

INSTRUCTIONS FOR USE

GIGLI SAW BLADES AND HANDLES

Product Code(s): GSN2001, GSN2003, GSN2061, GSN2101 and GBH1002

READ INSTRUCTIONS BEFORE USE!

Sterile single use device

Do not re-sterilise

Product description

The Gigli Saw Blades and Handles are registered as a single-use sterile device. Each device is double packed in a sealed pouch. See packaging and labelling for product dimensions. The device is a manual instrument, Gigli Saw Blades have an abrasive edge with loops to attach to the Gigli Saw Handles.

Intended Use

The Gigli Saw is designed to be used as a manual, flexible saw for cutting bone. It is intended to be used with a guide to prevent damage to the surrounding soft tissue. It is used in Osteotomy procedures, Craniotomy, Rib resection and for the amputation of small bones.

Contraindications

- The device is not suitable for use as an amputation device for large bones such as the Tibia or Femur.
- Do not use the Gigli Saw Blade or Handle in the presence of magnetic fields such as those that occur during magnetic resonance imaging. The device has not been tested for magnetically induced torque, radiofrequency induced heating or image artefacts.

WARNINGS AND PRECAUTIONS

- Proper surgical procedures and techniques are the responsibility of the medical professional. These instructions are for informational purposes only. Each surgeon must evaluate the appropriate use of this device, case by case, based on medical training, experience and the type of surgical procedure employed.

INSTRUCTIONS FOR USE

1. Check that the packaging is intact and not damaged. Do not use if the packaging is damaged.
2. Open the packaging onto sterile field.
3. Use the device as intended within the specialist area.
4. UDI traceable barcode is supplied to ensure traceability is maintained in theatre records and patient notes.

GRAPHICAL SYMBOLS USE ON LABELLING



"Sterilised using Ethylene Oxide"



"Use by Date"



"Batch Code"



"Do not reuse"

Manufactured by:
DTR Medical Ltd.
17 Clarion Close
Enterprise Park
Swansea
SA6 8RF



Notified body:
BSI
Say Building
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