INSTRUCTIONS FOR USE & FDA APPROVED VALIDATED STERILIZATION & CLEANING INSTRUCTIONS - CANNULAE AND NEEDLES

WARNINGS:

- Black & Black Surgical instruments are to be used in accordance with these instructions for use. Read all sections of this insert prior to use. Improper use of the instrument may cause a serious injury.

- Black & Black Surgical instruments should be handled and operated by healthcare professionals completely familiar with their use, assembly, and disassembly. Use instruments for their intended surgical purposes only.

- The Black & Black Surgical cannulae and needles are packaged non-sterile. Cleaning and sterilization must occur prior to use. It is the responsibility of the user to inspect the cannulae and needles prior to use in surgery. If the cannulae or needle does not function properly or there is damage, the cannulae or needle should be disposed of properly.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE:
The aspiration and infusion cannulae and needles are indicated for aesthetic body contouring and general tissue aspiration.

VALIDATED CLEANING INSTRUCTIONS:

- Soak within an enzymatic cleaner (such as Miltex EZ-Zyme) for 10 minutes.

- Rinse while manipulating under running tap water to loosen and remove gross debris.

- Completely immerse in an ultrasonic cleaning bath filled with neutral enzymatic detergent solution (such as Miltex EZ-Zyme®) prepared according to the manufacturer’s instructions

- Ultrasonicate for ten (10) minutes.

- Remove any remaining debris from crevices using a cleaning brush, giving close attention to threads, crevices, seams, lumens, and any hard-to-reach areas.

- Rinse devices while being manipulated under running tap water to loosen and remove gross debris

- After cleaning and prior to sterilization instruments should be wrapped.

Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization.

VALIDATED STERILIZATION:

PRE-VACUUM STERILIZATION

Temperature: 132°C (270°C)
Exposure Time: 4.0 Minutes
Drying Time: None
STERILITY ASSURANCE LEVEL (SAL)

The sterilization efficacy of the Black & Black Surgical Inc, Lipoplasty Devices was determined by processing in a steam sterilization pre-vacuum cycle at 132°C (270°F) for 4 minutes exposure. A method of steam sterilization was validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. The SAL was achieved by placing at least 1.0 \times 10^6 spores of Geobacillus stearothermophilus in the most difficult to sterilize locations of the devices and processed at one-half the expected full cycle exposure time. Following exposure, the biological indicators were aseptically transferred to culture media and incubated as required. Testing was performed two (2) additional times for a total of three (3) half cycles.

STEAM GRAVITY STERILIZATION

Temperature:  132°C (270°C)  
Exposure Time:  15.0 Minutes  
Drying Time:  None

STERILITY ASSURANCE LEVEL (SAL)

The sterilization efficacy of the Black & Black Surgical Inc, Lipoplasty Devices was determined by processing in a steam sterilization gravity cycle at 132°C (270°F) for 15.0 minutes exposure. A method of steam sterilization was validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. The SAL was achieved by placing at least 1.0 \times 10^6 spores of Geobacillus stearothermophilus in the most difficult to sterilize locations of the devices and processed at one-half the expected full cycle exposure time. Following exposure, the biological indicators were aseptically transferred to culture media and incubated as required. Testing was performed two (2) additional times for a total of three (3) half cycles.

DO NOT USE DAMAGED INSTRUMENTS. INSTRUMENTS SHOULD MEET THE FOLLOWING VISUAL INSPECTION CRITERIA

After each cleaning and before being placed into use, the cannula and needle should be visually inspected for fractures, cracks, dents, pitting, rust, burrs especially around the cutting orifices. If any of the above are observed, the cannula should not be used in surgery and should be disposed of following facility protocol. In addition the cannula should be checked for secure fit in the handle. This can be checked by holding the handle in one hand and the cannula in the other hand and by a gentle pulling motion make sure the cannula is not loose in the handle. If the cannula is loose, it should not be used in surgery and should be disposed of following facility protocol.

WARNINGS

a. This device will not, in and of itself, produce a significant weight reduction
b. This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes, heart, lung, or circulatory system disease or obesity.
c. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capacity of providing adequate, timely replacement is essential for patient safety

PRECAUTIONS

d. This device is designed to remove localized deposits of excess fat through small incisions and subsequently transfer the tissue back to the patients.
e. Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction Lipoplasty and tissue transfer.
f. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
g. Results of this procedure may or may not be permanent.
h. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
i. If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.