

Instructions for Use – Sterile Tubing



English

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05/10/2019
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B89200 B89205
B89213 B89209
B89216

1. Device Description

Black & Black Surgical supplies a range of sterile tubing to carry out plastic surgery procedures. These devices differ between each other for length and dimension as well as for number and component type.



Carefully read these instructions before using B&B sterile tubing. Keep them in a safe place for future reference
Improper use and handling of the sterile tubes may cause serious consequences

2. Indication for Use

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

2.1. Intended Users

Black & Black Surgical instruments should be handled and operated by healthcare professionals completely familiar with their use and connection with other medical devices involved in liposuction procedures such as cannulas, canisters and pumps.



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

Do not use the devices for any intended use other than the one claimed by manufacturer.
Do not use the devices on the following patient population:

- Pregnant women
- Neonate male
- Prepubertal male

4. Warnings and Precautions



Tubing contains DEHP

Tubing is latex free

Black & Black tubing is made out of PVC. Unplasticized PVC is hard and brittle at room temperature therefore DEHP (plasticizer) is added to increase the flexibility of the polymer. DEHP can leach out of the tubes into solutions that come in contact with the body. The amount of DEHP that will leach out depends on the temperature, the lipid content of the liquid, and the duration of contact with the plastic. Two factors determine the degree of risk posed by exposure to DEHP in a medical setting. The first is the patient's sensitivity to DEHP. Therefore the male fetus, male neonate, and prepubertal male are not to be exposed to DEHP. The second factor is the dose of DEHP received by the patient. This is determined largely by the type of procedure performed, as well as the frequency and duration of these procedures. However, suction and irrigation liposuction surgery is not mentioned among the procedures with high risks.

5. Mode of Use



The Black & Black tubes are delivered in sterile condition. Devices are sterilized by means of irradiation (Cobalt 60)



Do not reuse the device



Devices cannot be re-sterilized

B89200: High Flow Aspiration Tubing

B89205: High Flow Tapered Aspiration Tubing

B89209: Large Bore Softouch Infiltration Y Tubing – Molded Connectors

- Using sterile technique, remove tubing from pouch
- Within the sterile field, attach one end of the tubing to the barbed end of the cannula
- Pass other end of tubing outside sterile field and attach to "patient" port on collection canister
- Tubing is ready to use

B89213: Soft Pump Tubing Set – Single Spike

- Using sterile technique, remove tubing from pouch
- Within the sterile field, attach the male luer tubing connector to the female luer on the hand piece, or directly to a luer lock needle
- Pass other end of tubing with the bag spike outside sterile field
- Thread the tubing through the head of the infiltration pump
- Close the tubing clamp; attach the bag spike to the fluid source
- When ready to use, open the tubing clamp and operate the infiltration pump as per instructions

B89216: Tubing with Large Bore and Silicone Insert for Infiltration Pump System

- Using sterile technique, remove tubing from pouch
- Within the sterile field, attach the male luer tubing connector to the female luer on the hand piece, or directly to a luer lock needle
- Pass the end of tubing with the bag spike outside sterile field

- Thread the silicone section of the tubing through the head of the infiltration pump
- Attach the bag spike to the fluid source
- Tubing is ready to use



Do not use the device if packaging is damaged or there is any suspect concerning the sterility of the product

6. Storage

The storage room has to be dust-free, low microbiological contamination, dark and free of temperature fluctuations.

7. Used Symbols for IFU and Label

	Symbol for "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"	
	Symbol for "Do not Reuse"	
	Symbol for "Do not Resterilize"	
	Symbol for "Do not use if packaging is damaged"	
	Symbol for "Sterilized by Irradiation"	
	Symbol for "Latex Free"	
	Symbol for "Contains Phthalate"	
	Symbol for "Usable Until"	
	Conformity to MDD 93/42/EEC and related essential requirements with notified body DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt / Germany. Notified Body Code: 0297	
	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