

Processing Instructions according to EN ISO 17664: 2004 Blackline Shaver Blades

Manufacturer: ARTHRONET BV

Products: This processing instruction is regarding to reprocess able endoscopic medical devices (product BLACKLINE Shaver Blades) delivered by ARTHRONET BV.

! WARNING:

The cleaning of endoscopic instruments needs special attention. For cleaning and disinfection in a wash disinfector a special load carrier with adapter for flushing the inner Lumina is required.

Accessorily you need a universal connector like Medisafe universal connector red, 2 mm, Art-Nr. MED1226.1).

Medical devices, which are not dry after the cleaning and disinfection process be dried with a medical air supplying device. This is important for the sterilizing process.

RESTRICTIONS OF REPROCESSING

Frequent reprocessing has only small influence to this medical device.

The end of the durability is according to abrasion and damage due to the usage.

INSTRUCTIONS:

PLACE OF USAGE:

Clean the surfaces after usage with a soft compress. Lumina should be rinsed thoroughly with drinking water

TRANSPORT AND KEEPING:

No special treatments required.

Dry sanitation is recommended. Longer intermediate storage of blood covered medical devices can cause corrosion. The reprocessing should be done shortly after the usage

PREPARATION:

According to the manual for use the medical device should be disassembled before cleaning and disinfection.

CLEANING AND DISINFECTION: automatically

! In brackets are the products performed during the validation process.

Equipment: Washer-Disinfector according DIN EN ISO 15883

Cleaner: mild alkaline Cleaner pH > 10 at 55 °C (Sekumatic® Multiclean)

Neutralisation: phosphoric acid (Sekumatic® FNP)

1. The medical devices should be attached to the load carrier to rinse the inner Lumina. At the beginning and at the end of the program the adaption should be controlled.

2. Validated program parameters:

5 min cold pre-rinse < 30 °C drinking water

10 min cleaning 60 °C demin.-water

2 min neutralisation 60 °C mixed water

3 min disinfection 93 °C demin.-water

3. After the removing the medical devices they should be checked for cleanness and moisture visually. If necessary a manual subsequent cleaning should be done. Rinse with demin.-water and dry with a medical air supplying device.

CLEANING AND DISINFECTION: manually

To assure the hygienic safeness a manual cleaning and disinfection is not recommended.

MAINTANCE:

The medical devices should be checked for damages or abrasion. Blunted or damaged medical devices are not recommended for patient use.

CONTROL:

Before reassembling the medical devices they should be checked for damages and abrasion. Blunted or damaged medical devices are not recommended for patient use.

Take special care for the integrity of the o-ring.

After the visual check the medical devices should be reassembled according to the manual.

PACKAGE: Single:

A sterile barrier system according EN ISO 11607 should be used. The medical devices can be single or double packed. The package should be big enough for the medical device. No tension may be visible.

After sealing the joint should be checked for damages. If damages are visible, the medical device should be repacked and sealed again.

Sets: Put the medical device to the according set. Take care for a shock-proof transport. The weight of the set should not be more than 10 kg. For package a sterile barrier system according EN ISO 11607 should be used.

STERILISATION:

Equipment: steriliser according to DIN EN 285 or DIN EN 13060 with type B process

process: steam sterilisation with fractionate pre-vacuum, temperature 134 °C, time min. 3 minutes

All validated processes with fractioned pre-vacuum for endoscopic instruments are suitable.

Subsequently the process parameters used during the process validation.

Validated program parameter:

evacuation

1. pre-vacuum 200 mbar

2. pre-vacuum 200 mbar

3. pre-vacuum 200 mbar

Sterilisation

holding time 5 min 134 °C

drying 16 min 200 mbar

After the process the packages should be checked for damages, moisture or contamination. Complained packages should be defined to be not sterile. They have to be repacked and sterilized.

STORAGE: Dry and dust-free. No pressure fluctuation. No humid conditions.

FURTHER INFORMATION

The processing of medical devices should be only be done with validated processes.

Take care of maximal or minimal load in the sterilisation process.

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