

# PHA-GA01-B Instructions for Use Wire Rod Cutters (UMDNS 14-062)



## Manufacturer

Orthomed Inc

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## Products

These instructions for use apply to the product listed below:



OM 60-0180

## Important note



*Read these instructions for use carefully before each use and keep them handy for the user or appropriate skilled personnel.*



*Read through these symbol-marked warnings carefully. Improper use of the products can result in serious injuries to the patient, user or third parties.*

## 1 Area of application

The product listed above may only be used by personnel who have been trained and qualified accordingly. The products are only intended for the medical area given below and must therefore be used in an operation environment suitable for this. It is mandatory that the user as well as the corresponding skilled personnel familiarize themselves with the instruments before they use them.

## 2 Purpose

The wire cutter from Orthomed Inc is a hand-operated, manual, general surgical instrument with robust handles and a blade-like jaws for cutting orthopaedic wires,

cerclages and thin needles or bolts in the form of Kirschner wires, cobalt chrome or titanium rods. The wire cutter has a straight handle and is made of high-grade stainless steel. The cutting jaws at the working end are actuated via a simple joint, which transfers the required shearing/cutting force.

### Indication

The wire cutter has a function comparable to scissors. The cutting devices are intended for rods/wires having the following diameters:

- Ø 4.00-4.5 mm
- Ø 5.00-5.5 mm
- Ø 6.00-6.35 mm

### Contraindication

The wire cutter may only be used as intended and by trained and qualified personnel. In addition, the products must not be used or processed again after contact with patients who suffer from Creutzfeldt-Jakob disease (CJD or vCJD).

## 3 Precautionary measures and warnings



### User warning

Always make sure that the rods/wires are clean and are inserted in the intended hole (cutting device). **The cutting devices (holes) and rod slots are designed to cut and sever rods and wires with identical diameters. If a rod or wire with a much smaller diameter is cut and severed in a hole not suitable for this, the rods and wires can jam, and the rod cutter can be damaged. This will void warranty.**



### Material intolerance

Medical products should never be used if the user or skilled personnel discovers that the patient has material intolerances.



### Function impairment

Surgical instruments corrode and have impaired function if they encounter aggressive substances. For this reason, it is imperative that the processing and sterilization instructions be followed.



### Operation conditions

To ensure the safe operation of the previously named products, correctly maintaining and caring for the products is essential. In addition, a function check and visual inspection should be carried out before each use. For this reason, we refer to the corresponding sections in these instructions for use.



### Storage

There are no specific requirements for storing the products. We still recommend storing medical products in a clean and dry environment.

## 4 Liability and warranty

Orthomed Inc, as manufacturer, is not liable for consequential damage caused **by improper use or handling including cutting pins, rods, or wires that are too large or small for designated hole or cutting slot, cutting small rods in the larger slots will damage the rod cutter**. This particularly applies to the non-compliant use for the defined intended purpose or ignoring the processing and sterilization instructions. This also applies to repairs or modifications on the product made by unauthorized personnel of the manufacturer. These liability exclusions apply likewise to warranty services.

## 5 Sterility



### Delivery condition

The medical products are delivered in an unsterilized condition and must be processed and sterilized according to the following instructions before the first use and any further use.

## 6 Service life of the products

Since the medical products of Orthomed Inc are made of resistant materials, tried and tested over a long period of time in the medical technology sector, it is not possible to exactly define the service life. The service life depends on the wear and frequency of use. In this regard, observe the function check instructions before use.

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## 7 Processing



### Warnings

- Frequent reprocessing impairs the quality of the products.
- The municipal water to be used must meet the DIRECTIVE 98/83/EC OF THE COUNCIL from the 3rd of November 1998 regarding water quality for human consumption.
- In these processing instructions, the cleaning agent and disinfectant used for validation are specified. If an alternative cleaning agent or disinfectant (RKI- or VAH-listed) is used, the responsibility is borne by the processor.
- Reassemble disassembled products before sterilization.

### Location of use

Immediately after use, put the products in cold water (<40°C). Do not use warm water (>40°C) or fixating disinfectants, since this can lead to the residues fixating on the product (risk of protein coagulation, denaturation), which can influence the success of the subsequent processing steps.

Remove surface contamination with a disposable cloth/paper towel.



### Transport

The products must be removed in wet condition immediately after use. This means that the products are to be transported wet in a closed container so that the products do not dry out.

### Preparation for decontamination

As far as possible, the products are to be disassembled before the subsequent processing steps or should be in the open condition during the next processing steps. This particularly applies to the removable handle of the wire cutter. Unwashed areas are to be avoided. The products must be processed in suitable sieve baskets or drainage bowls (select size according to product). The products should be fixed in place in the cleaning basket with minimum spacing. Overlapping should be avoided in order to rule out damage to the products occurring during the cleaning process.

### Pre-cleaning

Rinse products under cold municipal water (<40°C) until all visible contamination has been removed. Remove stubborn dirt

with a soft brush or cleaning thorn. Intensively rinse (>30 s) hollow spaces and lumens with a water pistol (or something similar) with cold municipal water (<40°C).

### Cleaning

#### Manual cleaning process

1. Place products in an alkaline cleaner (0.5% *neodisher® MediClean forte*) in the ultrasonic bath for a sonication time of 10 min. and frequency of 35 kHz. Follow the instructions of the cleaning agent manufacturer hereby.
2. Completely reclean products with a soft brush. Intensively flush (>30 s) hollow spaces and lumens (if present) with a water pistol (or something similar).
3. Flush products under running municipal water to remove the cleaning agent (>15 s).

#### Automatic cleaning process

(Washing machine, RDG):

- 1-minute pre-cleaning with cold municipal water <40°C
- Water drainage
- 3 minutes pre-cleaning with cold municipal water <40°C
- Water drainage
- 5 minutes pre-cleaning at 55°C±5°C with 0.5% alkaline cleaning agent (0.5% *neodisher® MediClean forte*)
- Water drainage
- 3 minutes neutralization (0.1% *neodisher® Z*) with cold municipal water <40°C
- Water drainage
- 2 minutes rinsing with demineralized water <40°C

The special instructions from the manufacturer of the automatic cleaning machine are to be observed.

### Disinfection

#### Manual disinfection

1. Place products in an RKI- or VAH-listed disinfectant in the ultrasonic bath for a sonication time of 15 min. and a frequency of 35 kHz. Follow the instructions of the disinfectant manufacturer hereby. It must be made sure that the disinfectant really reaches all areas of the product.
2. The process is validated with the following disinfectant: 3% *Korsolex Plus*, 15 minutes in ultrasonic bath.
3. Flushing of products (cpl. flushing, inside, outside and

hollow spaces) in demineralized water >15 sec.

#### Automatic disinfection

Automatic thermal disinfection in cleaning and disinfection device, taking the national requirements for the A0-3000 value into account;

>5 minutes at 92°C±2°C

### Drying

#### Manual drying

Manual drying with lint-free disposable cloth. To largely avoid water residues in the hollow spaces, it is recommended to blow these out with sterile, oil-free compressed air.

The product must never be heated to above 140 °C.

#### Automatic drying

Automatic drying according to automatic drying process of the cleaning and disinfection device for 30 minutes at 60°C±5°C. If necessary, subsequent manual drying with lint-free cloth and blowing out of lumens using sterile, oil-free compressed air.

### Care after processing

Please never forget to treat the joints of the instrument with a Paraffin oil-based care product after every processing to keep the instrument working smoothly (OKS 370)

### Sterilization

Sterilize the products based on the fractionated pre-vacuum method (in acc. with DIN EN ISO 17665-1) taking the respective national requirements into account.

Carry out sterilization with a fractionated pre-vacuum method with the following parameters:

134°C / 273.2°F, 3 bar,

≥5 minutes holding time,

3 pre-vacuum cycles

Dry in the vacuum for at least 20 minutes

If prions are relevant: 134°C, 18 minutes

Flash sterilization is unsuitable for products with lumens.

Observe the instructions for use from the autoclave manufacturer and the recommended guidelines for the maximum load with products to be sterilized. The autoclave must be installed, maintained, validated and calibrated according to regulations.



### Additional information

The processor is responsible for making sure that the processing carried out with the used

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equipment, materials and personnel in the processing department achieves the desired results. For this, validation and routine monitoring of the process and used equipment is usually required.

## 8 Function check

Check products after processing and before sterilization with regard to the following aspects:

- Cleanliness
- Damage, including signs of corrosion (rust, pitting), discoloration, deep scratches, flaking, cracks and wear, etc.
- Proper function, including sharpness of the cutting tools, flexibility of flexible products, movability of hinges/joints/box locks and moving parts, e.g. handles and ratchets
- Missing or removed (ground off) part numbers
- Do not use improperly working or defective and excessively worn products, as well as products with unrecognisable markings, missing or removed (ground off) part numbers.

Check products for perfect surfaces, correct assembly and functionality. Do not use greatly damaged products, products with unrecognisable markings, signs of corrosion or dull cutting edges.

## 9 Combination products

To obtain an optimal, clean result, it is advisable to use a corresponding rod or wire holder. Perfect function of the wire cutter from Orthomed Inc is only ensured in combination with such a product.

## 10 Service and repair



### Service and repair

Do not carry out any repairs or modifications on the product without authorization. Only authorized personnel from the manufacturer is responsible and intended for this. If you should have complaints, claims or information regarding our products, we ask that you contact us.



### Return transport

Defective or non-compliant products must have run through the complete reprocessing process before sending back for repair/service. Please mark the products afterwards with the note "*hygienically safe*" or "*not decontaminated*" for this purpose.

## 11 Packaging, storage and disposal

The medical products of the manufacturer should be stored and

preserved in individual packaging, boxes or protective containers. Please handle the instruments with great care during transport, storage and processing. Maintaining the sterile condition after the sterilization process must be ensured by the user or skilled personnel employed for this purpose.

The products, packaging material and accessories must be disposed of according to the nationally valid regulations and laws. Specific instructions for this are not provided by the manufacturer.

## 12 Symbols used

	"Caution, consult accompanying documents"
	"Consult the instructions for use"
	"Catalogue number"
	"Batch code"
	"Conformity with the essential requirements"
	"Non-sterile"
	"Manufacturer"