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 authorizes 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.

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SYMBOL TRANSLATION
– see enztec.com/ifu

INSTRUCTIONS FOR USE

Single Use Sterile Instruments

enztec

Part No.: 12026-00
2024/12 Rev: 1

MATERIALS AND INTENDED USE
The device supplied by Enztec Limited (Enztec) is a surgical instrument intended for transient use during orthopaedic surgery. It is intended to be used in the manner described in the Surgical Protocol provided by Enztec or its representatives, as applicable.

The device is manufactured from medical grade metals and plastics and is supplied sterile for single-use. 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.

To ensure a safe connection and minimise the risk of patient or user harm, when instruments are driven by powered devices, the powered device must be used per the manufacturer's instruction for use, ensuring that the speed selected is appropriate for the application and does not result in excessive heating of the device. Reaming instruments should not be operated at speeds above 250rpm or with an input torque exceeding 17Nm.

EXAMINATION PRIOR TO USE
The device is supplied sterile, and the packaging and seal should be inspected for damage before opening. Sterility is only guaranteed it the packaging is undamaged and unopened. If the sterile barrier appears compromised in any way, the product must be assumed non-sterile and must be disposed of.

The device must not be used past the use-by date stated on the label.
The device should be carefully and completely examined for defects or damage by doctors and staff in operating centres prior to surgery. If damaged or defective the device should not be used and immediately be disposed of.

Enztec Limited shall not be responsible in the event of a device which is damaged or showing signs of having been previously opened, being used. End of useful instrument life is one (1) use.

STORAGE
The device should be stored in its original unopened packaging in a clean, dry and temperate place.

STERILISATION
The device has been sterilised using gamma radiation. The device is intended for single use and should not be re-sterilised or re-processed.

DISPOSAL
The device must be disposed of after use in accordance with the health care facility's procedures, ensuring protection from physical hazards such as exposed edges. Care must be taken to ensure that used devices are disposed of as infectious waste. The device should be destroyed in a manner that prevents potential reuse.

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

The packaging of the device should only be opened using aseptic technique for delivery of the device to the sterile field for immediate use. The device should not be used past the date stated on the label.

Do not re-use instrument. Re-using single use instruments may result in adverse effects to the patient, including but not limited to:

- risk of infection
- device jamming
- difficulty in removing the device
- misalignment of other instrumentation or implants
- Loss of bone tissue during removal of the device

CAUTION: Federal law restricts sale of this device to sale by or on the order of a physician or licensed practitioner.

ADVERSE EFFECTS
As a result of mechanical features required, the device is 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 metal 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 an Enztec Limited product has ever worked improperly and could have caused or contributed to a serious incident, serious injury, or death, Enztec or their representative, as well as the competent authority of the Member State in which the user and/or patient is established, must be informed as soon as possible by telephone 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.