MATERIALS AND INTENDED USE
The device(s) must be used in the manner described in the Surgical Protocol provided by Enztec Limited or its representatives, as applicable. The device(s) is manufactured from medical grade metals and plastics, and is supplied non-sterile. Prior to use, the operating surgeon shall have given careful consideration to all aspects of the surgical intervention as well as to the limitations of the device.

EXAMINATION PRIOR TO USE
The device(s) is supplied non-sterile, in device containers or individually packaged. Device packaging must be intact when received, and removed prior to sterilization.

The device(s) should be carefully and completely examined for wear or damage by doctors and staff in operating centres prior to surgery. The examination shall include a visual and functional inspection of the working surfaces. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, loosening of components, or other change.

Like any precision surgical device, the device(s) should undergo regular checks by authorised personnel to ensure that the devices remain in good condition and continue to act as intended. End of useful instrument life is generally determined by wear or damage in surgical use.

WARNINGS AND PRECAUTIONS
Enztec Limited devices can only be used by surgeons who are fully familiar with the surgical technique required and who have been trained to this end. The operating surgeon must take care not to exert inappropriate stress on the device and must fully comply with the operating procedure described in the Surgical Protocol.

Incorrect maintenance, cleaning or handling may render the device(s) unsuitable for its intended use, cause corrosion, dismantling, distortion and/or breakage, or cause injury to the patient or operating staff. Enztec Limited shall not be responsible in the event of a device being used which is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired or modified (either permanently or temporarily) outside the control of Enztec Limited or its representatives.

As a result of mechanical features required, the device(s) or component part(s) may be made of non-implantable materials. In the event of the device breaking, no fragment must remain in the patient as this could cause post-operative complications such as allergies, infections, or complications of a biological nature associated with the release of non-implantable components, possibly requiring further intervention.

COMPLAINTS
Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, durability, reliability, safety, effectiveness and/or its performance, should notify Enztec Limited or their representatives. Moreover, if the device has malfunctioned, or is suspected of having malfunctioned, Enztec Limited or their representative must be advised immediately.

If a Enztec Limited product has ever worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor or Enztec Limited must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please include the device name and catalogue number, a full description of any markings, contact name and address, and an exhaustive description of the event to help Enztec Limited understand the causes of the complaint. Please retain the device for investigation purposes.

WARRANTY STATEMENT
Enztec Limited devices are manufactured for use only by qualified medical personnel who are trained in their use. All Enztec Limited devices are warranted to be free from defects in workmanship and materials for one (1) year from the date of sale. Any Enztec Limited device with a defect during the applicable warranty period will be repaired or replaced. Enztec Limited shall not be liable, expressly or impliedly, for:

a. Any damages which arise or are caused, whether by the customer or by any of the users of the devices or equipment, as a result of

   (i) misuse, mishandling, and/or improper operation

   (ii) repairs, modifications, or alterations performed by any person or entity other than Enztec Limited, or their authorised representatives

   (iii) incorrect or incomplete inspection, cleaning and/or maintenance, or

   (iv) use in combination with adaptors and/or equipment, or use in any manner or medical procedure, other than those for which it is designed; and

b. Any special, indirect, and/or consequential damages of any kind and however caused arising from the sale or use of the device and equipment.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, AND/OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS AND/OR SUITABILITY FOR A PARTICULAR PURPOSE, AND ALL OTHER OBLIGATIONS OR LIABILITIES ON "ENZTEC LIMITED" BEHALF.

Enztec Limited neither assumes nor authorises any person to assume for it any other liabilities in connection with the sale of said devices and equipment. To ensure proper use, handling, and care of devices and equipment, consult the applicable catalogue, brochure, instruction manual, teaching film, and other literature which is included with the product and/or otherwise available from the company, upon request.

For further information relating to the use of this device or complaints please contact your Enztec Limited representative or distributor.

Rx: Federal law restricts this device to sale or use by or on the order of a physician.

European Union Requirements:

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Symbols:
DIST Distributed by

CLEANING AND STERILISATION
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1. Point of Use	- Remove gross contamination
2. Transport to Processing Area	- Avoid damage - Minimise time before cleaning
3. Preparation for Cleaning	- Disassemble where possible following disassembly instructions
4. Pre-cleaning	- Submerge in enzymatic detergent prepared according to manufacturer's recommendations - Soak for 15 minutes at 40°C (104°F) - Scrub while submerged with soft sponge and agitate - Use pipe cleaner or non-metallic brush for lumens and crevices. Actuate moving parts to loosen trapped soil - Rinse in 38°C-49°C (101°F-120°F) tap water for 1 minute - Thoroughly flush all lumens and difficult to reach areas - Actuate while rinsing
5. Cleaning	- Soak in ultrasonic bath in neutral pH detergent (Neutrad or acceptable alternative), prepared according to manufacturer's recommendations - Clean for 15 minutes at 40°C (104°F) - Rinse with clean, tap water, actuating moving parts while rinsing, for 1 minute; repeat rinse twice - Dry thoroughly with clean, lint-free cloth
6. Inspection	- Inspect for contaminants and damage - Repeat cleaning if contaminants remain - Contact Enztec Limited or its representatives if device is damaged
7. Preparation for Sterilisation	- Reassemble where possible following assembly instructions - Spray all moving components with Rudolf Oil Spray RU8880-00 or equivalent medical grade lubricant - Package loosely in suitable pouch or cloth wrap
8. Sterilisation	- Steam sterilisation, Pre-vacuum cycle - Temperature: 134°C (273°F) - Exposure Time: 4 minutes - Dry Time: 60 minutes

Other sterilisation methods are possible but must be validated beforehand. Automatic cleaners and autoclaves must be validated by the hospital and regularly checked to guarantee the recommended sterilisation temperatures are reached for the entire exposure time.

If sterilisation containers with paper filters are used, it is advisable to use a new filter for each sterilisation. If after having followed this sterilisation method there is still water in the sterilisation containers or on/inside the device, the device must be dried and sterilisation repeated.

STORAGE
The device(s) should be stored in individual packages or in containers. After use they must be stored in a clean, dry and temperate place.

IMPORTANT MEDICAL INFORMATION

enztec

Part No.: 10914-03 Rev: 1

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