



Apyx Medical
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Instructions for Use – Suction and Irrigation Instruments

Issue Date: 02.13.2025

Version: 0



AYON-IF-XXXX AYON-MT-XXXX
AYON-FT-XXXX AYON-MTC-XXXX
AYON-GT-XXXX AYON-ST-XXXX
AYON-IF-XXXX

1. Device Description

Black & Black has a wide range of suction and irrigation instruments applicable for plastic surgery procedures. This range include generic cannulas, liposuction cannulas, elevators and retractors.



Carefully read these instructions before using B&B suction and irrigation instruments. Keep them in a safe place for future reference.



Improper use of the instrument may cause a serious injury

2. Indication for Use

2.1. Liposuction Cannulas

The aspiration and infusion cannulas and needles are indicated for aesthetic body contouring and general tissue aspiration.

2.1.1. Intended Users

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.



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

3. Contraindications

The devices are contraindicated for all the intended uses other than the ones claimed in these instructions for use.

4. Warnings and Precautions

4.1. Warnings

- This device will not, in and of itself, produce a significant weight reduction
- 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.
- 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

4.2. Precautions

- Use of suction and irrigation instruments 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. Results of these procedures will vary depending upon patient age, surgical site, and experience of the physician.
- The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
- If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.

5. Reprocessing Instructions



The Black & Black suction and irrigation instruments are packaged non-sterile. Cleaning and sterilization must occur prior to use.



It is the responsibility of the user to inspect the suction and irrigation instruments prior to use in surgery. If the instruments do not function properly or there are damages, the suction and irrigation instruments should be disposed of properly.




For patients with Creutzfeld-Jakob-Disease, CJK-on-spec or its possible variants, Bovine Spongiform Encephalopathy or Transmissible Spongiform Encephalopathy country-specific regulations and laws concerning cleaning of instruments have to be observed

5.1. Manual Cleaning

The below validated steps have to be followed:

Step	Process Step	Reagents / Actions	Time (min)	T (°C)
1	Soak	Enzymatic cleaner (such as Miltex EZ-Zyme)	10	-
2	Rinse	Running tap water to loosen and remove gross debris	-	-
3	Ultrasonic Cleaning Bath	Neutral enzymatic detergent solution (such as Miltex EZ-Zyme®) prepared according to the manufacturer's instructions	10	-
4	Manual Brush	Remove any remaining debris from crevices using a cleaning brush, giving close attention to threads, crevices, seams, lumens, and any hard-to-reach areas.	-	-
5	Rinse	Running tap water to loosen and remove gross debris	-	-
6	Post-Cleaning	After cleaning and prior to sterilization instruments should be wrapped.	-	-

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Step	Process Step	Reagents / Actions	Time (min)	T (°C)
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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.

6. Sterilization

Steam Pre-vacuum sterilization procedure:

- Temperature: 132°C (270°F)
- Time of exposure: 4 min
- Drying Time: 20 min

Steam Gravity sterilization procedure:

- Temperature: 132°C (270°F)
- Time of exposure: 15 min
- Drying Time: None

7. Controls and Testing










Do not use damaged instruments. Instruments should meet the following visual inspection criteria

After each cleaning and before being placed into use, the suction and irrigation instruments should be visually inspected for fractures, cracks, dents, pitting, rust, burrs especially around the cutting orifices. If any of the above are observed, the instruments should not be used in surgery and should be disposed of following facility protocol. In addition the cannulas 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.

8. Storage

Suction and irrigation instruments must be stored until subsequent use in a suitable sterilization container for steam sterilization according to the standards. The storage room has to be dust-free, low microbiological contamination, dark and free of temperature fluctuations.

9. Used Symbols for IFU and Label

Symbol	Description		
	Symbol for "Manufacturer"	Legal Manufacturer: Black & Black Surgical, Inc. 5175 South Royal Atlanta Dr. , Tucker Georgia 30084 USA	Tel.: 770-414-4880 Fax: 770-414-4879 Email: info@blackandblacksurgical.com Web: http://www.blackandblacksurgical.com/
	Symbol for "Distributor"	Distributor: Apyx Medical 5115 Ulmerton Rd. Clearwater, FL 33760 USA	Tel: 1-800-537-2790
	Symbol for "Catalog Number"		
	Symbol for "Batch Code"		
	Symbol for "Consult the Instruction for Use"		
	Symbol for "Non-Sterile"		
	Symbol for "Caution, consult accompanying documents"		