Important note

Carefully read this instruction before using the described medical products. Keep them in a safe place for future reference and make them easily available.

Carefully read these warnings. Improper use of the instrument may cause a serious injury.

RxOnly *Caution: According to US legislation, this product may be used only by a physician or under his direct instructions.*

Scope

Suitably trained and qualified personnel may use the instruments according to the described intended use. It is imperative that the surgeon become familiar with the instruments in prior to surgical application. These instructions should be kept in a conspicuous place close to the instruments.

Intended User

The instruments may be used only as intended, in specialized medical fields, and by appropriately trained and qualified staff. The treating physician or the user is responsible for selecting the instruments for specific applications or a surgical procedure, and for appropriate training, information, and adequate experience for handling the instruments.

Product groups for which this user manual is valid

Tray, Bowl, Box, Cup, Sleeve, Tube

Product description and Intended use

An instrument, typically used in surgery to process different kind of materials. Reusable storage and processing instruments are intended to store, lay down or process instruments, objects or materials.

Indications

Reusable storage and processing instruments are intended to store, lay down or process instruments, objects or materials.

Contraindications

The products are contraindicated for any indication other than the mentioned.

Inclusions/Exclusions of patient groups

There are no special features to consider in adults or children.

Device Combination

The devices are intended to be used in standard surgical practices. The device does not contain specific interfaces to combination devices that would require specific attention.

Life-span

The Life-span of this product is highly dependent on the frequency and the care during the application. Based on the device design and its indications, a lifespan of 50 cycles can be guaranteed.

⚠ Caution

This instrument was designed only for surgical use and may not be used for any other purpose. Improper handling and care, as well as misuse of the instrument may result in premature wear. Use only with moderate force.

⚠ Caution

The instrument is **NOT STERILE**.

⚠ Caution

Before using the instrument for the first time, and before every subsequent use thereafter, it must be reprocessed according to the instructions for use.

Handling

During transport, cleaning, maintenance, and storage, the instruments must be handled with great care and kept in suitable containers. Instruments must be cleaned thoroughly immediately after every use, and special attention must be given to slits, locks, closures, and other areas that are difficult to reach. Heavy soiling is to be removed immediately after use by immersion and rinsing in cold water (<40°C). Do not use any solvents or hot water (>40°C), since this can result in encrustations and thus hinder the conditioning process. Remove corrosive residues such as caustics or pharmaceutical products (e.g. iodine), because otherwise there will be a risk of corrosion. Do not place instruments on top of each other during use or cleaning. To prevent damage, the mechanical sensitivity of the instruments should be taken into account when they are being set down or placed in storage. Never place instruments in physiological saline, since prolonged contact will result in pitting and rust.

Inspection prior to reuse

Each time the instruments are used, they must first be inspected for breaks, cracks, deformations, damage, and functional capability. Areas such as blades, points, closures, locks, snaps, and all moving parts must be inspected with special care. Worn, corroded, deformed, porous, or otherwise damaged instruments must be separated from the others.

⚠ Caution

Only use cleaning agents and disinfectants whose effectiveness and material compatibility with surgical instruments have been checked and approved by the manufacturer of the chemicals. Examples of suitable active ingredients:

1. Ortho-Phtalaldehyde
2. Ethandial, Didecyldimethylammoniumchloride
3. Fermacidal, Glutaraldehyde
4. Glucoprotamine
5. Sodium carbonate peroxyhydrate

Disinfectants that meet the test criteria of the VAH (Association for Applied Hygiene E.V.), FDA or other national certification bodies can also be used. Disinfectants containing peracetic acid without corrosion protection, phenols or chlorine components should not be used to reprocess evonos products.

Pre-cleaning

Clean instrument surfaces and cavities with soft brushes only (do not use metal brushes, abrasive sponges or abrasives). Clean the product in the solution until no residues are visible on the surface. Then clean with cold water and a water jet cleaning gun for about 10 seconds and a pressure of 2.5 - 4 bar. Make sure all areas are flushed. Check all moving parts for cleanliness to ensure proper operation. Instruments with joints should be opened and, if possible, cleaned in disassembled condition. If applicable, brush through non-visible surfaces at least 5 times with a suitable cleaning brush. Rinse the product completely (all accessible surfaces) under running water. Move moving components such as set screws and joints during flushing. Drain the remaining water sufficiently. Afterwards dry instruments. Use soft, lint-free cloths or compressed air if necessary. Use cleaning agents according to the manufacturer's instructions.

Ultrasonic cleaning (optional)

Clean instruments in the ultrasonic cleaning bath (frequency 35 kHz) for at least 3-5 minutes. Make sure that all accessible surfaces are moistened and acoustic shadows are avoided.

Sounding time:	3 - 5 min
Frequency:	35 - 40 kHz
Temperature:	max. 40°C/104°F

Temperatures above 50°C /122°F can lead to blood incrustation. For persistent residues, e.g. on joint parts: Hold instrument tip in ultrasonic bath and move. Insert articulated instruments into the ultrasonic bath when open.
After ultrasonic cleaning:
1. Thoroughly flush instruments with a cleaning gun with deionized water for at least 15 seconds.
2. Dry the instruments manually on the outside using a sterile, lint-free disposable cloth or swab, cavities with filtered compressed air.

Machine washing (automatic)

Follow the operating and loading instructions of the manufacturer of the washer. If possible, instruments should be disassembled for cleaning. Instruments with joints should be opened for cleaning. Place the instruments on a suitable instrument tray and load the washer-disinfector.
Machine - PH-Alkaline, > pH10

- 3 minutes pre-wash with cold water (<25°C /77°F)
- Drain-Wash for 10 minutes at 55°C/131°F with demineralised water (deionised water)
- Drain
- 2 minute intermediate rinse with demineralized water (deionised water), > 10°C/55°F
- Drain
- Perform mechanical thermal disinfection taking into account the national requirements regarding the A0 value (see DIN EN ISO 15883), with demineralised water (deionised water)
- Drying according to program for washer-disinfector

Machine drying

Drying of the instrument surfaces during the drying cycle (washer-disinfector). If necessary, a lint-free cloth can be used for manual drying after the automatic cycle. Sterile compressed air can be used to dry the inner lumens.

Inspection, function test, and care

After washing and disinfection, perform a visual inspection for cleanliness, put the instruments back together, if necessary, and perform a function test. The instrument must be free of visible soiling. Otherwise the instrument must undergo a cleaning process again. Instruments with spots must be separated from the others. Before each use, the instrument must be checked to make sure that it is intact (check for breaks, cracks, indentation, deformation, or malfunction). Particular attention is to be given to special areas like working ends (cutting edges), joints and closures, pins and bolted connections, snaps and locks, and all moving parts. Wear parts (e.g. silicone tubes, scalpel blades) are to be removed very carefully. After putting disassembled instruments back together, check them to make sure that they function properly. We recommend an autoclavable instrument oil (e.g. DAB 8 paraffin oil) to care for the instrument, especially the moving parts (e.g. joints). Remove excess oil.

Packaging

Sterilize the instruments in suitable packaging according to ISO 11607 and AAMI.

Sterilization

Sterilization of instruments with fractionated pre-vacuum method (steam sterilization according to ISO 13060 / ISO 17665) taking into account national requirements. Parameter pre-vacuum method:

- 3 pre-vacuum phases
- Heat up to a sterilization temperature of 134°C/273.2°F (maximum 137°C / 278.6°F)
- Holding time at least 3 minutes
- Drying time at least 20 minutes
- Observe manufacturer's instructions for sterilizers.

Sterilization (only for the USA)

Use a pre-vacuum process (steam sterilization), wrapped cycle, to sterilize the instruments. Parameters for the pre-vacuum process:

- Heat up to a sterilization temperature of 132°C/270°F (maximum 137°C / 278.6°F)
- Holding time at least 4 minutes
- Drying time at least 20-30 minutes
- Observe manufacturer's instructions for sterilizers.

Storage

Store sterile packaging in a dry, clean, and dust-free environment (e.g. storage cabinet).

Returning instruments

In the interest of the health of our employees, only cleaned and sterilized instruments will be accepted for return. They must be labeled as such, otherwise they cannot be processed any further.

Safety and liability

It is the sole responsibility of the user to examine the product with respect to suitability and potential use for the intended purpose before using the product. Use of the instruments is the responsibility of the user. The user of the product is responsible for the proper cleaning, disinfection and sterilization of the product. For additional information, please go to www.a-k-i.org. As the manufacturer of the products, evonos GmbH & Co.KG cannot accept any liability for direct and consequential damages caused by improper use, handling, conditioning, storage, maintenance or sterilization. Instruments may be repaired only by evonos GmbH & Co.KG. Failure to comply with the foregoing instructions will result in the exclusion of any warranty claims. In this case, evonos GmbH & Co.KG is exempt from all liability for damages caused by noncompliance.

Residual risk

The evaluated residual risks are:

- Damaged products
- Not performed sterilization

The inspection of the product and its integrity as well as the correct sterilization are the responsibility of the end user.

Disposal

The disposal of the devices, the packaging material as well as the accessories must be carried out according to the applicable national regulations and laws.

Symbols used on the label

REF	Catalogue number
LOT	LOT or Batch number
NON STERILE	Non Sterile
	Consult Reprocessing Instructions
	Caution, consult accompanying documents
	Keep dry
	The Green dot: Can be disposed of in the trash
	Recycling
RxOnly	Caution: According to US legislation, this product may be used only by a physician or under his direct instructions.
CE	European Conformity
	Date of Manufacture
	Manufacturer evonos GmbH & Co.KG Stockacher Str. 134 78532 Tuttlingen Germany
MD	Medical Device

All products listed are classified in critical B according to the DGSV 2013.

REF Products

This instruction for use is only valid for the following products of the manufacturer

WT118612, WT225300, WT226300, WT269700, WT279900, WT810175, WT813020, WT813022, WT841100, WT997000, WT997001, WT997002, WT997003, WT997004, WT997008, WT997010, WT997020, WT997030, WT997050, WT997100, WT997150, WT997408, WT119990, WT120602, 130128