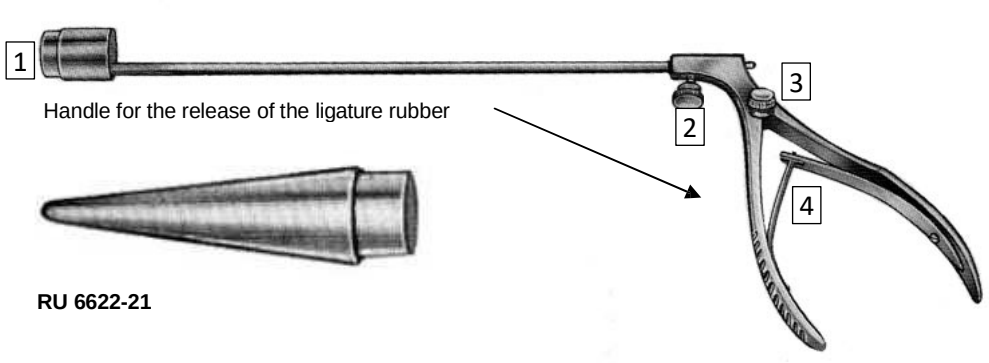
HAEMORRHOIDAL LIGATOR

Haemorrhoidal Ligator



RU 6622-21

Item numbers

RU 6622-21	RU 6621-00
RU 6622-00	RU 6621-01
RU 6622-05	

Indication

The reusable haemorrhoidal ligators are used to apply a ligature ring around the base of the haemorrhoidal nodule to cut off the blood flow to haemorrhoidal tissue. The interrupted blood supply will cause dry out and elimination of the hemorrhoid.

Contraindication

The use of haemorrhoidal ligators is not allowed if

- For large haemorrhoids (grade IV)
- The patient is using anticoagulants
- Septic conditions in the anorectal region are present
- Hypertrophied anal papilla and
- Chronic anal fissure

Description

1. Load the ligator with a latex-free o-ring by using the loading cone. Place the loading cone onto the ligator barrel and roll o-ring down the tip of the loading cone until it is seated evenly around the end of the ligator barrel in the maximum expanded diameter. Remove the loading cone.
2. Grasp the hemorrhoid with forceps approximately 1 centimeter proximal of the dentate line and pull the hemorrhoid into the drum of the ligator. If the patient indicates there is pain, a more proximal position for the band ligation should be selected
3. With the hemorrhoid pulled taut through the drum of the ligator and the ligator pressed up against the base of the hemorrhoid, the trigger should be squeezed to apply the ligation o-ring to the base of the hemorrhoid.

Lifetime

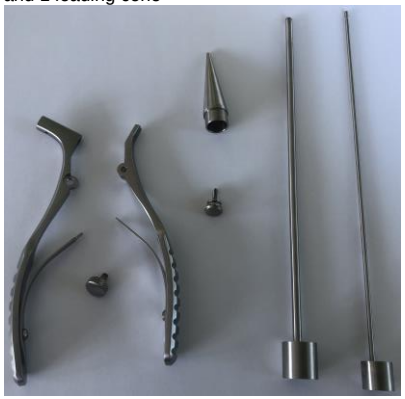
The useful life of the instrument is limited to handling of the device. Bending or overloading causes damages. Careful reprocessing and easy handling ensure more than 1000 operations.

Function check

Following delivery and before each use new instruments must undergo a thorough visual examination and must be tested for functionality.
If the instrument shows outwardly recognizable defects (scratches, breaks, cracks, indents, bent parts or operational difficulty/tightness) or it does not work as described in this instruction, immediately notify us, i.e. the manufacturer, or our distributor.

Assembly / Disassembly

The instrument consists of 7 parts:
2 handles, 2 thumb screws, 1 outer sheath, 1 plunger and 1 loading cone



Disassembly

1. Remove the cone from the plunger
2. Undo the thumb screw and gently pull out the inner plunger and outer sheath

3. Undo the thumb screw and disconnect the handles. This may require some force
4. Unhook the two springs

Assembly

1. Hook the two springs into each other
2. Press the inner joint of the rear handle into the outer joint of the front handle until the threaded holes are aligned. Redo the thumb screw.

3. Push the inner pestle into the outer sheath and insert it into the opening in the handle. Secure the sheath with the thumb screw
4. Insert the cone into the plunger

Warnings and precautions: Handling

- Do not use damaged instruments.
- The instrument has only a limited stability. Force applied too strongly can lead to damage and negatively affects it's functioning.
- Cannulas are extremely sensitive and bend with minimal recovery.
  Damaged cannulas must not be used any more.
- A new sterile cannula must always be used when drawing up liquids.
- To prevent the piston from sticking, always pull the piston back slightly after use.
- The individual parts of the syringe must not become unsterile during assembly.
  (inside cylinder/cap, piston, cannula, syringe attachment)

First use of new instruments

- The instrument is delivered non-sterile. It must be cleaned and sterilized before the first use.

Warnings and precautions: Cleaning

- During preparation, the temperature affecting the instrument must not exceed 137°C,
- Automatic cleaning and disinfection are to be preferred to manual cleaning and disinfection. The automatic cleaning and disinfection procedure are much safer.
- Never use metal brushes/sponges or abrasive cleaning agents for manual cleaning.
- Only clean instruments and instruments of low microbiological contamination enable a successful sterilization.
- In case of damage the devices should undergo the complete reprocessing process before being sent back to the manufacturer for repair.
- Never use cleaning agents with bleaching agents, such as sodium hypochlorite, as it causes severe corrosion.

Preparation for cleaning

- After use, the instruments must be prepared as fast as possible.
- Remove residues and stains on the instrument immediately after use with a single use cloth or tissue.
- Do not use a fixating agents or hot water (>40°C) as this can cause the fixation of residues which may influence the result of the reprocessing process.
- Deposit them preferably in a dry place.

- Rinse the instruments as soon as possible after use. Observe the other cleaning specifications for this purpose.
- Soak the instruments / Rinse the instruments in a solution with a suitable combination of cleaning and disinfecting agents. Please, observe the manufactures' instructions of the cleaning and disinfecting agents.
- Put the instruments in suitable wire baskets.
- Dismantle the instruments as much as possible

Transportation

- Safe storage and transportation in a closed container to the reprocessing area to avoid any damage of the instruments and contamination of the environment.

Preparation

⚠ **Note**	Please see our general preparation instruction A0462 for reusable instruments (thermostable). If you do not have these, please request them from us.

Cleaning

Automated cleaning

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) and with for the WD and the instrument validated procedure / program according to EN ISO 15883.
- Suitable WDs are provided with special cleaning baskets / slide-in carts for sensitive instruments.
- Avoid any rinsing shadows when loading the WD slide-in cart with instruments in order to obtain an ideal rinsing pressure for the entire instrument. Pay special attention to the jaws.
- Do not overload the WD slide-in carts, do not pile them up.
- Please observe the instructions for use and loading indications of the WD manufacturer.
- When choosing the appropriate cleaning agents see the respective lists and recommendations of the Robert-Koch Insitute (RKI) of the DGHM Deutsche Gesellschaft für Hygiene und Mikrobiologie (German society for hygiene and microbiology) and consider the instrument's material and characteristics. See additional information of the preparation instructions at hand.

Cleaning agents for automatic cleaning in WD:

Manufacturer	Trade name
Dr. Weigert GmbH & Co. KG	Neodisher FA
Borer Switzerland	Deconex 23 Neutrazym

***the suitability of the cleaning agent as well as subsequently described method has been demonstrated based on preclinical testing / validation by RUDOLF Medical.**

A - Cleaning program (Miele G 7735):

- 1 min. pre-cleaning with cold water
- Draining
- 3 min. pre-cleaning with cold water
- Draining
- 5 min cleaning at 55°C with 0,5 % alcaline detergent
- or 5 min cleaning at 45°C with 0,5 % enzymatic detergent
- Draining
- 3 min. neutralization with warm water (>40°C) and neutralizer
- Draining
- 2 min. rinse with warm tap water (>40°C)
- Draining

Maintenance, Control and Inspection

- After the cleaning and disinfection, the instruments must be inspected visually for cleanness. They must be macroscopically clean (no visible residues/soiling). Pay special attention to grooves, ratchets, closures and other difficult accessible areas.
- Should there still be any visible residues or liquids repeat the cleaning and disinfecting procedure.
- Prior to any sterilization the instruments must be assembled and inspected for function, wear and tear and for damages, and if necessary, it has to be exchanged.

Packaging

- Appropriate packaging for sterilization according ISO 11607 and EN 868.
- Generally, adjust the sterilizing accessories and the sterile packing to the content of the packing instrument and the sterilization procedure.
- Please, observe the manufactures' instructions of the sterilizer.

Sterilization

- Sterilization is to be carried out using a steam sterilization procedure validated by DIN EN ISO 13060 / ISO 17665 (fractionated vacuum procedure) in a sterilizer in accordance with EN 285, DIN 58946.
- 3 pre-vacuum phases with at least 60 mbar pressure
- 134°C - 5 min or 132°C - 4min.
- Drying time: minimum 10 min.
- Please, observe the manufactures' instructions of the sterilizer.

Storage

- The reprocessed instruments must be stored in suitable and reusable sterilization containers in accordance with DIN EN 868-1 and DIN EN 868-8 and should be stored until use in accordance with DIN 58953-9.
- The sterilizing container should be designed in such a way that the instrument is safely fixed and protected from damage.
- Storage of sterilized instruments in a dry, dark, low microbiologically contaminated clean and dust free environment at moderate temperatures of 5°C to 40°C.
- The storage area should be free of temperature fluctuations.

Additional Instructions

- If the described chemistry and machines are not available, it is the duty of the user to validate his process.
- It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly. Likewise, any modification by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

Repairs

- Even when used as intended surgical instruments are subject to more or less severe wear, depending on how intensely they are used. This wear cannot be avoided due to technical reasons.
- Please do not carry out any repairs yourself. Servicing and repairs may only be carried out by ourselves - the manufacturer - or by other persons we authorized.
- Surgical instruments that are to be sent back for repair have to be cleaned, disinfected and sterilized.

⚠ **Caution!**

Failure to observe the warnings and precautions can lead to death or serious injuries.

Symbols and explanations

	Please read these instructions carefully before using the product for the first time. Always follow the instructions in this manual. Keep these instructions for use in a safe place.
	Batch code
	Article number
	Non-sterile
	Indicates a possible danger to persons or property
	CE marking
	Symbol for manufacturer

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