TORS

Torsional Orthopaedic Revision System

Patient Handbook

CONTENTS

Conventions used in this document

Caution:
A statement that if not strictly followed could result in damage to the equipment

Intended use

TORS is an ultrasonic surgical device intended to be used for removal of polymethylmethacrylate (PMMA) bone cement in orthopaedic applications. It is also intended to be used for cutting and cauterising soft tissue during skin and muscle incision to access bone joints in limbs.

Intended user

TORS is intended to be used by surgical staff experienced with the operation of ultrasonic devices for cement removal and haemostatic tissue incision, in a professional clinical setting. See relevant **Error! Reference source not found.**.

Target Population

There are no specific restrictions based on age, weight, health status or ethnicity. No specific patient populations have been defined but patients with contraindication are to be excluded, see Contraindications.

Clinical Benefit

- During treatment with TORS, the patient benefits from the combination of two functions in one device: ultrasound bone cement removal and tissue coagulation/cutting.
- The use of an ultrasonic device for cement removal provides clinical benefit over mechanical cement removal methodologies, due to decreased trauma for the patient, leading to shorter recovery times.

Please note:

- This document does not reference surgical techniques.
- The safety & effectiveness of any ultrasonic surgical equipment is mostly dependent upon the surgeon and nursing staff.

Indications

TORS is indicated for use in the removal of polymethylmethacrylate (PMMA) bone cement in orthopaedic applications. It is also indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important.

Contraindications

- Do not use, if in the judgment of the surgeon, the use of ultrasonic surgical techniques are not in the best interest of the patient.
- Do not use for incising bone.
- The Soft tissue transducer is not indicated for the cutting of vessels exceeding 1.5mm in diameter or bone tissue.

Please read all Cautions contained in this document

The TORS System

TORS Patient Contacting Accessories

Figure 1: TORS Cement Transducer

Figure 2: TORS Soft Tissue Transducer + Probe

Figure 3 – Axial Grip with TDCR and Probe fitted

Figure 4 – Cement Probes

Safety ⚠

Cautions

- U.S. law restricts this device to sale by or on the order of a licensed physician.
- The nursing staff must be trained so that they are familiar with the equipment to be used.
- Avoid allowing an energized Probe to come into contact with any metal surface.
- Do not sterilize the TORS generator or Footswitch.
- Do not block or otherwise restrict the vents on the rear and bottom panels.
- Never allow electrosurgical equipment to contact the Probe.
- Always transport TORS using the supplied transport cases.
- The TORS generator has an Equipotential terminal on the back panel. This is provided for compatibility with other medical systems requiring such connections. This conductor is not intended for protective earthing. Refer to EN 60601-1 for details of use with ME Systems.
- TORS:

  i. should be used only for those procedures for which it is indicated.
  ii. should be used with an appropriate power level commensurate with the required task.
  iii. should be used with correct surgical technique.

  If used correctly the TORS should cut and coagulate tissue and remove PMMA cement to the satisfaction of the user.

  The equipment should inform the user of its status either by audio or visual means, unless ultrasound output is not possible. However, if a fault with the audio or visual indicators occurs whilst a cut is in progress, it may allow that cut to be completed without indication.

Complications and Potential Side-effects

General risks and complications of arthroplasty surgery

- Bone loss during prosthesis and/or cement removal
- Cortical perforation
- Fracture in the bone around the artificial joint
- Recovery time, pain and potential for arthritis associated with deliberate osteotomy
- Nerve/vascular lesions
- Rebleeding or haematoma / seroma
- Ligament, artery or nerve damage in the area around the knee joint
- Blood clots or deep vein thrombosis or pulmonary embolism
- Haemorrhage caused by tissue injury or ineffective haemostasis
- Bone/joint infection
- Late infection
- Infection of the wound and/or the tissue around the artificial joint
- Thromboembolism
- Implants or metal parts remaining in joint
- Fatigue fracture
- Excess bone forming around the artificial joint (knee) restricting movement
- Excess scar tissue forming and restricting movement
- Kneecap or hip dislocation
- Numbness in the vicinity of the wound scar
- Loosening of the artificial joint (normally after 10-15 years)
- Joint wear and tear
- Joint stiffening
- Bone cement implantation syndrome
- Hypoxia
- Hypotension
- Cardiac arrhythmias
- Cardiovascular collapse
- Thermal injury due to cement polymerization (setting) reaction
- Contact inhalational exposure to PMMA monomer leading to hypersensitivity
- Asthmatic reactions
- Neurological symptoms
- Localized irritation
- Personal risks from anesthetic or the surgery itself

Potential side-effects of ultrasonic arthroplasty surgery

- Necrosis and clinical dysfunction in femoral cortex and surrounding soft tissue due to heat transmission from ultrasonic probe/cement interface
- Intramedullary canal perforation
- Different tissues and bone cement will be heated to different degrees with the same ultrasound parameters
- Each cell type has a different susceptibility to thermal injury
- Pathologic humeral fracture
- Microscopic bone cracks
- Plume production (95% water, 5% cell debris)
- Radial nerve palsy
- Risk of cross-infection from re-sterilized reusable parts of the system

General complications of powered dissection in open soft tissue surgery

- Acute or delayed bleeding (blood loss), organ perforation or fistula formation
- Haemorrhage caused by tissue injury or ineffective haemostasis
- Necrosis due to excessive heat transmission from the dissector
- Infections at the site of application
- Nerve lesions/damage

Potential side-effects of ultrasonic powered dissection in open soft tissue surgery

- Necrosis in soft tissue due to cavitation/shock waves or excessive heat from ultrasonic probe
- Visibility reduction due to plume production (95% water, 5% cell debris) or smoke production
- Risk of transmission of mutagenic or toxic chemicals in the plume
- Risk of cross-infection from re-sterilized reusable parts of the system
- Device breakage and loss of components in the body cavity

Serious Incident

The Medical Device Regulation defines a serious incident as:

> "…any incident that directly or indirectly led, might have led or might lead to any of the following:
>
> (a) the death of a patient, user or other person,
>
> (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
>
> (c) a serious public health threat"

In the event that a serious incident occurs in relation to the TORS device, the user and/or patient should report the serious incident to the Manufacturer and to the Competent Authority of the state in which the user and/or patient is established.

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