

# Processing Instructions according to EN ISO 17664: 2004 Hand instruments

**Manufacturer: ARTHRONET BV**

Products: This processing instruction is regarding to reprocess able endoscopic medical devices (product MILLENNIUM and Vario Suction Punch) 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:**

Disassemble before Transport. Carry shock-proof in a suitable transport container  
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:**

Oil the joint carefully with a small amount of suitable oil. The oil should be adequate for sterilisation processes. Silicon oil is not recommended. 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.  
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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