Standard Handpiece Instructions for Use

For additional information not contained in this manual, please visit ww.misonix.com or contact your local sales representative.

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 ensure 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

- Rx ONLY Caution: United States Federal law restricts this device to sale by or on the order of a physician or health care practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; Not applicable in the European Union.
- The neXus® Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.
- All health care institution personnel are to be trained in the healthcare institution's procedures for universal precautions for bloodborne pathogens and the use of appropriate 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, LLC. 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 ensure 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 health care institution 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.

- All Misonix reusable items must be sterilized by moist heat (steam sterilization/autoclaved) after manual cleaning.

- Automated cleaning-disinfection is not the final step prior to use. All Misonix reusable items must be sterilized by moist heat (autoclaved) after automated cleaning and disinfection.

- Misonix LLC has validated all cleaning and sterilization cycles given 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. However, other end-user validated cleaning agents, cleaning procedures, and/or sterilization cycles may be used. **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 in accordance with applicable local laws and regulations on cleaning and sterilization of reusable medical devices in the healthcare environment.**

- For all sterilization protocols listed below, always ensure the tethered cap is placed securely on the cable connector to protect the connector during sterilization.
- 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
  - Rx ONLY Caution: United States Federal law restricts this device to sale by or on the order of a physician or health care practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; Not applicable in the European Union.
  - The neXus® Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.
  - All health care institution personnel are to be trained in the healthcare institution's procedures for universal precautions for bloodborne pathogens and the use of appropriate 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.
- Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving. Refer to the Pre-cleaning step below.
- Do not immerse the ultrasonic handpiece or the handpiece cable. These items are not sealed against liquids and damage to equipment will result.
- Use softened, filtered, or deionized water for diluting cleaning agents and for the final equipment rinse. Deionized water is recommended for the final rinse, if available. Mineral residues from hard water in the final rinse step can cause water stains and/or affect cleaning and disinfection.
- The tethered handpiece cable cap should be placed on the handpiece cable connector immediately after the cable is disconnected from the console to prevent damage to the connector pins and remain on during precleaning, manual cleaning, automated cleaning/disinfection, and sterilization procedures.
- Misonix does not recommend "FLASH" sterilization. Misonix has not validated "FLASH" sterilization.

- Poor steam quality may impair the sterilization process. For this reason, various norms (European standard EN 285 and the United States standard ANSI/AAMI ST79) recommend maximum impurity levels for steam feed water of autoclaves and sterilizer used in the medical field. Misonix recommends using water of a quality that conforms to the norms, the health care institution validated specifications for water quality, or otherwise using deionized water to generate steam for moist heat sterilization.
- 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, LLC., Farmingdale, NY
- ASP Enzol® and Prolystica® are registered trademarks of STERIS Corporation, Mentor OH

1.5 Symbol Definition Chart

CE 0482	Misonix CE number
PHT DEHP	Contains DEHP and/or Phthalates
	Caution: Consult accompanying documents
Rx ONLY	Caution: United States Federal law restricts this device to sale by or on the order of a physician or health care practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; Not applicable in the European Union.
	Manufacturer
	Date of Manufacture
STERILE EO	Sterilized using Ethylene Oxide
LOT ABC123	Lot or Batch Code
EC REP	Authorized Representative
	Warning: Hearing Protection
	Disposal to be compliant with EN 50419 (WEEE directive)
REF	Catalog number
UDI	Unique Device Identification is specific to a manufacturer and a device

MD	Identifies product as a medical device
	Single sterile barrier system
Rx ONLY	Restricted to sale by or on the order of a physician only
NON STERILE	Non-sterile medical device
	Do not use if package is damaged
LATEX	Contents are latex-free
	Single use (do not re-use)
	Do not re-sterilize

Table 1.2 Symbol Definitions

1.6 List of Accessories

Probe Part Number	Probe Description	EEU Device Class
110-31-1110	10mm, Blunt Blade and Tubeset	Class IIb
110-31-1120	20mm, Blunt Blade and Tubeset	Class IIb
110-31-1121	20mm, Unilateral Serrated Blade and Tubeset	Class IIb
110-31-1125	25mm, Blunt Blade and Tubeset	Class IIb
110-31-1210	Micro Hook Shaver and Tubeset	Class IIb
110-31-1220	Macro Hook Shaver and Tubeset	Class IIb
110-31-1230	Diamond Shaver and Tubeset	Class IIb
110-31-2110	10mm MIS, Blunt Blade, Sheath and Tubeset	Class IIb
110-31-2120	20mm MIS, Blunt Blade, Sheath and Tubeset	Class IIb
110-31-2210	Micro Hook Long Curved, Shaver, Sheath, and Tubeset	Class IIb
110-31-5501	Standard Decompression Kit (20mm blade, micro hook shaver and Tubeset)	Class IIb
120-31-10R1	Cylindrical Probe and Tubeset	Class IIb
120-31-10X1	Hatched Probe and Tubeset	Class IIb
120-31-13C2	SharpVac and Tubeset	Class IIb
120-31-13C3	Curette Tip Excel Kit	Class IIb
120-31-13X2	SonicVac and Tubeset	Class IIb

2. Indications and Contra Indications

2.1. Indications

The Misonix LLC. **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 *for use with BoneScalpel® and Sonic One®*	
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 reception such as segmetectomies, 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)** ensure patients less than 50" (127 cm) tall 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 health care institution 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

Part #	Description
100-21-0001	Standard Handpiece
100-21-0002	Front Housing (BoneScalpel)
100-21-0003	Front Housing (SonicOne)
100-60-0000	Standard Handpiece Counter Wrench
100-61-0000	Standard Handpiece T-wrench
100-70-0000	Standard Sterilization Tray

4.2. Handpiece Inspection (prior to assembly)

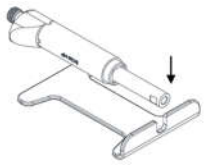
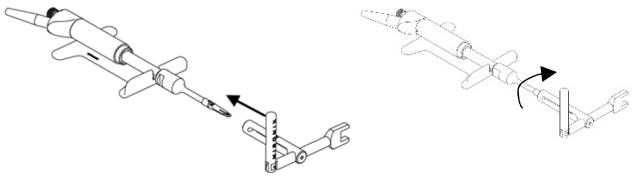
Perform an inspection of handpiece and all components prior to assembly.

Handpiece Inspection	
Inspect Handpiece	• Inspect the handpiece housing and front cover for damage and signs of wear such as scratches, cracks, and chips. • Inspect the handpiece cable to ensure it is not cut or frayed. • Inspect the handpiece cable connector, connector pins, and the tethered cap to ensure they are not damaged. • Place the tethered cap on the connector after inspection and leave in place until connection to the generator. • Do not use damaged handpieces or handpiece components. Contact Misonix Customer Service if damage is noted. • The neXus handpiece should be fully inspected for loose or missing components and tested for proper operation prior to each procedure.
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.	

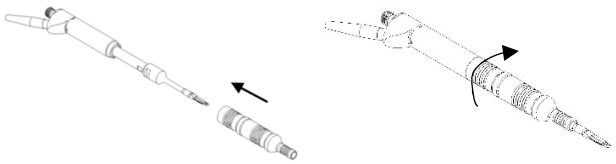
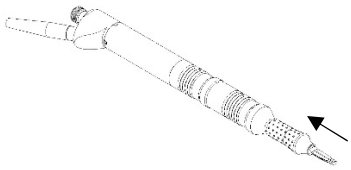
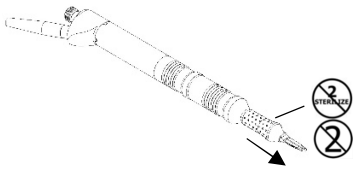
3. Install and tighten appropriate Front Housing, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation and tightening instructions.	
4. Install appropriate sleeve, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation instructions.	
5. Connect 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

Note: After disconnection of the cable connector from the generator, place the tethered cap onto the cable connector. Leave the cable connector on during cleaning, disinfection, and sterilization.	
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.	

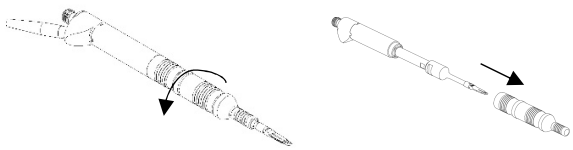
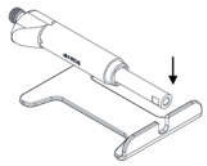
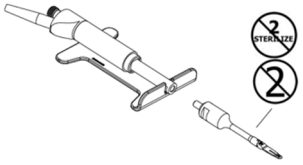
3. Remove Front Housing, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation and tightening instructions.	
4. Insert handpiece in Counter Wrench, refer to procedure pack (i.e., 110-31-1B10) Instructions For Use for installation and tightening instructions.	
5. Remove probe, 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 health care institution 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

5.1. Dispose of Single-Use Items

WARNING: Follow the health care institutions protocol for Universal Precautions for Blood Borne Pathogens including the use of Personal Protective Equipment (PPE) when cleaning and disinfecting reusable items after a clinical procedure.

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 health care institution 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.

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 health care institution procedures for disposal of biohazardous waste.

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

Part #	Description
100-21-0001	Standard Handpiece
100-21-0002	Front Housing (BoneScalpel)
100-21-0003	Front Housing (SonicOne)
100-60-0000	Standard Handpiece Counter Wrench
100-61-0000	Standard Handpiece T-wrench
100-70-0000	Standard Sterilization Tray

Misonix LLC. 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 LLC. has validated all cleaning and sterilization cycles given 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. However, other end-user validated cleaning agents, cleaning procedures, and/or sterilization cycles may be used. **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 in accordance with applicable local laws and regulations on cleaning and sterilization of reusable medical devices in the healthcare environment.**

5.2. Point of Use Cleaning

Point of Use Cleaning	Following use, flush the handpiece lumen with a minimum of 100ml of saline to clear the bore of biological debris. Then remove visible blood and biological debris from the surface of the handpiece and components. • Misonix recommends the use of CaviWipes® or equivalent quaternary ammonium compound surface disinfectant wipes to remove visible blood and biological debris from the surface of the handpiece and components. Please follow manufacturer's instructions for surface cleaning and disinfection of hard non-porous surfaces, including, without limitation, following the instructions for the use of personal Protection Equipment (PPE) for blood borne Pathogens. Dispose of the used wipes in accordance with the health care institution protocol and local regulations regarding the disposal of biological hazardous waste. Place the handpiece into a tray and transport to the health care institution decontamination processing area. • CAUTION: To avoid drying of biological soil: — Transport the neXus Standard Handpiece to the decontamination processing area as soon as practical after the clinical procedure for cleaning. — If transport to the decontamination processing area is delayed, cover the tray with a water dampened cloth or spray the tray and its contents with a pre-cleaning foam. The pre-water dampened cloth or cleaning foam will minimize the drying of biological soil and facilitate later decontamination processing. Transport the neXus Standard Handpiece to the decontamination area as soon as practical. • CAUTION: DO NOT use saline to wet the tray and tray contents before transport to the decontamination processing area. • CAUTION: DO NOT mix other heavy devices with the neXus Standard Handpiece during transportation to avoid damage to the handpiece.

5.3. Manual Cleaning/Washing Procedure

Standard Handpiece Probe Covers and Wrenches	
General Cautions and Notes.	• WARNING: All Misonix reusable items must be sterilized by moist heat (steam sterilization/autoclaved) after manual cleaning. • WARNING: Follow the health care institutions protocol for Universal Precautions for Blood Borne Pathogens including the use of Personal Protective Equipment (PPE) when cleaning and disinfecting reusable items after a clinical procedure. • 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. Refer to the Pre-cleaning step below. • CAUTION: Do not immerse the ultrasonic handpiece or the handpiece cable. These items are not sealed against liquids and damage to equipment will result. • WATER QUALITY CAUTION: Use softened, filtered, or deionized water for diluting cleaning agents and for the final equipment rinse. Deionized water is recommended for the final rinse, if available. Mineral residues from hard water in the final rinse step can cause water stains and/or affect cleaning and disinfection.
Wash & Brush	• Disassemble the handpiece. Refer to Section 4.4. • Prepare the alkaline enzymatic cleaning solution. ○ Misonix has validated and recommends the use of ASP Enzol® or Steris Prolystica® alkaline enzymatic detergents. Please follow manufacturer's instructions preparation of the detergents, including, without limitation, the use of recommended Personal Protection Equipment (PPE).

	• Misonix recommends following the health care institutions protocol for Universal Precautions for Blood Borne Pathogens including the use of Personal Protective Equipment when cleaning reusable items after a clinical procedure. Dispose of single use items in accordance with local regulations regarding the disposal of biological hazardous wipes. • Thoroughly wet all surfaces of the handpiece covers and wrenches with an enzymatic detergent solution such as ASP Enzol® or Steris Prolystica® in accordance with the directions provided in the manufacturer's Instructions for Use. • Probe cover and wrenches may be fully immersed. • Thoroughly wet a brush with warm cleaning solution. 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. Attention should be given to hard to clean features such as crevices, channels, joints, or hard to reach areas where soil may be difficult to remove by brushing. Flush hard to reach areas using a sterile syringe filled with the enzymatic detergent in accordance with the directions provided in the manufacturer's Instructions for Use. • Item's exterior surface can be cleaned using a standard soft bristle cleaning brush.
Rinse	• Rinse item under warm running softened, filtered, or deionized water for a minimum of 1 minute to clear soap residue.
Dry	• Drain and then dry item fully with lint-free cloth, paper, or with medical-grade compressed air, 20 PSI (1.4 atm). • Dispose of lint-free cloth or paper in accordance with Health care institution 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. If soil remains, repeat the cleaning and rinsing procedure using fresh warm cleaning solution.

Table 5.1 Cleaning of Probe Cover and Wrenches

Standard Handpiece	
General Cautions and Notes.	• WARNING: All Misonix reusable items must be sterilized by moist heat (autoclaved) after manual cleaning. • WARNING: Follow the health care institutions protocol for Universal Precautions for Blood Borne Pathogens including the use of Personal Protective Equipment (PPE) when cleaning and disinfecting reusable items after a clinical procedure. • 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. Refer to the Pre-cleaning step below. • CAUTION: Do not immerse ultrasonic handpiece, handpiece cable. These items are not sealed against liquids and damage to equipment will result. • WATER QUALITY CAUTION: Use softened, filtered, or deionized water for diluting cleaning agents and for the final rinse of equipment. Deionized water is recommended for the final rinse if available. Mineral residues from hard water in the final rinse step can cause water stains and/or affect cleaning and disinfection. • TETHERED HANDPIECE CABLE CAP: CAUTION: The tethered handpiece cable cap should be placed on the handpiece cable connector immediately after the cable is disconnected from the console to prevent damage to the connector pins and remain on during precleaning, manual cleaning, automated cleaning/disinfection, and sterilization procedures.
Wipe Cable	• Misonix recommends the use of CaviWipes® or equivalent quaternary ammonium compound surface disinfectant wipes to remove visible blood and biological debris from the surface of the handpiece and components. Please follow manufacturer's instructions for surface cleaning and disinfection of hard non-porous surfaces, including, without limitation, following the

	instructions for 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 waste.
Wash & Brush	• Misonix recommends the use of ASP Enzol® or Steris Prolystica® alkaline enzymatic detergents. Please follow manufacturer's instructions preparation of the detergents, including, without limitation, the use of recommended Personal Protection Equipment (PPE). • Misonix recommends following the health care institutions protocol for Universal Precautions for Blood Borne Pathogens including the use of Personal Protective Equipment when cleaning reusable items after a clinical procedure. Dispose of single use item in accordance with local regulations regarding the disposal of biological hazardous wipes. • Wash and brush the handpiece with an enzymatic detergent such as ASP Enzol® or Steris Prolystica® in accordance with the directions provided in the manufacturer's Instructions for Use. • The handpiece cannot be immersed. • Brush all passages (lumen) 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 Health care institution 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. • Inspect the handpiece housing and front cover for damage and signs of wear such as scratches, cracks, and chips. • Inspect the handpiece cable to ensure it is not cut or frayed. Inspect the handpiece cable connector and the tethered connector cap to ensure they are not damaged. • Do not use damaged handpieces or handpiece components. Contact Misonix Customer Service if damage is noted. • The neXus handpiece should be fully inspected for loose or missing components and tested for proper operation prior to each procedure.

Table 5.2 Cleaning the Standard Handpiece

5.4. Automated Cleaning/Washing Procedure

Handpiece, Front Housing and Wrenches	
General Cautions and Notes.	• WARNING: Automated cleaning-disinfection is not the final step prior to use. All Misonix reusable items must be sterilized by moist heat (autoclaved) after automated cleaning and disinfection. • WARNING: Follow the health care institutions protocol for Universal Precautions for Blood Borne Pathogens including the use of Personal Protective Equipment (PPE) when cleaning and disinfecting reusable items after a clinical procedure. • 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. Refer to the Pre-cleaning step below. • CAUTION: Do not immerse ultrasonic handpiece, handpiece cable. These items are not

	sealed against liquids and damage to equipment will result. • WATER QUALITY CAUTION: Use softened, filtered, or deionized water for diluting cleaning agents and for the final rinse of equipment. Deionized water is recommended for the final rinse if available. Mineral residues from hard water in the final rinse step can cause water stains and/or affect cleaning and disinfection. • WASHER-DISINFECTOR Note 1: Misonix recommends using a washer-disinfector designed and labeled for washing and disinfecting medical devices or meeting local regulations or regulatory standards and guidance. Note 2: For health care institutions and health care practitioners in the EEU, Misonix recommends the use of a washer-disinfector meeting the requirements of the ISO 15883 *Washers- Disinfectors,* Parts 1-5. • TETHERED CAP: Caution: The cable tethered cap should be on the cable connector during precleaning and automated cleaning and disinfection procedures.
Pre-Cleaning	The following should be performed on a disassembled handpiece: • Remove the probe and all housing components. Refer to Section 4.4 or instructions on disassembly of the handpiece and components. • Prepare neodisher® MediClean forte in accordance with the directions provided in the manufacturer's Instructions for Use. • 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. **Durations listed are minimums acceptable. Longer durations than those specified for cleaning and disinfection are acceptable.*
Post-Cleaning	Inspect all items for cleanliness and damage following cleaning and prior to terminal sterilization. • Inspect the handpiece housing and front cover for damage and signs of wear such as scratches, cracks, and chips. • Inspect the handpiece cable to ensure it is not cut or frayed. Inspect the handpiece cable connector and the tethered connector cap to ensure they are not damaged. • Do not use damaged handpieces or handpiece components. Contact Misonix Customer Service if damage is noted. The neXus handpiece should be fully inspected for loose or missing components and tested for proper operation prior to each procedure.

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.)

5.5. Sterilizing by Steam Autoclave

Sterilization Methods and terminology are based on current editions of ANSI/AAMI ST81 and EN ISO 17664 standards.

CAUTION: For all sterilization protocols listed below, always ensure the tethered cap is placed securely on the cable connector to protect the connector during sterilization.

WARNING: Follow the health care institution protocol for using a chemical or biological indicator with every sterilization load to ensure proper sterilization conditions of time, temperature, and saturated steam penetration.

WARNING: Misonix LLC. has validated all cleaning and sterilization cycles given 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. However, other end-user validated cleaning agents, cleaning procedures, and/or sterilization cycles may be used. **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 in accordance with applicable local laws and regulations on cleaning and sterilization of reusable medical devices in the healthcare environment.**

CAUTION: Misonix does not recommend “FLASH” sterilization. Misonix has not validated “FLASH” sterilization.

CAUTION: Water Quality for Steam Generation:
Poor steam quality may impair the sterilization process. For this reason, various norms (European standard EN 285 and the United States standard ANSI/AAMI ST79) recommend maximum impurity levels for steam feed water of autoclaves and sterilizer used in the medical field. Misonix recommends using water of a quality that conforms to the norms, the health care institution validated specifications for water quality, or otherwise using deionized water to generate steam for moist heat sterilization.

Reusable, Autoclavable Components

Misonix Part #	Description
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
100-70-0000	Standard Handpiece Sterilization Tray

Table 5.5: Standard Handpiece Reusable, Autoclavable Components

Items for sterilization.

Item	Comment
Autoclave	Misonix has validated several autoclave cycles for the sterilization of the Standard Handpiece reusable components. However, the specific autoclave design and performance can affect the efficacy of the process. Health care institutions should verify the process used, employing the actual equipment and personnel in place. Responsibility for verification of the sterilization process lies directly with the health care institution.
Chemical or Biological Steam Sterilization Indicators	Follow the health care institution protocol for using a chemical or biological indicator with every sterilization load to ensure proper sterilization conditions of time, temperature, and saturated steam penetration.
Sterilization Wrap	Misonix has validated several autoclave cycles with sterilization wrap for maintenance of package integrity post sterilization. Misonix has validated the cycles using Kimberly Clark KC 300 KIMGUARD or Kimberly Clark KC 600 KIMGUARD. The chart on sterilization parameters indicates the specific wrap used for the cycle. Follow the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN or EORNA) recommended guidelines for appropriate wrapping configurations.

Table 5.6 Items Required for Sterilization

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 Tray wrapped in Kimberly Clark KC300 KIMGUARD sterilization wrap.	Items placed in Misonix Sterilization Tray #100-70-0000 Tray wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.
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

*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 LLC. reusable medical devices are able to sustain such sterilization cycles.

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 Items wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.	Items wrapped, NO TRAY Items wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.	Items wrapped, NO TRAY Items wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.
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

*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 LLC reusable medical devices are able to sustain such sterilization cycles.

CAUTION	Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage

5.6. Deviations to Cleaning, Sterilization, Decontamination Instructions

Misonix LLC. has validated all cleaning and sterilization cycles given 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. However, other end-user validated cleaning agents, cleaning procedures, and/or sterilization cycles may be used. **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 in accordance with applicable local laws and regulations on cleaning and sterilization of reusable medical devices in the healthcare environment.**

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

5.7. Transportation, Storage, and Handling Prior to Use

- Transport wrapped equipment to storage in a manner to prevent damaging the sterile barrier.
- Refer to the KIMGUARD Instructions for Use for maximum shelf-life information.
- Store wrapped equipment in a controlled environment to avoid temperature and moisture extremes.
- Avoid excessive handling or wrapped equipment to avoid damage to the wrapping and cause a breach in the sterile barrier.
- Inspect the wrapping for openings, cuts, pinholes, and other damage that would indicate a possible breach in the sterile barrier prior to use. Do not use the equipment if the wrapping is damaged. Clean and sterilize the equipment again.

5.8. Expected Life, Reusable Components

The sterilization life of handpiece components is listed below is based on cleaning and sterilization in accordance with the instructions in this manual. Life estimates may be affected by rough handling, damage, wear due to vigorous cleaning, or using alternative cleaning and sterilization procedures.

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.

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

7. 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.

8. Important Notice

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

	Misonix, LLC.
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.

Any serious incident occurring in relation to the neXus® Ultrasonic System should be reported to Misonix, LLC (using the contact information listed above) and the competent authority of the Member State in which the user is established.

By returning any material to Misonix, LLC. 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, LLC. The correct return address should read as follows:

MISONIX (Misonix, LLC.)
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:

EC REP

CE 0482

EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

MISONIX®

BETTER MATTERS™