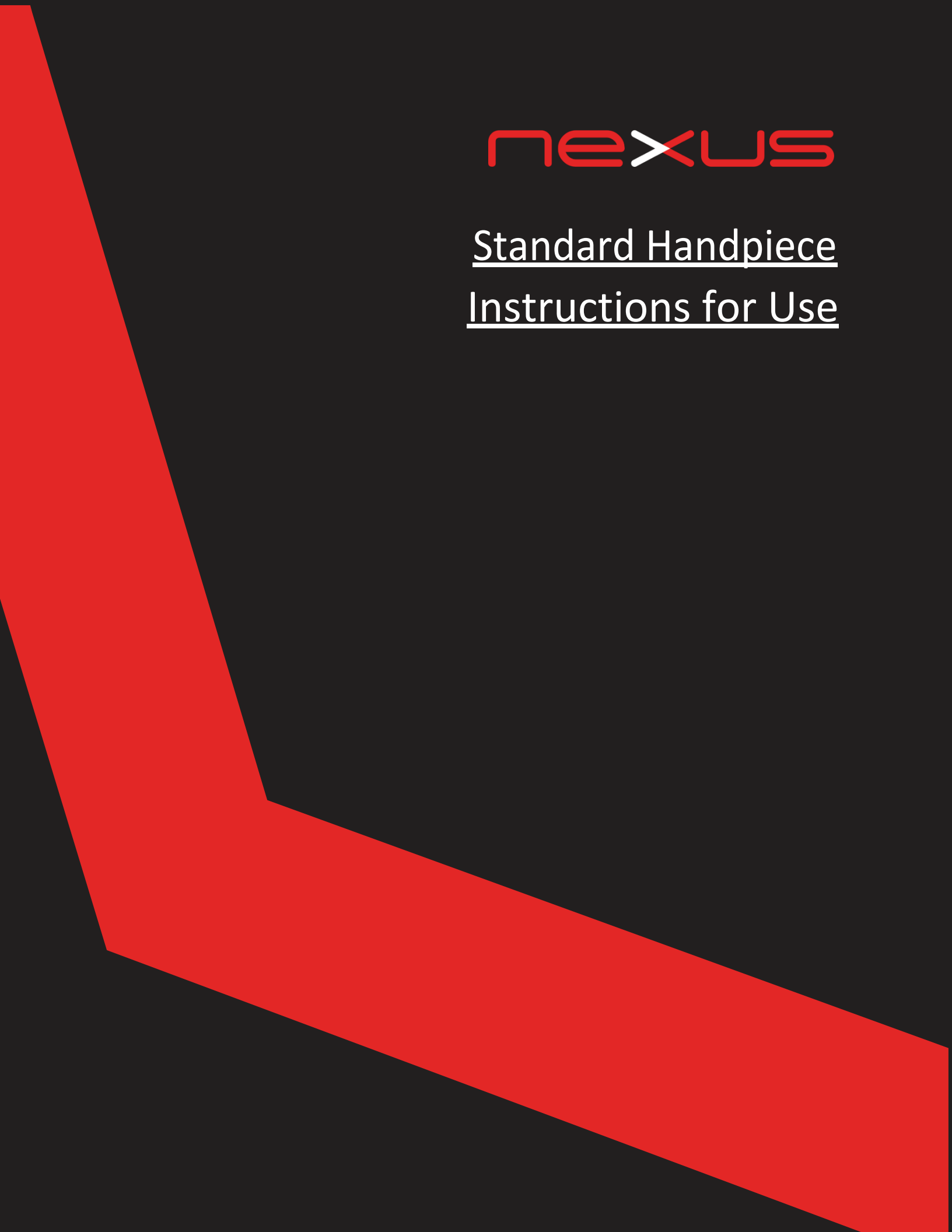




nexus

Standard Handpiece
Instructions for Use

1. General Safety Statements

- WARNING

The neXus® Ultrasonic Surgical Aspirator System is an electro-mechanical device, which under certain circumstances could present an electrical shock hazard to the operator and/or patient. Please read manual thoroughly and follow directions stated herein to assure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.
- WARNING

The neXus® Ultrasonic Surgical Aspirator System is intended to be used in various types of invasive, surgical procedures. There may be indirect danger to the patient should the device fail during the procedure. It is recommended that the facility follows its back-up equipment protocols.
- CAUTION

Special Skills Training Requirements

- U.S. federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.
 - The neXus® Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.
 - All Hospital personnel are trained in universal precautions and use of PPE

1.1 Summary of Safety Notices

Please read this section of the manual carefully. It contains a summary of all precaution, warning and caution statements contained in the manual. However, the user is advised to read the entire manual and operate the device only in accordance with all of the instructions contained herein.

Servicing of this device should only be performed by qualified technicians authorized by Misonix, Inc. There are no service controls accessible to the user.

Conventions on Warnings and Cautions	
WARNING	Denotes potentially dangerous situation that could result in death or serious injury to patient, operator or staff.
CAUTION	A caution contains information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device.

Table 1.1: Conventions on Warnings and Cautions

1.2 List of Warnings

- The neXus® Ultrasonic Surgical Aspirator System is an electro-mechanical device, which under certain circumstances could present an electrical shock hazard to the operator and/or patient. Please read manual thoroughly and follow directions stated herein to assure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.
- The neXus® Ultrasonic Surgical Aspirator System is intended to be used in various types of surgical procedures. There may be indirect danger to the patient should the device fail during the procedure. It is recommended that the facility follows its back-up equipment protocols.
- Explosion Hazard: Never use the neXus® Ultrasonic Surgical Aspirator System in the presence of a flammable or explosive atmosphere, such as flammable anesthetics.
- Only use the Standard Handpiece with BoneScalpel or SonicOne OR probe accessory kit configurations for the indications for use charted in Section 2.1.
- Tip and irrigation temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal, set the irrigation flowrate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 70, a minimum flow setting of 70% should be used. Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures..
- Tissue necrosis may result if tip is not moved relative to tissue. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert tip frequently.
- Contact to vibrating elements like extension and ultrasonic tip may cause burns and should be avoided by all means. The handpiece should only be held at the black housing area. An optional, protective silicone sleeve, included with certain tips, reduces the risk of thermal damage but does not eliminate it. Contact with the silicone sleeve should be avoided or kept brief with minimal amount of contact pressure. Pressure and extended exposure can still result in excessive frictional heat and cause burns.
- Ultrasonic tips can break under excessive use in extreme conditions, e.g. when cutting for extended / duration in tight cavities with limited lateral motion. The tip could break into two or more fragments with the main fragment remaining attached to the handpiece. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. It is possible that a fragment is propelled outside of the surgical cavity. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that the broken piece is outside of the surgical cavity.
- Breakage of ultrasonic tips will result in sharp edges that can be harmful to soft tissue even without activation of ultrasound. Tips can bend or deform before they actually brake. Tips showing signs of deformation or cracking should be replaced immediately since tip breakage is otherwise imminent. Do not bend or twist the ultrasonic tips since it reduces the structural integrity and can result in tip breakage during use. Dispose of deformed or broken tips immediately in a sharps container.
- Immediately suspend operation if Electrical Fault appears on display and/or an Electrical Fault audible indicator sounds. Remove ultrasonic tip from surgical site. Turn Mains Power OFF. Do not touch any metallic parts of handpiece, extension, ultrasonic tip or generator while fault is indicated.
- Improper connection of the handpiece cable may present a shock hazard. Confirm that handpiece connector is dry prior to plugging it in.

- Heat is being generated at the tip/tissue interface. A continuous, lateral sweeping motion is recommended for general bone/tissue removal in order to minimize contact duration with the ultrasonic tip and minimize the temperature increase.
- Remove probe cover, ultrasonic tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.
- Single-use items (tips, sheaths, tubing sets) are marked with the international symbol for “do not reuse - single use only” (ⓧ). Discard these items following each surgical procedure in accordance with the hospital protocol for biohazardous waste. Tips are to be disposed of in a biohazardous sharps container.
- All reusable handpiece parts and accessories must be properly decontaminated, cleaned and sterilized before each use as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient death.
- Misonix Inc. has validated all cleaning and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the neXus® Ultrasonic Surgical Aspirator System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.
- The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.
- The neXus® Ultrasonic Surgical Aspirator System and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits.
- No Modifications of this equipment is allowed except as noted for cleaning and sterilization. The user should return to Misonix or an authorized service center

1.3 List of Cautions

- Special Skills Training Requirements
 - U.S. federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.
 - The NeXus® Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.
 - All Hospital personnel are trained in universal precautions and use of PPE.
- The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the device. Use only Misonix branded equipment and accessories.
- The console should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the console should be observed to verify normal operation in the configuration in which it will be used.
- Ultrasonic energy is inhibited if excessive physical force is applied to the ultrasonic tip; use only enough force to guide the tip to the surgical site and to advance it through the tissue. Do not force the tip; allow the ultrasonic action to do the work.
- This Instructions for Use Manual provides instructions on using the neXus Standard Handpiece. Refer to the neXus Console Instructions for Use Manual prior to using the neXus Ultrasonic Surgical Aspirator System.
- Insufficient irrigation and high tip pressure (loading) under extended exposure, e.g. in tight cavities, are to be avoided while removing hard tissue. It is recommended to withdraw and re-insert the ultrasonic tips (e.g. Blades & Shavers) repeatedly to re-establish adequate cooling and lubrication.
- Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary when removing very dense, hard osseous structures.
- All reusable system components like handpiece, probe covers, counter wrench, and T-wrench are supplied industrially cleaned, but NON-STERILE. All items intended for use in the sterile field must be cleaned and sterilized as per the indicated instructions before first clinical use and before every subsequent clinical use.
- All items intended for use in the sterile field must be cleaned and sterilized as per indicated instructions before each clinical use.
- The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.
- Prime the irrigation tubing prior to use. At all times ensure that the irrigation flows towards the handpiece when footswitch is depressed. If no irrigation is flowing, cease use until flow is restored.
- The system check should always be done in advance of preparing patient for surgery to minimize risk to patient in case of system malfunction.
- Ensure all connections and mating surfaces of handpiece, extension and ultrasonic tip are clean and dry before assembly.
- Do not use ultrasonic cleaners to clean the handpiece as this method could damage handpiece.
- Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.
- Do not immerse ultrasonic console, handpiece, irrigation pump, remote footswitch or electric cables. These items are not sealed against liquids and damage to equipment will result.
- Ensure all connections and mating surfaces of handpiece, extension and ultrasonic tip are clean and dry before assembly.

- Loose tip/tissue contact upon an initial bone incision can cause a thin tip to resonate not only longitudinally but also transversely. This can cause a thin tip to break. It is necessary to engage bone actively and with a minimal tip pressure greater than zero in order to prevent the shattering.
- Contact of the ultrasonic tip or the exposed extension with metal, surgical instruments or other objects during ultrasound use must be avoided. Such contact can damage the ultrasonic components very easily and may result in compromised performance, including failure. Discard any extensions or tips that show signs of damages like gouges, nicks or fractures. External aspiration may be used but it is recommended that a plastic suction tip should be used when in proximity with the probe tip.
- The handpiece must be placed into the counter wrench. Do not attempt to tighten or loosen handpiece components by holding the handpiece case or endcap. Always use the T-wrench wrench when tightening or un-tightening the tip or an extension. Never apply a pipe or strap wrench to the handpiece case. Do not over-tighten the tip or the extension.
- Always tighten or un-tighten the probe cover by hand and without using any wrenches. Do not over- tighten the probe cover.
- Always hold the handpiece at its metallic endcap when tightening or un-tightening the irrigation tubing. Always tighten or un-tighten the irrigation tubing by hand and without using any wrenches. Do not over- tighten the tubing connector.
- Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage.
- The reuse life given takes into account wear and tear due to cleaning and sterilization only. Damage or wear caused by actual use in treatments will affect life of components.

1.4 Trademark Information

- Misonix®, neXus®, BoneScalpel® and SonicOne® are registered trademarks of Misonix, Inc., Farmingdale, NY
- ASP Enzol® and Prolystica® are registered trademarks of STERIS Corporation, Mentor OH

1.5 Symbol Definition Chart

	Misonix CE number
	Contains DEHP and/or Phthalates
	Caution: Consult accompanying documents
	Restricted to sale by or on the order of a physician only
	Manufacturer
	Consult Instructions for Use
	Sterilized using Ethylene Oxide
	Lot or Batch Code
	Authorized Representative
	Warning: Hearing Protection
	Disposal to be compliant with EN 50419 (WEEE directive)
	Catalog number

Table 1.2 Symbol Definitions

2. Indications and Contra Indications

2.1. Indications

The Misonix Inc. **neXus® Standard Handpiece** is intended for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue. The indications for use for the Standard Handpiece in combination with BoneScalpel and SonicOne OR probe kit accessory configurations and the indications are charted below.

NEXUS INDICATIONS FOR USE BY HANDPIECE AND PROBE KIT ACCESSORY COMBINATION	
Standard Handpiece <i>for use with BoneScalpel® and Sonic One®</i>	
Indications for Use BoneScalpel ®	Indications for Use SonicOne ®
Indicated for use in the fragmentation and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties: • Neurosurgery • Gastrointestinal and Affiliated Organ Surgery • Urological Surgery • Plastic and Reconstructive Surgery • General Surgery • Orthopedic Surgery • Gynecology External genitalia - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts Abdominal area - any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids. • Thoracic Surgery Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and metastatectomies. • Wound Care The neXus Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.	Indicated for use in the fragmentation and aspiration of soft and hard tissue (i.e. bone) in the following surgical specialty: • Wound Care The neXus Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement. • Plastic and Reconstructive Surgery

2.2. Contraindications

2.2.1 The neXus Ultrasonic Surgical Aspirator System probe tips are not indicated for and should not be used for direct contact with cardiac tissue (direct cardiac application).

2.2.2 The irrigation pump is not indicated for and should not be used for the administration of parenteral fluids, infusion of drugs, or for any life sustaining purposes.

2.2.3 This neXus Ultrasonic Surgical Aspirator System device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

3. Adverse Effects

WARNING The neXus Ultrasonic Surgical Aspirator System and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits.

Limits For Airborne Acoustic Exposure		
Distance from operator's or patient's ear		Maximum Exposure Period Within a 24-hour period
3" - 24"	8 cm – 60 cm	28 minutes
> 24"	> 60 cm	287 minutes

Table 3.1: Limits for Airborne Acoustic Exposure

CAUTION When using the **SonicOne® OR Wide Hatch Probe (120-31-13X2)** assure patients less than 50" (127 cm) tall are to wear hearing personal protection devices (Hearing PPE) during debridement.

WARNING Tip and irrigation temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal, set the irrigation flowrate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 70, a minimum flow setting of 70 should be used. Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures.

WARNING Tissue necrosis may result if tip is not moved relative to tissue. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert tip frequently.

4. Handpiece Assembly and Disassembly

Handpiece assembly in the sterile field should be performed by trained and authorized OR staff only. Once the handpiece has been assembled, refer to neXus Console Instructions For Use for connectivity with system.

- CAUTION

Ensure all connections and mating surfaces of handpiece, extension and ultrasonic tip are clean and dry before assembly.
- CAUTION

Single-use items (tips, sheaths, tubing sets) are marked with the international symbol for “do not reuse - single use only” (ⓧ). Discard these items following each surgical procedure in accordance with the hospital protocol for biohazardous waste. Tips are to be disposed of in a biohazardous sharps container.
- CAUTION

All reusable handpiece parts and accessories must be properly decontaminated, cleaned and sterilized before each use as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient death.
- CAUTION

The handpiece must be placed into the counter wrench. Do not attempt to tighten or untighten handpiece components by holding the handpiece case or endcap. Always use the T-wrench wrench when tightening or un-tightening the tip or an extension. Never apply a pipe or strap wrench to the handpiece case. Do not over-tighten the tip or the extension.
- CAUTION

Always tighten or un-tighten the probe cover by hand and without using any wrenches. Do not over-tighten the probe cover.
- CAUTION

Always hold the handpiece at its metallic endcap when tightening or un-tightening the irrigation tubing. Always tighten or un-tighten the irrigation tubing by hand and without using any wrenches. Do not over- tighten the tubing connector.

4.1. Items Required for Handpiece Assembly

- Standard Handpiece
- Counter Wrench
- Torque Wrench
- Front Housing (BoneScalpel or SonicOne specific)
- Standard Handpiece Sterilization Case

4.2. Handpiece Inspection (prior to assembly)

Perform an inspection of handpiece and all components prior assembly.

Handpiece Inspection	
Inspect Handpiece	Inspect the black handpiece housing for any visual cracks. Inspect the front metallic portion probe for surface damage like nicks, gouges and cracks. Replace if damaged.
Inspect Mating Surface	Inspect mating face of handpiece to verify that it is clean and dry.

Table 4.1 Handpiece Inspection

4.3. Standard Handpiece Assembly

Once the handpiece inspection is complete, the handpiece can be assembled in conjunction with the corresponding procedure pack (i.e., 110-31-1B10) Instructions For Use (included in the sterile packaged product).

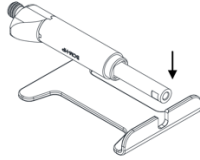
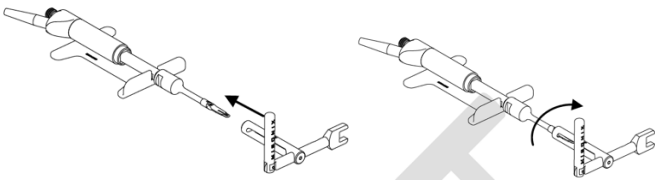
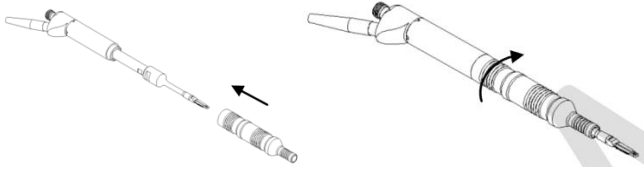
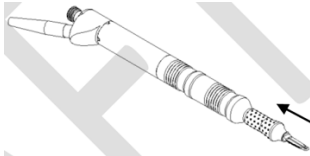
1. Insert handpiece in Counter Wrench, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation and tightening instructions.	
2. Install and tighten desired probe, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use assembly for installation and tightening instructions.	
3. Install and tighten appropriate Front Housing, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation and tightening instructions.	
4. Install appropriate sleeve, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation instructions.	
5. Connect tubing (irrigation / aspiration), refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation instructions.	

Table 4.2 Irrigation Tube Disassembly

The handpiece is now ready for use and can be connected to the neXus Console, refer to the neXus Console Instructions For Use (IFU) for additional instructions and information.

4.4. Standard Handpiece Disassembly

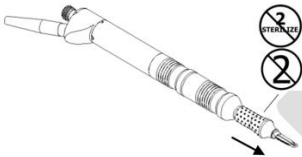
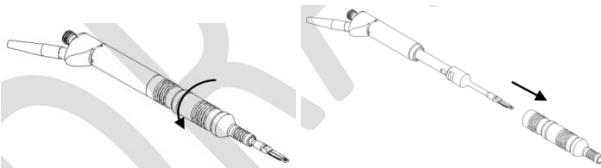
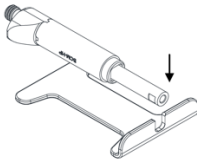
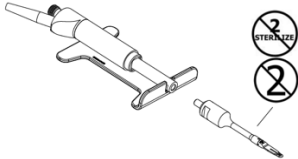
1. Disconnect tubing (irrigation / aspiration), refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation instructions.	
2. Remove sleeve, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation instructions.	
3. Remove Front Housing, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation and tightening instructions.	
4. Insert handpiece in Counter Wrench, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation and tightening instructions.	
5. Remove probe, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use assembly for installation and tightening instructions.	

Table 4.2 Irrigation Tube Disassembly

CAUTION	All reusable handpiece parts and accessories must be properly decontaminated, cleaned and sterilized before each use as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient death.
CAUTION	Single-use items (tips, sheaths, tubing sets) are marked with the international symbol for “do not reuse - single use only” (⊗). Discard these items following each surgical procedure in accordance with the hospital protocol for biohazardous waste. Tips are to be disposed of in a biohazardous sharps container.
WARNING	Remove probe cover, ultrasonic tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.
CAUTION	The handpiece must be placed into the counter wrench. Do not attempt to tighten or untighten handpiece components by holding the handpiece case or endcap. Always use the T-wrench wrench when tightening or un-tightening the tip or an extension. Never apply a pipe or strap wrench to the handpiece case. Do not over-tighten the tip or the extension.
CAUTION	Always tighten or un-tighten the probe cover by hand and without using any wrenches. Do not over-tighten the probe cover.
CAUTION	Always hold the handpiece at its metallic endcap when tightening or un-tightening the irrigation tubing. Always tighten or un-tighten the irrigation tubing by hand and without using any wrenches. Do not over-tighten the tubing connector.

5. Cleaning and Sterilization

Misonix recommends the use of CaviWipes® or equivalent quaternary ammonium compound surface disinfectant wipe. Please follow manufacturer’s instructions for surface cleaning and disinfection of hard non-porous surfaces, including, without limitation, the use of personal Protection Equipment (PPE) for blood borne Pathogens. Dispose of the used wipes in accordance with local regulations regarding the disposal of biological hazardous wipes.

Dispose of Single-Use Items

All items marked single use must not be reused. Reuse of these items could result in severe patient injury or death.

Once used, dispose of single use items in accordance with standard hospital procedures for disposal of biohazardous waste.

WARNING	Remove probe cover, ultrasonic tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.
WARNING	Single-use items (tips, sheaths, tubing sets) are marked with the international symbol for “do not reuse - single use only” (ⓧ). Discard these items following each surgical procedure in accordance with the hospital protocol for biohazardous waste. Tips are to be disposed of in a biohazardous sharps container.
WARNING	The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

The following items are considered reusable items and should be cleaned as recommended:

- Standard Handpiece
- Counter wrench
- T-wrench
- BoneScalpel Front Housing
- SonicOne Front Housing
- Standard Handpiece Sterilization Case

Misonix Inc. has validated the cleaning procedures outlined below.

Misonix continually updates its sterilization and cleaning instructions as required. For the latest instructions and reuse recommendations please contact your local Misonix representative.

WARNING	All reusable handpiece parts and accessories must be properly decontaminated, cleaned and sterilized before each use as per instructions contained in this manual. Failure to do so may lead to transmission of disease.
WARNING	Misonix Inc. has validated all cleaning and sterilization cycles for reusable items in this manual. To prevent transmission of disease or malfunction of the neXus® system, Misonix recommends that the procedures given in this manual for cleaning and sterilizing the neXus® Ultrasonic Surgical Aspirator System and related accessories be followed. Misonix does not prefer the validated cleaning agents, cleaning procedures or sterilization procedures over others that are available. Other cleaning agents, cleaning procedures and/or sterilization cycles may have equal or superior performance. However, alternatives must be verified by reviewing the product information from the cleaning agent supplier and/or by physical and microbiological testing in accordance to applicable global regulatory guidance on cleaning and sterilizing reusable medical devices in the health care environment.

5.1. Manual Cleaning/Washing Procedure

Standard Handpiece Probe Covers and Wrenches	
Wash & Brush	- Wash items with hot water mixed with an enzymatic detergent such as ASP Enzol® or Steris Prolystica® according to standard hospital protocol. Follow manufacturer's directions for preparing solutions. - Probe cover and wrenches may be fully immersed. - Brush all passages at least four (4) times from FRONT to REAR, rotating the brushes during insertion and inserting the brushes fully. This ensures clearing of debris from the internal passages. - Item's exterior surface can be cleaned using a standard soft bristle cleaning brush.
Rinse	Rinse item under warm running water for a minimum of 1 minute to clear soap residue.
Dry	Dry item fully with absorbent towel or paper. Dispose of cloth or paper in accordance with Hospital or Clinic practices for contaminated wastes.
Inspect	Inspect wrenches and remove any item which shows signs of damage (cracks, gouges, fractures etc.). Mark damaged items clearly to prevent future use before disposal.
Post Cleaning	Inspect all items for cleanliness and damage following cleaning and prior to terminal sterilization.

Table 5.1 Cleaning of Probe Cover and Wrenches

Standard Handpiece	
Wipe Cable	Wipe cable with cloth or absorbent paper moistened with an enzymatic detergent such as ASP Enzol® or Steris Prolystica®. Follow manufacturer's directions for preparing solutions. Clean all surfaces of bloodstains and obvious signs of contamination.
Wash & Brush	- Wash and brush handpiece with hot water mixed with an enzymatic detergent such as ASP Enzol® or Steris Prolystica®. Follow manufacturer's directions for preparing solutions. - The handpiece cannot be immersed. - Brush all passages at least four (4) times from FRONT to REAR, rotating the brushes during insertion and inserting the brushes fully. This ensures clearing of debris from the internal passages. - The item's exterior surface can be cleaned using a standard soft bristle cleaning brush.
Rinse	Rinse item under warm running water for a minimum of 1 minute to clear soap residue.
Dry	Dry item fully with absorbent towel or paper. Dispose of cloth or paper in accordance with Hospital or Clinic practices for contaminated wastes.
Inspect	Inspect handpiece and cable and remove any item which shows signs of damages (cracks, gouges, fractures etc.). Mark damaged items clearly to prevent future use before disposal.
Post Cleaning	Inspect all items for cleanliness and damage following cleaning and prior to terminal sterilization.

Table 5.2 Cleaning the Standard Handpiece

- CAUTION Do not use ultrasonic cleaners to clean the handpiece as this method could damage the handpiece.
- CAUTION Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.
- CAUTION Do not immerse handpiece or electric cables. These items are not sealed against liquids and damage to equipment will result.

5.2. Automated Cleaning/Washing Procedure

Handpiece, Front Housing and Wrenches	
Point of Use	Immediately following procedure perform the following: • Flush handpiece lumen with minimum 100 mL of saline to clear the bore of debris. • Wipe all reusable devices to remove visible blood and debris. CAUTION: DO NOT use saline to wet the tray and tray contents before transport to the decontamination processing area. CAUTION: If transport to the decontamination processing area is delayed, cover the tray with a damp cloth or spray the tray and its contents with a pre-cleaning foam. The pre-cleaning foam will minimize the drying of soil and facilitate later decontamination processing.
Pre-Cleaning	• The following should be performed on a disassembled handpiece: • Remove the probe and all housing components. • Prepare neodisher® MediClean forte at 3.9 mL per liter of water (5/8 oz. per gallon water). Water should be lukewarm (<40°C, <104°F). • Use a tight-fitting brush dipped in the prepared cleaning solution to clean the lumen of the hand- piece by inserting the brush fully through the lumen until visible from the other side a minimum of four times, rotating the brush as it is inserted. • Rinse all residual soap from the handpiece under warm running water for a minimum of one minute. • Visually inspect internal and external surfaces of the handpiece including the pin cavity and repeat the above steps as required until all visible debris and staining are removed.
Automated Wash and Disinfection	When placing the handpiece into the automated washer, place on the top shelf of the washer. Attempt to align the lumen in the general direction of the water jet flow in the washer but at a slight angle to facilitate draining during the drying cycle. Process the handpiece and all reusable components and accessories using the cycle parameters, in the table below. <i>*Durations listed are minimum acceptable. Longer durations than those specified for cleaning and disinfection are acceptable.</i>
Post-Cleaning	Inspect all items for cleanliness and damage following cleaning and prior to terminal sterilization.

Table 5.3 Cleaning of Handpiece, Front Housing, and Wrenches.

Phase	Time*	Parameters	Detergent Type and Concentration
Pre-Wash 1	2 minutes	Cold tap or purified water	None
Wash 1	2 minutes	≥65.5°C (150°F)	neodisher® MediClean forte 2mL/L (¼ oz. / gallon)
Rinse 1	1 minute	Hot tap water	None
Disinfection	1 minute	≥90°C (194°F)	None
Drying	6 minutes	≥98.8 °C (210°F)	None

Table 5.4: Automated Wash Cycle Parameters (*Durations listed are minimum acceptable. Longer durations than those specified for cleaning and disinfection are acceptable.)

CAUTION Do not use ultrasonic cleaners to clean the handpiece as this method could damage the handpiece.

CAUTION Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.

CAUTION Do not immerse ultrasonic console, handpiece, irrigation pump, remote footswitch or electric cables. These items are not sealed against liquids and damage to equipment will result.

5.3. Sterilizing by Steam Autoclave

Sterilization Methods and terminology are based on ANSI/AAMI ST81 and EN ISO 17664:2004 standards.

Reusable, Autoclavable Components

100-21-0000	Standard Handpiece
100-61-0000	T-Wrench
100-60-0000	Counter Wrench
100-21-0003	SonicOne Front Housing
100-21-0002	BoneScalpel Front Housing
100-70-000	Standard Handpiece Sterilization Case

Table 5.5: Standard Handpiece Reusable, Autoclavable Components

Handpiece **DISASSEMBLED** using Misonix Sterilization Tray: Probe, Tubing, and Housing should be REMOVED.

	132°C (270°F)	134-137°C (274-279°F)
Configuration	Items placed in Misonix Sterilization Tray #100-70-0000 ¹	Items placed in Misonix Sterilization Tray #100-70-0000 ²
Cycle	Prevacuum	Prevacuum
Preconditioning Pulses	4	4
Minimum Exposure Time	4 minutes*	3 minutes*
Minimum Dry Time	30 minutes	30 minutes

Table 5.6: Sterilization Parameters for Handpiece **DISASSEMBLED** using Misonix Sterilization Tray

Handpiece **DISASSEMBLED** without Sterilization Tray, Items Wrapped: Probe, Tubing, and Housing should be REMOVED.

	132°C (270°F)	134-137°C (274-279°F)	134°C (273°F)
Configuration	Items wrapped, NO TRAY ³	Items wrapped, NO TRAY ³	Items wrapped, NO TRAY ³
Cycle	Prevacuum	Prevacuum	Gravity
Preconditioning Pulses	4	4	None
Minimum Exposure	4 minutes*	3 minutes*	20 minutes
Minimum Dry Time	45 minutes	30 minutes	5 minutes

Table 5.7: Sterilization Parameters for Handpiece **DISASSEMBLED** without Sterilization Tray, Items Wrapped

CAUTION	Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage
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¹ Tray wrapped in Kimberly Clark KC300 KIMGUARD sterilization wrap.

² Tray wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.

³ Items wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.

*Exposure time can be increased up to a maximum of 18 minutes to comply with local requirements and/or recommendations of the World Health Organization (WHO), Robert Koch Institute (RKI), etc. Misonix Inc reusable medical devices are able to sustain such sterilization cycles.

5.4. Deviations to Cleaning, Sterilization, Decontamination Instructions

Misonix Inc. has validated all cleaning, disinfection and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the NeXus® Ultrasonic Surgical Aspirator System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.

Technical Assistance: Should the user wish further information or instructions regarding any aspect of cleaning or sterilizing procedures, please contact Misonix Inc. or an Authorized Representative.

5.5. Expected Life, Reusable Components

All handpiece components need to be examined regularly, prior to each use and be replaced if damaged.

The estimated sterilization life of handpiece components is listed below. All sterilization life estimates are approximate and may be affected by rough handling, damage, wear due to vigorous cleaning, etc.

Estimated Sterilization Life	
Item	Number of Steam Sterilization Cycles
Handpiece with attached cable	~ 200 cycles
Probe covers: BoneScalpel & SonicOne	~ 300 cycles
Wrenches: Handpiece/counter wrench and T-wrench	~300 cycles

Table 5.8 Reusable Component Estimated Re-Use Life

CAUTION	The reuse life given considers wear and tear due to cleaning and sterilization only. Damage or wear caused by actual use in treatments will affect life of components.
WARNING	The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

5.6. Handpiece Specifications

Standard Handpiece	
Operating frequency	22.5 kHz
Cable length	15' 4.6 m
Dimensions	5.9" L (without probe) x 0.8" D 15 cm x 2.0 cm
Weight with tip	4.4 oz. 125 g

Table 5.9: Handpiece Specifications

6. Repair, Service and Replacement Parts

All requests for repairs and replacement parts should be directed to Misonix or an authorized Misonix representative. Always provide model and serial number of malfunctioning items.

When returning items include model, serial and RMA number as well as purchase order number on all documents. Always prepay return shipping and specify method of shipment.

WARNING	No Modifications of this equipment is allowed except as noted for cleaning and sterilization. The user should return to Misonix or an authorized service center.
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7. Important Notice

Please contact Misonix with any questions regarding the specifications, use, sterilization, limitations or maintenance of the NeXus® Ultrasonic System:

	Misonix, Inc.
Web	www.misonix.com
Phone	+1.631.694.9555 / 1-800-694-9612
Fax	+1.631.694.9412
Address	1938 New Hwy Farmingdale, NY 11735 U.S.A.

By returning any material to Misonix, Inc. the customer or the customer's agent must certify that any and all materials so returned are or have been rendered free of any hazardous or noxious matter or radioactive contamination and are safe for handling under normal repair shop conditions.

Do not return any material for which such certification cannot be made without prior approval from

Misonix, Inc. The correct return address should read as follows:

MISONIX (Misonix, Inc.)
Medical Service Department
RMA # _____
1938 New Hwy
Farmingdale, NY 11735
U.S.A.

Please contact Misonix for a list of other authorized service centers.

The authorized EC representative is:



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands