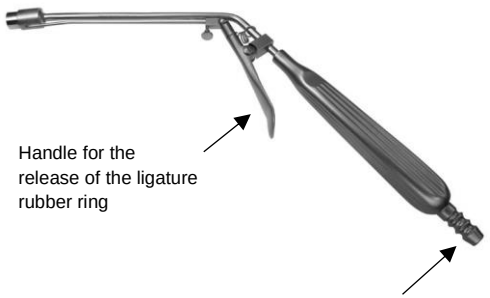
Haemorrhoidal Ligator

Haemorrhoidal Ligator



Item numbers

RU 6620-00		

Intended Use

- The decision on the suitability of the instrument for the intended application lies with the user. We assume no liability for the consequences of improper application and preparation.

Function test

- A new instrument must undergo a thorough visual and functional inspection after its delivery and before each use.
- If the instrument shows outwardly recognisable 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.

⚠ **Warning notices and precautions.**	- Never use a damaged instrument. - If damaged after sterilisation, the instrument must be repaired or disposed according to regular hospital practice.

Operation and safety instructions

- A white cone (RU 6620-10), an aspiration tip (RU 6620-11 or RU 6620-16) and a package of ligature rubber rings (RU 6620-50) come with each Haemorrhoidal Ligator.
- The cone facilitates the loading of the ligator. The Haemorrhoidal Ligator can be connected with a suction device by means of a plastic tube which shall be placed at the bottom of the handle.
- Please pay attention that the ligature rubber ring is placed neatly and correctly. By pushing the handle, the outer cylinder will advance and the ligature rubber ring will be released.

Preparation instructions

Materials:	Stainless steel according to DIN EN ISO 7153 Ligator Tecaform AH (POM Copolymer) Loading cone
⚠ Warnings and precautions:	Instruments made from stainless steel may not be placed in a physiological saline solution (NaCl solution) because long-term contact leads to corrosions such as holes and stress cracks. - Long waiting times before preparation after use (over 6 hours) should be avoided because of the risk of corrosion.
Limitations on reprocessing:	Frequent reprocessing has little effect on the instrument. The end of service life is normally determined by wear and damage due to use.

Instructions

! These preparation instructions only apply to the associated loading cone

Because the loading cone is only used to fit the rubber rings and does not come in contact with the patient, but only with the sterilised ligator, it is usual, according to our knowledge, simply to purge the loading cone in a solution. However, the loading cones can only be sterilised for a short time at a temperature of 134°C. This upper temperature limit should be complied with during sterilisation, however, because the properties of the material change at higher temperatures.

Instructions for Ligator:

- **From point of use:**
  Long waiting times before preparation after use (over 6 hours) should be avoided because of the risk of corrosion. The instrument can be disinfected manually immediately after use so as to reduce the risk of infection for users. (Follow the manufacturer's instructions for the disinfectant solution.)

- **Preparation for decontamination:**
  The suction head of the ligator should be unscrewed before preparation. The instrument should be placed on a suitable instrument holder ready for purging. The instrument holder (e.g. strainer bowl) must be designed so that subsequent cleaning in the ultrasound or cleaning and disinfection device is not impeded because of areas that the ultrasound or cleaning device cannot reach.

- **Preliminary ultrasound cleaning:**
  Instruments with inaccessible parts are to be cleaned in the ultrasound tank. If preliminary ultrasound cleaning is used, please note: The tank must be filled according to the manufacturer's instructions. The water must have a suitable cleaner or combined disinfectant and cleaner added for ultrasound cleaning. The manufacturer's specifications for the concentration, temperature and contact time of the disinfectants and cleaners must be complied with. Temperatures of 40° to 50°C promote cleaning. Higher temperatures lead to incrustation. The instrument must be completely covered by the disinfectant solution. The instrument may only be presented on a suitable wash basket that does not impede the effectiveness of the ultrasound. Do not overload the suitable wash baskets. A high level of impurities in the ultrasound tank will impair cleaning and increase the risk of corrosion. The cleaning solution must be renewed regularly, depending on the conditions of use. The criterion is visible impurity. Under all circumstances the tank must be changed frequently, i.e. at least once per day. National guidelines are to be followed. After ultrasound treatment, the instrument must be subsequently rinsed in such a way as to remove the remains of cleaners and disinfectants. To prevent water marks, demineralized water should be used for the final rinse. The specifications of the ultrasound device and cleaner manufacturers must always be followed.

- **Automatic cleaning and thermal disinfection:**
  The machine and the way in which it is used must ensure that hollow instruments (suction tube of the ligator) are also rinsed sufficiently internally. If a thermal process is used, disinfection takes place at higher temperatures of 80-95°C and appropriate contact time. The A0 value was introduced as a measure of effectiveness of the disinfectant. This is determined by the temperature to time ratio, depending on the microbiological contamination and the intended purpose of the instruments. (pr EN ISO 15883-1)
  1. Preliminary rinse Softened water, no heating, no additives, holding time 1 min.
  2. Preliminary rinse Softened water, no heating, no additives, holding time 3 min.
  3. Cleaning
  Hot, softened water. Dosing of cleaner at 40°C heating to 55°, holding time 10 min. The cleaners used are suitable pH-neutral or alkaline cleaners. The choice of cleaner depends on the properties of the instrument and national directives and recommendations. (e.g. RKI recommendation in Germany).
  4. First intermediate rinse Cold water. The adding of a neutralising agent on an acid base makes it easier to purge alkaline cleaner residue. Also, when neutral cleaners are used, the use of neutralizing agents can prevent a build up of deposits. Holding time 1 min.
  5. Second intermediate rinse Hot or cold water (preferably full demineralised) without any additives Holding time 2 min.
  6. Thermal disinfection
  Fully demineralised water, thermal disinfection takes place at temperatures of 80-95°C and appropriate contact time as per A0 concept, pr EN ISO 15883-1. Water marks, deposits and corrosion can be avoided by using fully desalinated water.
  7. Drying
  Adequate drying is to be assured by means of the cleaning and disinfection device.
  8. Cleaning agents
  The parameters specified by the manufacturer of the cleaner in relation to the concentration, temperature and contact time mist be complied with and automatic dosing equipment must be controllable.

- **Cleaning: manually**
  1. Cleaner / disinfectant
  The cleaners and disinfectants used must be suitable for the manual cleaning and disinfecting of instruments and must be compatible with each other. The effectiveness of the disinfectant must be certified. The contact times, temperatures and concentration specified by the disinfectant and cleaner manufacturer must be complied with. Freshly mixed solutions are to be used each day. If there are high levels of impurity, the solution must be changed more often.
  2. Procedure for manual cleaning Place the instrument in the cleaning solution; the specifications of the cleaner manufacturer in relation to the application period must be met. When placing the instrument in the tank, move it about to make sure that all air bubbles are allowed to escape from cavities, thus ensuring that the entire internal surface is coated. Any impurities attaching to the exterior are removed by also brushing the instrument down with a synthetic brush (never use a metal brush). A steam cleaner can be used to clean thoroughly in nooks and crannies. Rinse the instruments at least five times with fresh, demineralised water, repeating the cleaning process if there are still signs of impurities on the instrument.

- **Disinfection: manually**
  1. Cleaner / disinfectant
  The cleaners and disinfectants used must be suitable for the manual cleaning and disinfecting of instruments and must be compatible with each other. The effectiveness of the disinfectant must be certified. The disinfectant and cleaner manufacturers'specifications for the concentration, temperature and contact time must be complied with. Freshly mixed solutions are to be used each day. If there are high levels of impurity, the solution must be changed more often.
  2. Procedure for manual disinfection Place the instrument in the disinfectant solution. The specifications of the disinfectant manufacturer in relation to the application period must be met. Rinse the instruments at least five times with fresh, demineralised water, repeating the complete cleaning/ disinfectant process if there are still signs of impurities on the instrument.

- **Drying**
  Drying with compressed air is particularly gentle and effective and is thus preferable to any other method of drying.

- **Maintenance, control and testing:**
  After cleaning / disinfection, the instrument must be macroscopically clean, i.e. free from visible residue. Pay special attention to difficult accessible areas, such as joints and cavities require particularly close inspection. The ligator (in particular the suction tube) must be checked to ensure it is not blocked. If a ligator is inadequately cleaned or is blocked, it must always be cleaned again and then rinsed thoroughly. After cleaning/ disinfection, the instrument must always be subjected to a functional inspection. Defective instruments (hairline cracks, deformation, wear or signs of reduced functionality) should generally be replaced because they no longer serve their intended function, or at least not sufficiently.

- **Packaging**
  Reusable sterilising containers, bags, hoses, sterilisation paper and sterilizing packaging must me designed to suit the contents of the package and the sterilization process to be used. (EN 868, T1-10)

- **Recommendations for sterilisation:**
  Steam sterilisation: as per EN 554
  Temperature: 134°C
  Pressure: 3 bar
  Duration: at least 5min.
  Drying: at least 15 min.

- **Sterilisation**
  Only cleaned and disinfected instruments may be sterilised. Only the sterilisation processes listed in DIN EN 13060, DIN EN 13485 and DIN EN 554 can be used. We shall not accept responsibility if other sterilisation processes are used.

- **Storage**
  After sterilisation the Haemorrhoidal Ligator should be stored in a suitable reusable sterilisation container acc. to DIN EN 868-2 and DIN EN 868-8 until use acc. to DIN 58953-9. The sterilisation container should have the necessary quality to secure the instruments and protect them against damage. Instruments can corrode due to storage conditions. To prevent this, instruments should stored in a dry, dust-free environment. To prevent the build-up of condensation, large variations in temperature should be avoided. Chemicals may not be stored with instruments. The permissible storage period depends on the type of packaging.

- **Further information (supplement):**
  The best way to standardise cleaning and disinfection is by means of a mechanical process. Thorough cleaning will also maintain value and is essential for successful sterilisation. Only validated mechanical cleaning and disinfection processes should be used to comply with standards and directives.

  The following points should be noted during mechanical preparation:
  - For effective mechanical preparation, the suitable wash baskets must be loaded correctly for purging purposes.
  - Wash baskets may not be overloaded.
  - In order to avoid rinsing shadows please take care that the instruments are too crowded in the washer basket. Instruments having a large surface should therefore be stored on the sides of the bottom.
  - The instruments must be designed and stored in line with their mechanical sensitivity, so that damage is prevented.
  - The material to be rinsed must be taken out of the machine immediately the program is complete as residual moisture can lead to corrosion if the devices are left in the
  machine.

- **Note:**
  Successful preparation is solely the responsibility of the operator. Please note the instructions and specifications of the relevant national regulations in this regard.

- **Warranty**
  The user/preparer is responsible for ensuring that the preparations made (equipment, material, personnel) are suitable to achieve the required results. We cannot guarantee that the products are suitable for the relevant intervention. We accept no liability for coincidental or resulting damages if the device is used incorrectly or if instructions are not followed. If the device is used on patients with Creutzfeldt-Jakob disease or HIV infection, we accept no responsibility for re-use.

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 by yourself. Servicing and repairs may be carried out only by ourselves – the manufacturer - or by other persons we authorised.

Surgical instruments that are to be sent back for repair have to be cleaned, disinfected and sterilised.

Safety information and explanation of symbols

	Follow the instructions for use
REF	Order number
	Non-sterile
	Manufacturer
	Failure to observe warnings and precautions can result in death or serious injury
LOT	Lot-Number
CE	CE marking notified body number

RUDOLF Medical GmbH + Co. KG
Zollerstr. 1, 78567 Fridingen, Germany
Tel. +49 7463 9956-0
Fax +49 7463 9956-56
sales@rudolf-med.com
www.rudolf-med.com