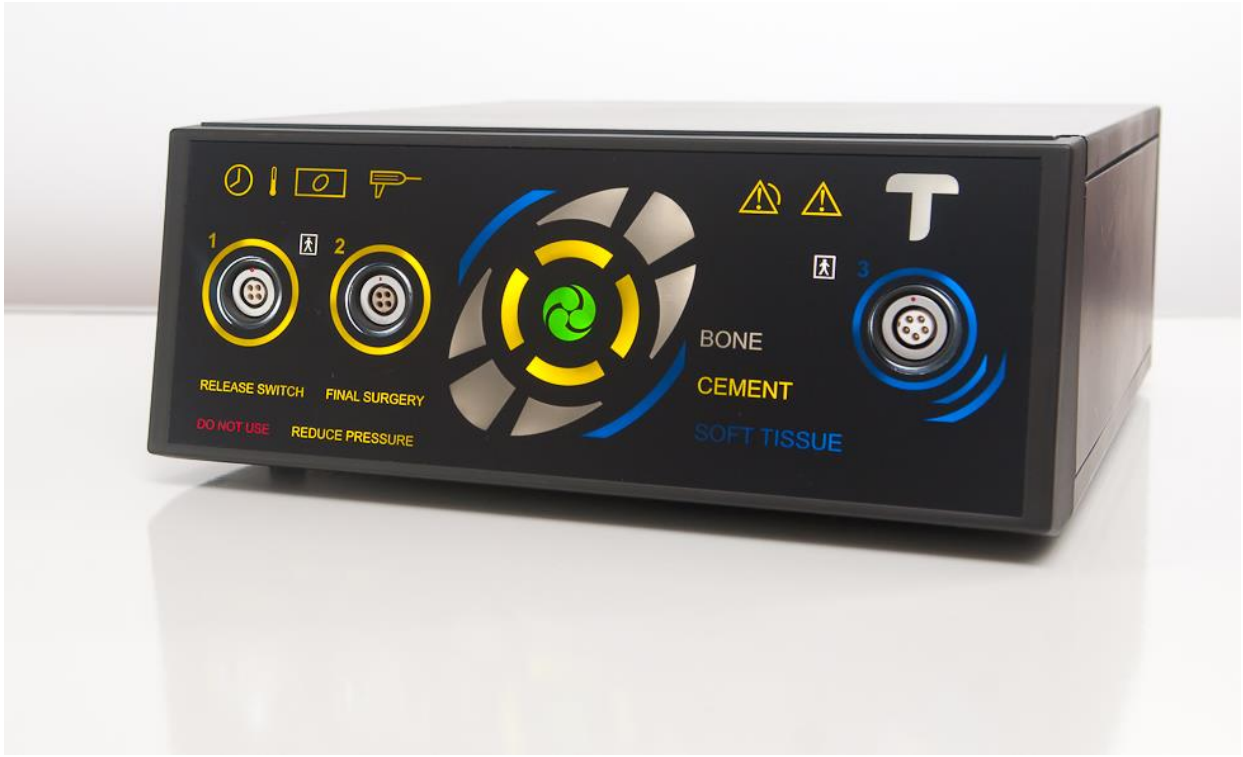
TORS

Torsional Orthopaedic Revision System

Patient Handbook



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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.

Intended user

TORS is intended to be used by surgical staff experienced with the operation of ultrasonic devices for cement removal, in a professional clinical setting.

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 ultrasound bone cement removal.
- **TORS is a state-of-the-art device for efficient cement removal in orthopaedic revision surgeries**. It provides clinical benefit over mechanical cement removal methodologies through reduced risk of perforation compared to conventional **mechanical** methods in hip. It may also be used in knee, elbow and shoulder.

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.

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.

Please read all Cautions contained in this document

The TORS System

TORS Patient Contacting Accessories

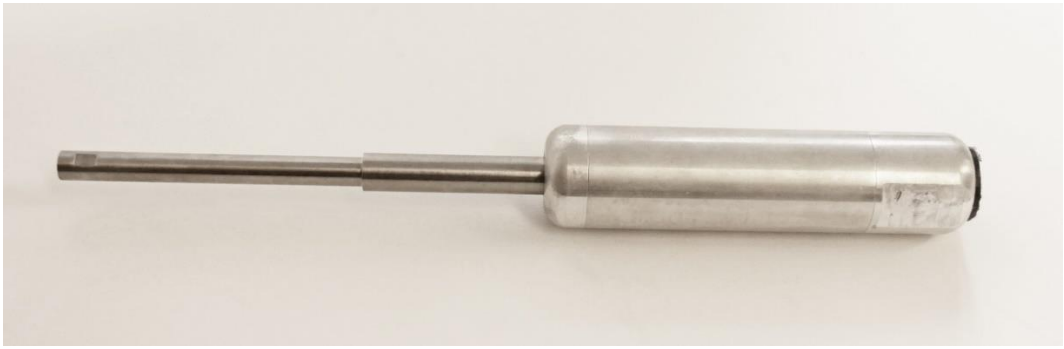

Figure 1: TORS Cement Transducer

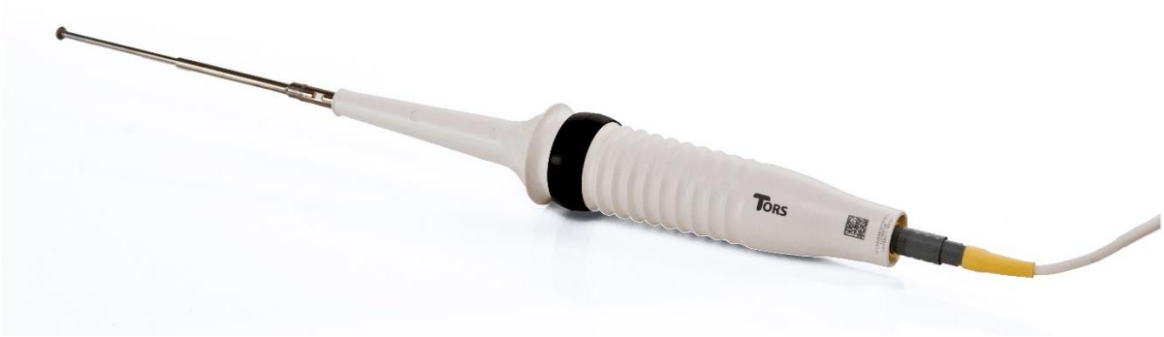

Figure 2 – Axial Grip with TDCR and Probe fitted

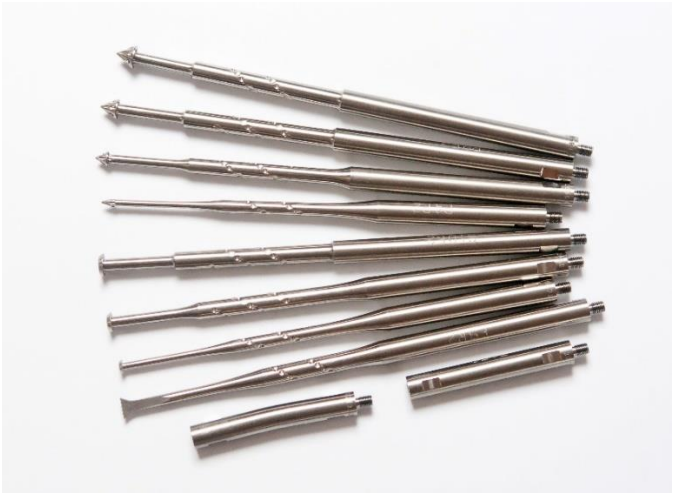

Figure 3 – Cement Probes

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.
- Before any sterile packed (single use) accessory for TORS is opened, it must be inspected for packaging integrity. The outer carton may be dented, crumpled or even punctured so long as the sealed pouch inside is not punctured. If a bend or wrinkle in the pouch makes puncture likely DO NOT OPEN/USE but return to manufacturer.
- Avoid allowing an active probe to come into contact with any metal surface. Any damage increases the risk of fatigue, which might result in tip detachment from the probe.
- Do not sterilize the TORS generator or Footswitch.
- Do not allow the generator to enter the sterile field in theater.
- Do not block or otherwise restrict the vents on the rear and bottom panels.
- Never allow electrosurgical equipment to contact the Probe.
- Do not spill any liquid upon the generator.
- Ensure that more than one single use axial-grip handpiece is available in case of accidental contamination.
- 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

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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