


Reprocessing Instructions A

Black & Black Surgical, Inc.
 5238 Royal Woods Pkwy., Ste. 170
 Tucker Georgia 30084
 USA

Issue Date: 16.06.2016
Revision: 1
EN

1. Device Description

Black & Black Surgical has a wide range of devices with several technical features to cover the large demand for medical devices. This range includes diagnostic, therapeutic and health care devices.



B2xxxx – B8xxxx (Representative for Art. No.)



These reprocessing instructions are applicable to devices labeled with:
 [i] Reprocessing Instructions A / Rev. 1



Carefully read these instructions before using B&B devices. Keep them in a safe place for future reference.

2. Intended Use

Black & Black's devices are used during general, reconstructive, and plastic surgical procedures.

3. Intended User

Black & Black's devices are intended to be used, handled and managed in a healthcare setting by appropriately trained and qualified surgeons and personnel.



The user is responsible for selecting the right instrument for a specific applications or surgical procedure

4. Contraindications

The devices are contraindicated for all the intended uses other than the ones claimed by manufacturer. The devices are not to be used in contact with both central circulatory system and central nervous system.



Improper handling and misuse of the devices may result in premature wear



The application of excess or improper force may cause devices breakage

5. Reprocessing Instructions


These devices are delivered in non-sterile state. Before the first and any subsequent use, the devices must be reprocessed according to the validated reprocessing instruction described below.



It is the responsibility of the user to ensure that the reprocessing is performed using appropriate equipment, materials and personnel to achieve the desired results



Follow the instructions and warnings issued by the suppliers of any cleaning and equipment used



Alkaline agents (pH>9) can damage products (e.g. part or devices made out of aluminum)



The quality of water used to reprocess the devices are to conform to Directive 98/83/EC



Washer/Disinfectors, cleaners and detergents must have a proven efficacy "FDA approved, VAH listed or CE mark". Use of different products is under user responsibility.



Do not exceed 140 °C – 284 °F throughout reprocessing steps

5.1. Limitation of Reprocessing

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on device's life span and function. The life span is mainly affected by wear or damage during surgical use as well as proper care and handling techniques.

5.2. Point of Use

Remove the excess soils with a disposable cloth or paper wipe promptly after any use. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

4.2 Preparation for Cleaning

Disassembly is not required.

5.3. Manual Cleaning

Equipment:	Enzymatic Cleaner (e.g. <i>Miltex EZ-Zyme</i>)
	Neutral Enzymatic Detergent Solution (e.g. <i>Miltex EZ-Zyme</i>)
	Cleaning Brush (e.g. <i>Soft Bristle Brush</i>)
	Ultrasonic Cleaning Bath

Steps:	1) Soak the device in an Enzymatic Cleaner for 10 minutes in accordance to manufacturer's specifications
	2) Rinse the devices under running tap water to remove debris
	3) Immerse the devices in an Ultrasonic Cleaning Bath filled with Neutral Enzymatic Detergent Solution in accordance to manufacturer's specifications for 10 minutes
	4) Remaining debris are to be removed using a Cleaning Brush
	5) Rinse the devices under running tap water to remove debris

5.4. Automatic Cleaning

Equipment:	Ultrasonic Bath
	Alkaline Cleaner (e.g. Dr. Weigert Neodisher FA)
	Cleaning and Disinfectant Device (Miele G 7736 CD)

Steps	1) Immerse the devices into an Ultrasonic Bath with 0.5% Alkaline Cleaner for 15 minutes at 40 ° C.
	2) Automatic Cleaning in the Cleaning and Disinfectant Device following the steps below:
	2a) 1 min pre-cleaning with cold water
	2b) Discharging
	2c) 3 min pre-cleaning with cold water
	2d) Discharging
	2e) 5 minutes with 0,5 % Alkaline Cleaner at 55°
	2f) Discharging
	2g) 3 minutes Neutralization with warm Water (>40°C)
	2h) Discharging
	2i) 2 minutes brushing with warm Water (>40°C)
	2j) Discharging

5.5. Manual and Automated Disinfection

Manual: Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer. Place the instruments in the disinfectant bath and observe the specified soaking time. Rinse the products thoroughly with fully demineralized water to remove the disinfectant without residue.

Automatic: Machine operated thermal disinfection has to be carried out in consideration of the national requirements with regard to the A0 value (see ISO 15883).

5.5.1. Inspection and Functional Testing

Black & Black's devices must be inspected after processing and prior to sterilization for:

- Cleanliness
- Damages, included but not limited to: corrosion, discoloration, excessive scratches, cracks and wear

- Proper function, including but not limited to: cutting instruments should be sharp, straight instruments should not be bent, movement of hinge/joints/movable parts should be free



Do not use the devices if any of the above-mentioned problems are present. Discard damaged instruments

5.6. Packaging

Equipment:	- Sterilization Wraps
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Steps:	Wrap instrument in accordance with local procedures and using standard techniques such as those described in ANSI/AAMI ST77, ANSI/AAMI ST79 and ISO 11607
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5.7. Sterilization

Equipment:	- Steam Pre-Vacuum or Gravity Sterilizer		
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Steps:	Cycle Type	T (C° - F°)	Time (min)
	Pre-Vacuum	132 - 270	4
	Gravity	132 - 270	15

5.8. Storage

Store the packaged devices in a normal environmental condition free from dust, insects, vermin as well as temperature and humidity fluctuations.

6. Used Symbols for IFU and Label

	Symbol for "Manufacturer"	Black & Black Surgical, Inc. 5238 Royal Woods Pkwy., Ste. 170 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 "Serial Number"	
	Symbol for "Consult the Instruction for Use"	
	Symbol for "Non-Sterile "	
	Symbol for "Caution, consult accompanying documents"	
	Symbol for "Do not Reuse"	
	Symbol for "Conformity to the Essential Requirements"	
	Symbol for "European Representative"	MEDAGENT International GmbH Griesweg 47 78570 Mühlheim Germany Tel.: +49.7463.9954.0 Fax: +49.7463.9954.10 E-mail: info@medagent.de

EC REP
MEDAGENT International GmbH
 Griesweg 47
 78570 Mühlheim
 Germany