

Instructions for Use – Suction and Irrigation Instruments



English

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B61084 to B61099	B8B-BAS-XXX PWR to B8B-STD-XXX PWR	B8FIC-III-CC1610-LL to B8FIC-III-CV1610-LL
B611xs to B611xsS-XT	B8BAS-1115LL to B8BAS-632L B8BEC-1120-LL to B8BEC-532L	B8FIC-V-1120-LL to B8FIC-V-423-LL
B61184 to B61199	B8BEC-1115-LL	B8III-1215-LL to B8III-CV226L
B63850 to B63851	B8CC-215L to B8CC-632L	B8KEL-315L to B8KEL-532L
B67000 to B67035	B8COB-315L to B8COB-532L	B8LV-1030-LL to B8LV-532-L
B87-BAS-XXXQSC	B8DBAS-1115-LL to B8DAS-532-L	B8LVH-1220-LL to B8LVH-432L
B87-MER-XXXQSC	B8DMER-420-SYR to B8DMER-432-SYR	B8LVI-1420-LL
B89ASH-LL	B8DV-440L to B8DV-550L	B8LVI-CC1415LL to B8LVI-CC1425LL
B89IH-NC	B8FAC-1115-LL to B8FAC-426-SYR	B8MBAT-1215-LL to B8MBAT-536L
B89LL-XX	B8FAN-1235-LL to B8FAN-1615-LL	B8MER-1115-LL to B8MER-636SYR
B89TAH-60CC	B8FIC-I-1115-LL to B8FIC-I-426-SYR	B8SAT-1215-LL to B8SAT-432SYR
B89TFL	B8FIC-II-1215-LL to B8FIC-II-197-LL	B8SPA-1215-LL to B8SPA-615L
B89TTH-C	B8FIC-II-CC1215-LL to B8FIC-I-CV1610-LL	B8STD-1215-LL to B8STD-626L
B89TML	B8FIC-II-1215-LL to B8FIC-II-197-LL	B8STD-II-149-LL to B8STD-II-526L
B89TOOMEY	B8FIC-II-CC1410-LL to B8FIC-II-CV1610-LL	B8TI-1015-LL to B8TI-840-LL
B89TOMMEY W/LUER	B8FIC-III-1215-LL to B8FIC-III-197-LL	B8TON-1415-LL to B8TON-426-SYR

1. Device Description

Black & Black has a wide range of suction and irrigation instruments applicable for surgical plastic 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. Intended Use

2.1. Cannulas

The suction and irrigation cannulas are intended for instillation or aspiration of fluid to/from a targeted area of the body.

2.2. Liposuction Cannulas

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

2.3. Elevators

The suction and irrigation elevators are intended for lifting tissues or anatomic structures.

2.4. Retractors

The suction and irrigation retractors are intended for separating tissues or other anatomical parts.

3. Indication for Use

3.1. Cannulas

Application for general surgical procedures.

3.2. Liposuction Cannulas

Application for aesthetic body contouring and general surgical procedures.

3.3. Elevators

Application for general surgical procedures.

3.3.1. Retractors

Application for general surgical procedures.

4. 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.

5. Contraindications

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

6. Side effects, risks, and complications

6.1. Device related risks

- Collateral tissue laceration and damage
- Blockage of cannula due to aspiration of fibrous tissues

6.2. Treatment related risks and complications

- | | |
|--|----------------------|
| • Perforation of one or several intraperitoneal organs | • Seroma |
| • Contour irregularities | • Hematoma |
| • Infection | • Skin discoloration |
| • Sepsis | • Skin slough |
| • Necrotizing fasciitis | • Pulmonary embolism |
| • Hypoesthesia | • Viscus perforation |
| • Edema | • Lidocaine toxicity |
| • Ecchymosis | • Death |

6.3. Undesired side effects

- | | |
|------------------------|-----------------|
| • Scars | • Long recovery |
| • Excessive blood loss | • Nausea |
| • Skin flaccidity | |

7. Warnings and Precautions

7.1. 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

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7.2. Precautions

- A proper clinical examination, knowledge of the risk factors and a careful technique are necessary to reduce the occurrence of possible risks and complications.
- The primary factors increasing risk of death include excessive amounts of fluid and local anesthesia, excessive fat removal, performance of multiple unrelated procedures in the same surgical session, poor patient selection or patient health and inadequate post-operative monitoring of patients undergoing large-volume fat removal.
- 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.
- The aspiration of human fluids depends on the design of the cannula
- If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.
- Retractors in "Tebbetts Fiberoptic Retractor" Family (B61084-B61191) should only be used with 3.5 mm fiberoptic bundle light cables. Using a bundle with a larger size could cause the metal at the insertion point of the light cable to the retractor to heat up and potentially cause thermal damage at points of contact.
- Do NOT lay lighted retractors down on patient.

8. 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

8.1. 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.	-	-



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.

9. Sterilization

Steam Pre-vacuum sterilization procedure:

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

10. 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.

11. 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.

12. 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 "Catalog Number"		
	Symbol for "Batch Code"		
	Symbol for "Consult the Instruction for Use"		
	Conformity to the essential requirements with notified body DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt / Germany. Notified Body Code: 0297		
	Symbol for "Non-Sterile "		
	Symbol for "Caution, consult accompanying documents"		
	Symbol for "European Representative"	MEDAGENT International GmbH Griesweg 47 78570 Mühlheim	Tel.: +49.7463.9954.0 Fax: +49.7463.9954.10 E-mail: info@medagent.de