
* When operating or testing the handpiece, ensure the bur is properly inserted and locked into the bur collet.