



» ELLIK EVACUATOR «





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Instructions for use – Please read before use

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In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully followed. The use, preparation and testing of the instruments may only be carried out by trained specialists.



The products are delivered non-sterile and must go through the complete processing cycle (cleaning, disinfection and, if necessary, sterilization) before the first and every subsequent use.

1 SCOPE



These instructions for use are valid for the Ellik evacuators from Tekno-Medical Optik-Chirurgie GmbH (hereinafter "Tekno-Medical") (See product list in the last section.)

2 INSPECTIONS

The products must be checked for functionality before each use. Damage to the surface such as scratches, cracks, nicks, nicks, etc. means that the product must not be used. The products must then be disposed of in the usual hospital manner. Damaged products must not be used!

3 HANDLING

The products may only be used for their intended purpose by appropriately trained and qualified personnel. The treating physician or user is responsible for the selection of instruments for specific applications or operational use, the appropriate training of personnel and the experience in handling the products.

4 PURPOSE

The evacuators are used to flush the urethra and evacuate the bladder via an appropriate shaft or catheter. The products are only intended to support medical procedures or other treatments. The duration of use is temporary (intended for uninterrupted use for a period of less than 60 minutes under normal conditions) in accordance with Regulation (EU) 2017/745.

5 INDICATIONS

The evacuators are generally used to support various examinations and procedures in urology and gynecology.

6 CONTRAINDICATION

In general, the use of the head support system is contra-indicated in cases where the use of other surgical techniques is indicated. In addition, there are contraindications:

- in case of unwillingness of the patient;
- if the technical requirements are not met.

The responsible doctor or user must decide based on the general condition of the patient whether the intended application can take place.

7 PATIENT POPULATION

Apart from the contraindicated uses listed in these instructions for use, there are no restrictions on the patient population.

8 DISPOSAL

If the instruments can no longer be repaired and reprocessed, the instruments must be disposed of in accordance with the applicable country-specific regulations and laws.

Defective products must usually have gone through the entire reprocessing process before disposal.

9 INSTRUCTIONS FOR REPROCESSING

In general, medical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the preparation of instruments can be found in the "Red Brochure" of the AKI.

Under www.a-k-i.org you will also find links to laws, standards and reprocessing expert committees.

9.1 Cleaning, disinfection and care

Clean the ball, the glass cylinder and the hose part with soapy water. Do not use alcohol-based disinfectants; these can destroy the ball! Use an aldehyde- and amine-free disinfectant for wiping disinfection.





Disinfection by briefly boiling:

- Remove the adapter and hose from the ball.
- Place all pieces in a bath of boiling water. Make sure that all parts can move freely in sufficiently bubbling water
- Prolonged temperatures above 80°C can destroy the product; A short-term temperature increase of up to 100° C when boiling is still possible.



Gas sterilization is possible.
Steam sterilization is not possible!
Not microwave safe!
Do not expose to direct sunlight!

9.2 Information about the material of the ball

- The ball is made of soft PVC (medical-grade soft PVC, PVC-P),
- the ball is latex-free,
- The ball is physiologically harmless according to the recommendation XLVII-BGA, white,
- the ball is lead and cadmium free,
- the ball does not contain any plasticizer DEHP.

Temperature resistance information:

The optimal functional range of the ball is between -10°C and + 40°C.

If the balls are exposed to temperatures outside this range, they must not be compressed by other parts, otherwise permanent deformation and other damage could occur.

10 ADDITIONAL INSTRUCTIONS



If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly. It is the responsibility of the user to ensure that the remanufacturing process, including resources, materials and personnel, is suitable to achieve the required results.

The state of the art and national laws require the following of validated processes.

11 REPORTABLE EVENTS



In accordance with the requirements of the Medical Device Regulation EU MDR 2017/745 and our quality management system, even the smallest problems with this product should always be reported to Tekno-Medical. If you cannot reach us directly for reportable events, please send an e-mail to: safety@tekno-medical.com.

Serious incidents must also be reported to the competent authority in their place

12 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno-Medical accepts no liability for any incidental or consequential damages. Tekno-Medical assumes no liability if it can be proven that these instructions for use have been violated.



Attention: In case of use of the instruments in patients with Creutzfeldt-Jakob disease or its variants (vCJD, BSE, TSE), Tekno-Medical declines any responsibility for reuse.

13 SERVICE AND REPAIR

Do not carry out repairs or modifications of the product on your own. Repairs only by authorized personnel. Defective products must have gone through the entire remanufacturing process before being returned for repair. For returns, use our RMA request form and decontamination certificate.

Forms at: https://www.tekno-medical.com/de/service/repair_service





14 SYMBOLS

The symbols used in this instruction and on the label have the following meaning according to DIN EN ISO 15223-1:

| | | | |
|--|------------------------------|--|-------------------------------|
| | Attention! | | Manufacturer |
| | Medical device | | Date of manufacturing |
| | Non-sterile | | Read the instructions for use |
| | Catalogue number | | Protect from sunlight |
| | Lot-number | | Store in a dry place |
| | Unique device identification | | CE marking |

REF

15 PRODUCT LISTING

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| 30430-00 | 30430-01 | 30430-03 | 30430-05* |
| 30431-00 | 30430-02 | 30430-04 | 30430-06 |