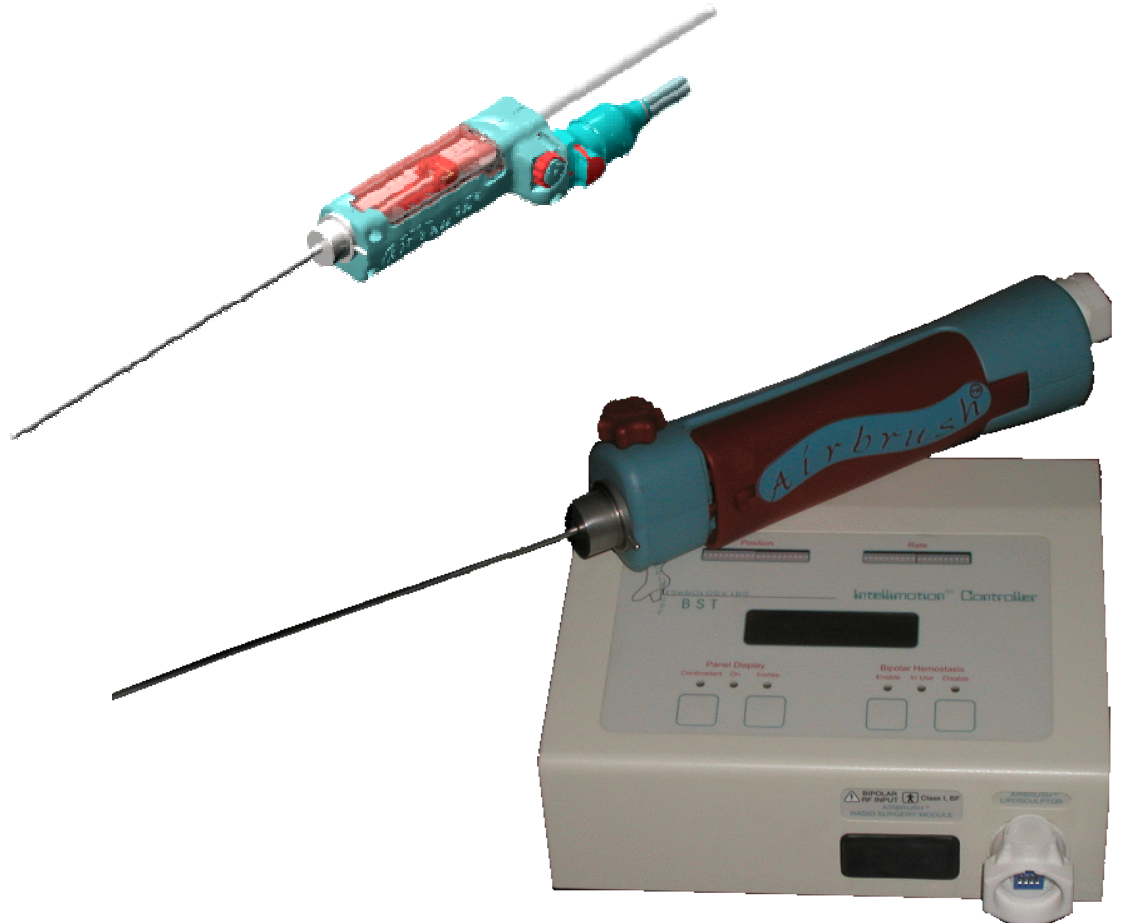


Instruction Manual for the *Airbrush Liposculpture® Systems*

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² Rev 1/11/2008

This manual describes the recommended procedures to maintain your *Airbrush® I or Airbrush® II Liposculptor* in optimal working condition. Throughout it two symbols are used to call your attention to required precautions:



- **WARNING:** This symbol indicates that the safety of the patient, surgeon or hospital personnel could be jeopardized.



- **CAUTION:** This symbol is used to indicate precautions or special procedures that must be followed to avoid damaging the instrument.

Introduction

The *Airbrush Liposculpture® System* consists of a patented³ state of the art reciprocating handpiece, the *Airbrush® Liposculptor*, interchangeable twin cannulas, an *Intellimotion® Power Control Console*, and a special multicore connecting cable. A variety of cannulas are available for the differing demands of regional liposculpture with and without the ability to enable bipolar hemostasis.

While operating, the rate of reciprocation and length of stroke of the inner cannula can be varied from 0 to 300 cycles per minute 0 and 10 centimeters respectively. The unit is pneumatic and powered by nitrogen or compressed air. It may be used with any standard vacuum source.



- Use of this device is limited to physicians who have attained proficiency in suction lipoplasty by means of formal professional training or sanctioned continuing medical education and supervised operative experience.
- Powered liposuction devices cannot produce significant weight reduction in and of themselves.
- Extreme caution is urged when liposuction is carried out in patients with diabetes, cardiac, pulmonary or circulatory impairment, or obesity.
- The *Airbrush Liposculpture® System* is independently tested and FDA cleared in 510(k) No. K031181.

³ U.S. Patents 5,112,302, 5,348,535, 5,643,198, 5,795,323, 6,346,107, 6,394,973, 6,652,522, 6,761,701, 6,872,199, 7,112,200 B2, EPO 94306845.2 and multiple other patents pending



- The volume of blood and/or endogenous body fluids lost must be monitored with timely and appropriate replacement to avoid hemodynamic compromise of the patient in the intraoperative or postoperative period.
- If used, tumescent solution must be administered in a controlled manner to avoid fluid overload or anaesthetic overdose.
- This device is designed to contour the body by removing localized deposits of fat through small incisions **using the smallest cannula set suitable for the problem.**
- Results of this procedure will vary depending upon the patient's age, patient's condition, the surgical site treated, and the skill and experience of the physician.
- Fat removal should be limited to that necessary to achieve a desired cosmetic effect.
- The **outer cannula should be maintained in continuous, slow motion** to avoid removal of too much fat from any one location.

Assembly

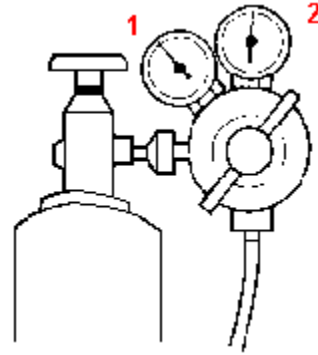
Pressurized Gas Source

Airbrush[®] *Liposculptor* can be operated on either compressed nitrogen or compressed air. Compressed air should be dried and filtered to 3 microns to avoid residue that may damage the system or shorten its lifespan. Medical grade or "H" tanks are suitable.

If a reservoir compressor is employed, the reservoir should be bled of condensation prior to each use.

Air Pressure

The system is designed to operate reliably between 75 and 100 PSI as indicated on the **instrument pressure gauge** (2 on the diagram), that valve seated on the regulator that is closest to the instrument. Set the pressure to show 95 PSI while the unit is in operation at full throttle. Pressures above 100 PSI should not be employed.



Once the valve atop a non-empty tank of gas is opened, the **tank pressure gauge** (1 on the diagram) that closest to the tank, should show at least 500 PSI or it should be replaced.



- Do not turn on the instrument pressure until the hose has been connected from the regulator to the Power Control Console



- Our pneumatic tank to controller hose anticipates a standard ¼” NPT Schraeder female connector which we can supply if needed..
- Operating pressures over 100 PSI may harm system components

Multicore Connecting Cable

Insert the quick connect multicore connector between the instrument and the power control console. Do not attempt to sterilize the disposable connection cables as they are not meant for reuse. The plug is keyed so it may only be inserted in one position, please do not attempt to force it.

Intellimotion® Power Control Console

Attach the power cable from the back of the unit to a grounded outlet and plug the other end into a grounded receptacle. Do not turn the power control console on until all pneumatic connections have been made between the console and the instrument and gas source.



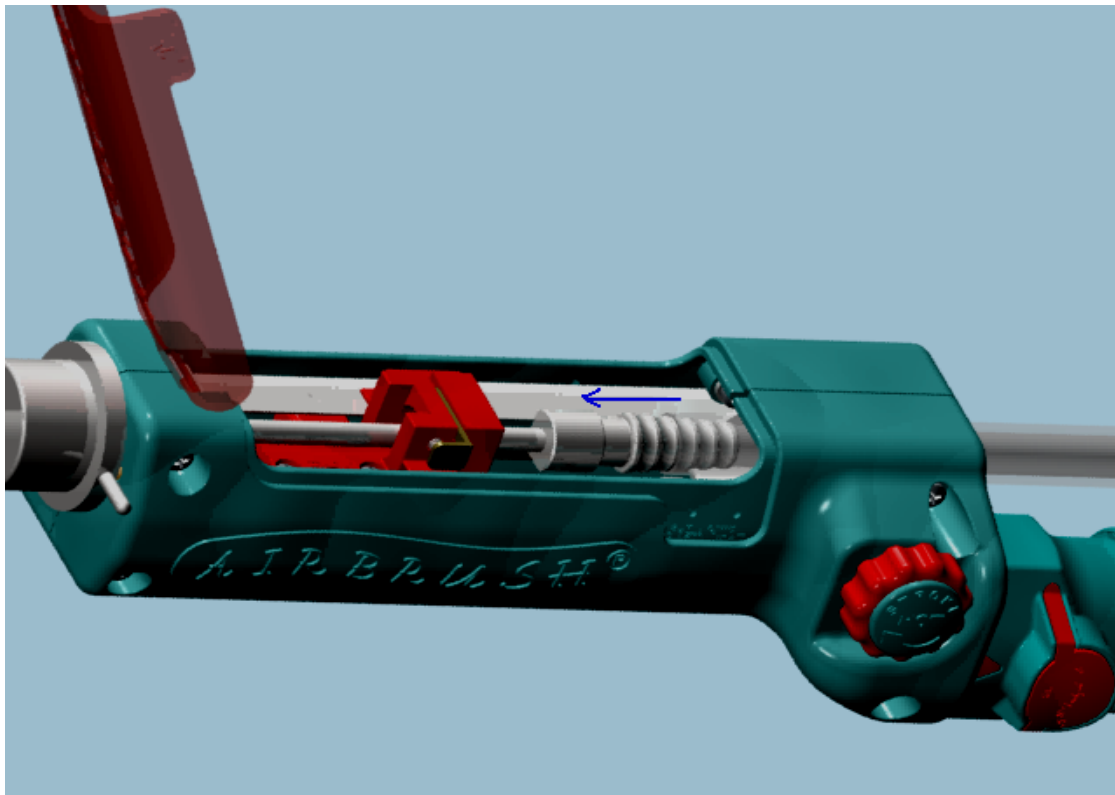
- Unattached gas lines can whip around and be injurious to operating room personnel.
- Never pressurize a system or turn on the console until all

connections have been made secure.

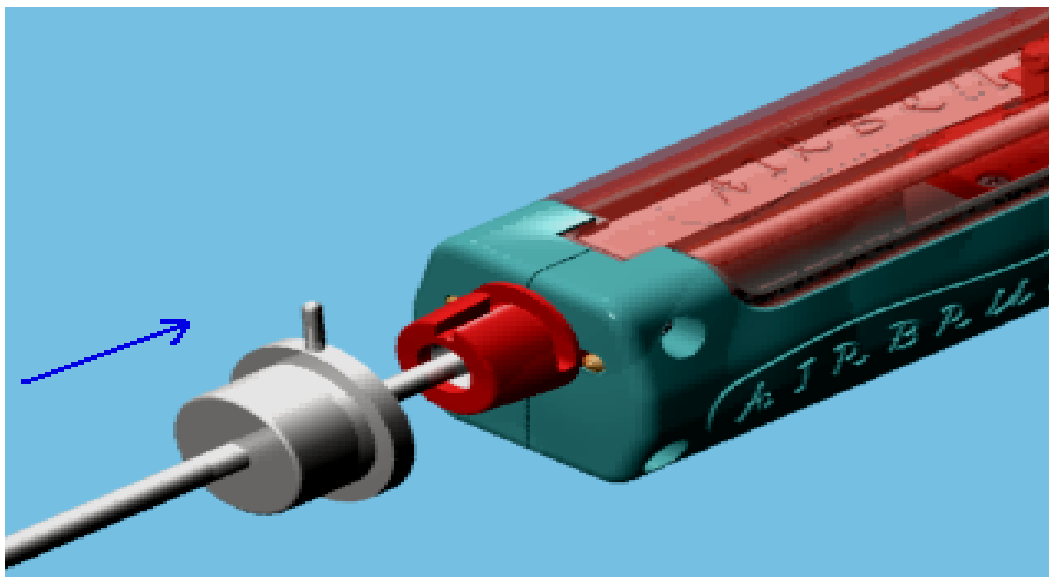
Cannula and Suction Tubing

The *Airbrush*[®] *Liposculptor* can operate with any of the standard suction tubing employed in liposuction. We recommend standard 0.5” outer diameter tubing. To prepare your instrument for surgery or change cannulas please follow the prescribed sequence:

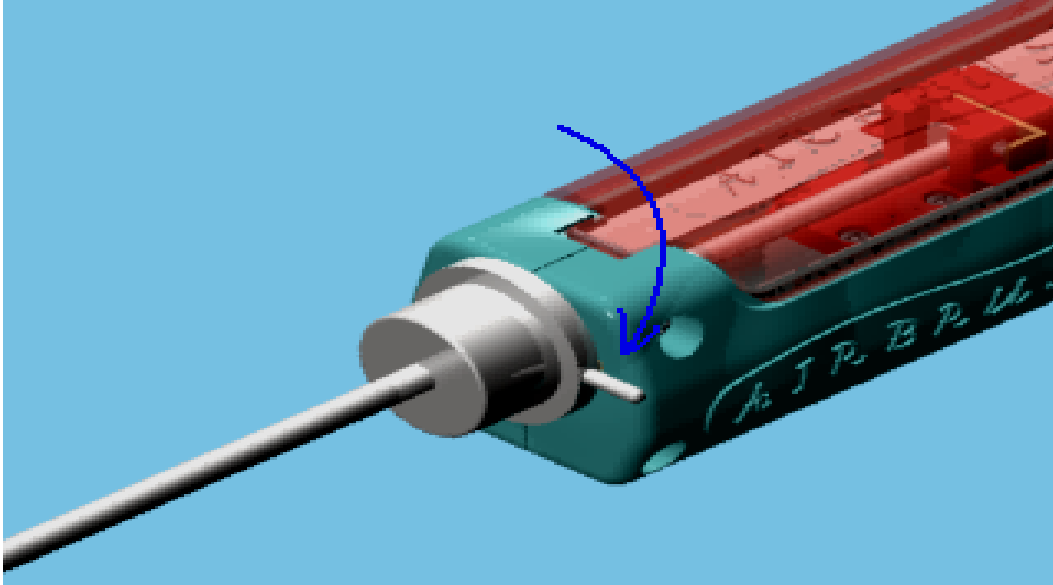
1. After proper connections have been made as described above, turn on the controller and wait until the panel display indicates the handpiece is ready for use.
2. Position the carriage for cannula changing by turning the Stroke knob counterclockwise all the way to zero “off” and turning the Rate knob clockwise all the way to absolute minimum [*Airbrush*[®] I]. This is the “ready” position suitable for **cannula change** or **manual liposuction**.
3. Firmly attach the vacuum tubing to the barbs on the hub of the chosen inner cannula. Slide the tubing on so that it is securely fastened.
4. Insert the inner cannula, with vacuum tubing firmly attached, into the hole at the back of the hand piece above the multicore connector oriented with the flat side of the inner cannula hub facing down towards the multicore connector.
5. Without rotating it or changing its orientation, gently push the inner cannula inwards so that its tip emerges at the front of the instrument. Open the cannula housing and push the cannula forward so that it securely snaps into place.
6. If you encounter any resistance or it does not snap into place with gentle pressure, it has rotated out of proper alignment. Simply remove it, make sure the vacuum tubing is firmly attached, and reinsert it with the flat side down.



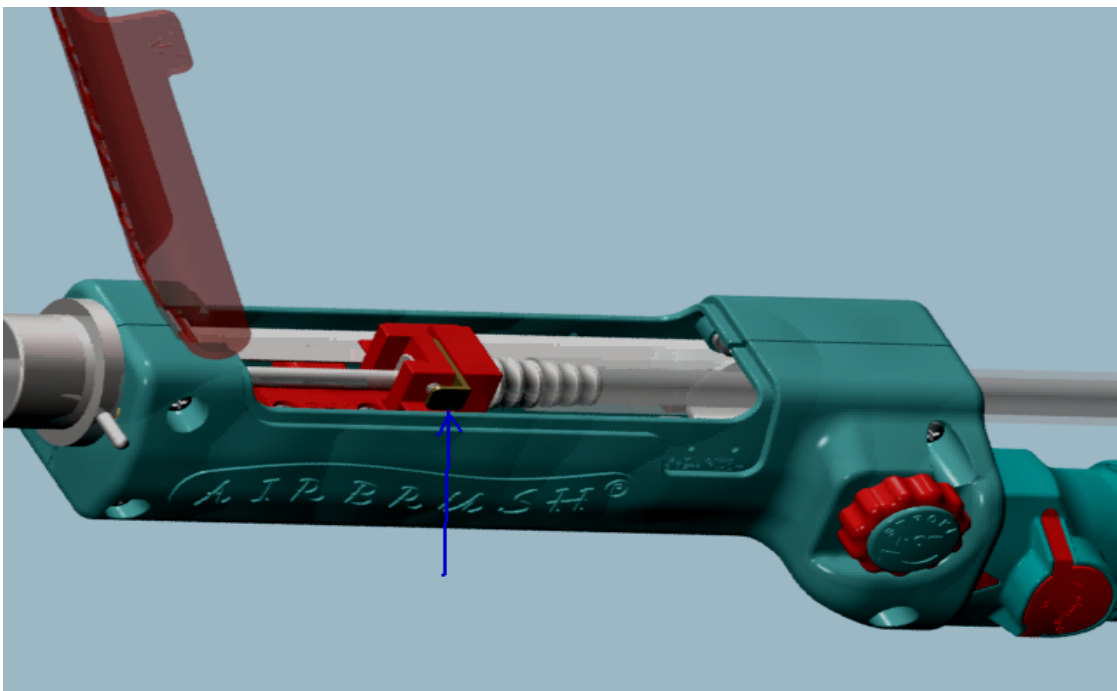
7. Once the inner cannula is firmly seated and snapped into position, slide the matching outer cannula over the inner cannula with the pin oriented in the center of the trigger until the outer cannula hub fits over the mount.



8. Looking down on the instrument, rotate the hub pin clockwise towards the stroke knob to secure it.



9. Your *Airbrush*® *Liposculptor* is now ready for operation, set on maximum stroke to begin reciprocation initially and then reduce stroke to that necessary for rapid reciprocation and desired stroke without unnecessary vibration.
10. Should the vacuum tubing become detached during operation, you can open the trigger by elevating the tab near the rate knob for access. Turn the stroke knob to zero before opening.



11. At any time the inner cannula can be removed by stopping reciprocation by first turning the stroke knob to zero, opening the cannula housing, and **depressing the cannula release button** on the cannula mount.
12. You can gently pull on the vacuum tubing while depressing the cannula release of the Airbrush II button if gravity from pointing the tip of the instrument upwards isn't sufficient.
13. To remove the cannulas or to change to a different set of twin cannulas, first remove the outer cannula by rotating the hub so the pin faces the trigger and sliding it off, then remove the inner cannula as directed above and repeat the insertion steps.
14. To eliminate drag, decrease vibration, and increase the speed of reciprocation you may temporarily fasten the vacuum tubing, with about 3" of slack, to the multicore cable using a sterile cable tie approximately 2' behind the hand piece.

Hand Piece

The *Airbrush*® *Liposculptor* contains the latest space age components and motion control technology. Although it contains both hardware and software safeguards against careless use you are advised to observe good operating procedures and avoid dangerous practices:



- Never attempt to power up the unit when the cannula housing is open. The carriage will move as the unit is programmed to self-calibrate on power-up or after power interruption and lock the carriage in the forward position for ease of cannula insertion.
- Never lay down the unit until you have turned both rate and stroke completely to zero and allowed the carriage and/or the inner cannula to completely come to rest. At a slow rate of reciprocation there may be a slight delay.



- Avoid total immersion of the instrument either before or after the surgical procedure. Follow the instructions given in ***Cleaning and Sterilization*** below.

Turning the stroke knob counterclockwise reduces the stroke length and when it is reduced to zero, turns the instrument "off" and positions the inner cannula in the forward most position for manual liposuction or temporarily putting the instrument down.

Airbrush*® *Liposculptor I: Increasing the rate by turning the Rate knob clockwise turns the instrument on and increases the rate from zero to maximum provided the stroke is not set at zero. Either zero stroke or zero rate turn the instrument "off." In

this case, the inner cannula is automatically positioned and locked at its foremost position, **manual liposuction position** which is also the **cannula changing position**.

Airbrush® Liposculptor II: Increasing the stroke by turning the Stroke knob clockwise turns the instrument on. Setting zero stroke turns the instrument off and positions the inner cannula for either manual liposuction or cannula changing.

The end-of-stroke cushioning is set at the factory at the default preferred by most surgeons to provide sufficient feedback for stroke awareness without undue vibration. Your manufacturer's representative is able to customize the setting to your taste if you prefer to have even more stroke awareness or none at all.

If the inner cannula should encounter hard tissue or is subjected to too much friction by too much bending of the outer cannula, the **carriage safety mechanism will cause it to disengage** and preclude further operation. When the pressure or blockage is removed, the inner cannula may still reciprocate but motion will be slower than normal or with an incomplete stroke. Turn the stroke knob all the way counterclockwise and slide the trigger latch forward. Open the trigger door and push the carriage atop the cylinder all the way to the front of the cylinder. You will hear a snap and the magnets will have reengaged. You can then close the trigger door, latch it, and proceed with surgery.



- Never use an inner cannula without an overlying outer cannula securely snapped in place.



- Use **only certified Airbrush® Liposculptor** cannulas with the system to avoid damage to the system or possible injury to yourself or the patient.

Cleaning

Dried blood, saline, and other deposits inside the cannula housing are a major cause of equipment malfunction. Proper cleaning and inspection prior to sterilization will avoid unnecessary delays and the need for instrument repairs.

Please follow the following procedure for routine cleaning and decontamination of the instrument before sterilization. If the instrument was not being used, you can proceed directly to (5).

1. First remove the outer and inner cannulas as directed above. Cannulas can be totally immersed and cleaned in gentle detergent (e.g. Ivory) and water cleansed internally with the aid of a non-worn pipe cleaner. Avoid the use of steel wool as it can damage their surfaces as can pipe cleaners that have lost their brushes.
2. Turn the knob on the gas tank “off” and run the instrument to bleed the gas lines. Remove the hose from the regulator and the **Intellimotion® Power Control**

Console. Remove the hose from the regulator and the **Intellimotion® Power Control Console**.

3. Remove the quick connect multicore connector from the Power Control Console but leave it connected to the back of the instrument as a safeguard from water entry into the cylinder.
4. Unlatch the trigger, open the trigger door, disconnect the vacuum tube, lift the inner cannula out of the carriage by gentle upwards pressure, and slide out the inner cannula from the instrument.



- Do not totally immerse the instrument in any liquid or allow any liquid to enter into the cylinder by way of the quick connect multicore plug at the rear of the hand piece.



- Do not ultrasonic clean the hand piece, multicore cable assembly, coated or disposable cannulas.

5. Clean the handpiece thoroughly with warm water, mild detergent (e.g. Ivory), and a soft brush. Pay particular attention to any debris caught in crevices. With the multicore connecting cable still attached, rinse the handpiece under running water to remove all traces of detergent. If possible use distilled water for the final rinse.
6. Dry the hand piece with a lint-free towel, remove the multicore cable from the instrument, and allow the handpiece to dry.
7. Discard any disposable multicore cable at this point and proceed to clean any reusable cannulas with a small cannula brush and a gentle detergent. Rinse and dry the cannulas as described above. Cleanse, rinse and dry the multiple use silicone multicore connector if one was used.

Lubrication

1. Once the instrument is dry, open the trigger door and **sparingly** spray the exposed cylinder on either side of the carriage with the **BioSculpture Instrument Lubricant**, gently sliding the carriage back and forth to assure complete lubrication. **Very little lubricant is needed**; afterwards wipe clean with a soft, lint-free cloth. Lubricant should be used on instrumentation *after* cleaning and *prior* to autoclaving.
2. Spray lubricant is suggested and may also be **used on the cannula shafts** after cleaning and before autoclaving to prolong their lives but application to the hubs, apertures, and cannula interiors should be avoided.

Accidental Immersion

Should the instrument accidentally become immersed in disinfectant, cleaning fluid or any other corrosive substance, damage can be minimized by carrying out the following steps:

1. Briefly immerse the hand piece in distilled water for 60 seconds to dilute and remove any residue.
2. Connect the instrument to a pressurized gas source and run the hand piece (no cannula is necessary) for five minutes.
3. Autoclave the instrument to remove any remaining moisture.
4. Apply **BioSculpture Instrument Lubricant** to the cylinder as described above and return the instrument to BioSculpture for service.

Sterilization

Steam autoclaving shortens the lifespan of all powered instruments; however its effects can be lessened by using distilled water and double-wrapping the handpiece or sterilization case to filter out contaminants during autoclaving.

Do not seal the hand piece in a peel pouch. All instruments should be pre-cleaned before sterilization by the above procedures; do not immerse the handpiece in any liquid. Do not attempt to sterilize disposable cannulas or single use multicore connecting cable.



- Do not flash autoclave! Please follow the below recommended sterilization procedures for BioSculpture Systems to ensure optimal functioning.



- Do not run the instrument while warm. Cool by exposure to room temperature. Operation of a hand piece that is not completely cool and dry may decrease performance and/or reliability. Do not immerse in liquid to cool.

Gravity Displacement Sterilization



- Set exposure for 30 minutes at 250° F (121° C), 15 PSI and drying time for a minimum of 8 minutes.
- An eight (8) minute minimum dry cycle is strongly recommended on all hand pieces and attachments every time the device is sterilized. Failure to use a dry cycle may lead to reduced performance or premature product failure.

- Hand pieces and cables should be individually wrapped and not in direct contact with cannulas or other metal objects such as trays shelves, or autoclave chamber wall..
- Do not coil the Multicore cable too tightly as to place it under unnecessary tension during autoclaving and storage.

Routine Maintenance



- The instrument should be cleaned according to the directions provided above before storing and between usages. The cylinder should be lubricated after cleaning and before autoclaving with *BioSculpture Aerosol Lubricant* approximately every fourth usage.



- **There are no user serviceable parts within the Instrument hand piece or Controller.** Other than the replacement of a blown fuse the user is advised against opening the controller as it will expose the user to a danger of shock and void any outstanding warranty.

Service and Repairs

In-Hospital Service

All powered instrumentation should be inspected and periodically tested in keeping with the bioengineering protocols of each facility. Service records should be maintained.

Periodic Inspection

Periodic inspections and factory-authorized service is essential to the maintenance of powered instruments. If repairs are indicated, they can be carried out quickly with rapid turn around times.

Because of the stressful nature of surgical usage, decontamination and sterilization, BioSculpture recommends that all equipment be returned to the factory for routine inspection and service at least once every two years if subject to light usage and once a year if subject to heavy usage. There is no charge for this service during the warranty period.

Warranty

All instruments pass a series of rigorous tests to make sure they will perform as expected under the rigorous demands of surgery. **BioSculpture Technology, Inc.** warrants its *Airbrush*[®] *Liposculptor Systems* to be free from defects in material and workmanship in their manufacture for a period of 6 months from the original purchase date by the end customer. This warranty is limited to the repair or replacement of the product without charge. The warranty is voided in the event of abuse, misuse, use in any other than a normal surgical environment, or in the event of disassembly, alteration, unauthorized repair, or noncompliance with the written instructions furnished by the manufacturer. This limited warranty covers both parts and labor but not shipping or insurance.

All other expressed or implied warranties or other warranties of fitness of merchantability are excluded here from and the manufacturer shall have no liability of any kind for incidental or consequential damages.

Following the recommended procedures will help preserve your warranty as well as the life of your instrument.

Extended Warranty

An extended warranty is available on all BioSculpture instruments. If the purchase warranty has expired, all BioSculpture instruments must first be inspected and, if necessary, restored to a fully serviceable condition before being eligible for an extended warranty.

Should there be a problem at any time, whether or not a warranty is in effect, our technicians can rapidly assess the damage, make repairs, get you a replacement unit if necessary, and return your instrument back to you in working order in the shortest possible time.

Service

You may contact our ***Service Department*** for instructions on returning an item to the factory. To avoid biologic dangers to receiving and service personnel, all instruments which have been employed in surgery are to be first cleaned and sterilized before returning and accompanied by physician's certification that the instrument has been sterilized after use.

Telephone	(212) 977-5400
Telephone Facsimile	(212) 586-9529
E-Mail	<i>service@biosculpturetechnology.com</i>

Shipping and Transport

Shipping and transport of the instrument and controller should be accomplished at temperatures between +10°C and +40°C, in a non-condensing environment, and at conditions with less than 93% relative humidity. Any shipping containers should be externally marked to ensure observance of these precautions and protection of the fragile contents within.

The original storage case in which the unit shipped with its contoured foam is ideal for offering protection against ordinary hazards.

Disposal

If the unit is to be discarded, it should first be cleaned and sterilized to remove any dangers posed by virtue of contamination with biological waste and then disposed of in accordance with local laws describing the disposal of its metal and plastic components.

Contact

You may obtain the name of your regional manufacturer's representative from our E-commerce website or contact us directly.

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