

RSL DECONTAMINATION CERTIFICATE



PRODUCT CODE & DESCRIPTION	0105060634770309 – T1IK - INSTRUMENT KIT
SALES ORDER No.	SO

Tick box A, if applicable to this product.

Otherwise complete all parts of B, providing further information as requested or appropriate.

- A** This equipment is new.
- B** Some or all of this equipment has been cleaned and decontaminated: **YES / NO**

If **YES**, provide details of the method of decontamination (Please tick only one option below):

Full Manual Clean/Disinfection, followed by Autoclave Cycle @ 270°F to 277°F for 3 minutes.

Decontamination Certificate received from previous user (available upon request).
 Equipment subjected to additional Autoclave Cycle only @ 270°F to 277°F for 3 minutes, as part of our routine servicing/repair process.

Please note, that although Radley Scientific Ltd have performed the tasks detailed above as part of our routine servicing/repair process, the decontaminated equipment is supplied clean but not sterile. As such, the equipment should be cleaned, disinfected and sterilised prior to the final intended use, following the guidelines stipulated in the supplied reprocessing instructions and in agreement with the local decontamination policy.

If **NO** and the equipment was unable to be decontaminated, please provide reason below:

The most likely cause of contamination is:

The equipment has been prepared to ensure safe handling / transportation: **YES / NO**

I declare that the above information is true and complete to the best of my knowledge and belief:

(Please note, that this certificate can only be compiled and signed, by the appropriate trained personnel, in accordance with WIG0006)

Signed:	Company:	Radley Scientific Ltd
Print Name:	Address:	Bremridge House Ashburton Devon UK
Position:	Postcode:	TQ13 7JX
Decontamination Technician/TORS TDCR Build + Service	Telephone Number:	+ 44 (0)1364 653899
Date:	Email:	enquiries@tors.co.uk
	Website:	www.tors.co.uk

TRAY CONTENTS

ALL PARTS OF THE INSTRUMENT KIT ARE REUSABLE

Item	Code	Description	S/N	New/Used*
1	P4R2	Cement 200 Ø4 Piercer Probe	1868-	NEW
2	P6R2	Cement 200 Ø6 Piercer Probe	1851-	NEW
3	P8R2	Cement 200 Ø8 Piercer Probe	1864-	NEW
4	P10R2	Cement 200 Ø10 Piercer Probe	1866-I3-	NEW
5	S6R2	Cement 200 Ø6 Scraper Probe	1867-I2-	NEW
6	S8R2	Cement 200 Ø8 Scraper Probe	1828-I3-	NEW
7	S10R2	Cement 200 Ø10 Scraper Probe	1836-I3-	NEW
8	ECR1	Short Curved Extension Bar	2311-I1-	NEW
9	ESR1	Short Straight Extension Bar	2310-I1-	NEW
10	T1S	Spanner	2069-I4-	NEW
11	T1S	Spanner	2069-I4-	NEW
12	T1CC	Cement Cable	1073-I7-	NEW
13	T1CC	Cement Cable	1073-I7-	NEW
14	T1CT	Cement Transducer	1313-I8-	NEW
15	T1CT	Cement Transducer	1313-I8-	NEW

DECONTAMINATION

In order to replicate the validated decontamination and sterilization processes for the TORS device, Sterilization and Decontamination Units must operate procedures and equipment that conform to ISO 17665-1. Validation of the sterilization process has been completed for steam autoclave cycles with an active phase of 3 minutes at 134°C.

The Cement handpiece is supplied pre-sterilized and is designed for single patient use.

After use the Cement handpiece should be disposed of as per normal theatre protocol, ideally in a suitably sized biohazard container.

The Cement Handpiece is not designed for cleaning and sterilization after use. Post-operative cleaning and sterilization processes have not been validated by the manufacturer and any attempt at such process could cause the Cement handpiece to malfunction.

The Cement Transducer can be cleaned and sterilized after use. See Equipment Care below for guidance on inspecting and replacing transducers and Cement Probes.

Cement probes are detached from Cement transducers for decontamination.

	<p>T1AH - Cement axial grip handpiece (Single Use)</p> <p>Supplied sterile (ethylene oxide)</p> <p>DO NOT USE IF PACKAGING HAS BEEN DAMAGED!</p>	
	<p>T1CT - Cement transducer (Reusable Applied Part)</p>	<p>These accessories are supplied in a non-sterile condition. The end user must complete decontamination and sterilization processes before use.</p>
	<p>T1CC Cement cable (Reusable)</p>	<p>The end user must complete decontamination and sterilization processes before use.</p>
<p>Figure 1 Patient contacting parts that must be sterile</p>		

	<p>Cement probes</p> <p>P4R2 P6R2 P8R2 P10R2</p> <p>S6R2 S8R2 S10R2</p> <p>Extension bars</p> <p>ESR1 ECR1 (Reusable Applied Parts, user sterilized)</p>	<p>These accessories are all supplied in a non-sterile condition. The end user must complete decontamination and sterilization processes before use.</p>
<p>Figure 1 (continued) Patient contacting parts that must be sterile</p>		

Reprocessing Guidelines: Immediately After Use in Operating Theatre (OR)

- Immediately after use wipe down all components and remove any surplus body fluids and debris.
- After final use some of the cement may remain adhered to the probe distal end, particularly within holes in the Piercer probe heads. This is easily removed by activating the blade in a suspension of fine abrasive grit in water. This is provided with the TORS system in the form of a single use cleaning cell.

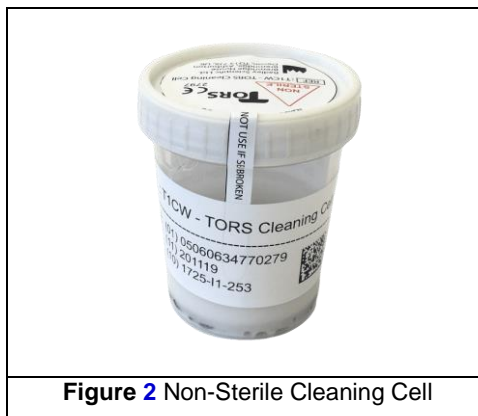


Figure 2 Non-Sterile Cleaning Cell

IMPORTANT: The cleaning cell is NOT sterile.

NOT for use *during* procedure

ONLY use at the end of the procedure prior to washing and re-sterilization of probes

Unscrew the cleaning cell lid and pierce the foil seal with the first probe. Activate each used probe in turn in the grit/water suspension in the cleaning cell, swirling the head around in the suspension for 20s. at least. Repeat if necessary. This will remove cement adhered to the surfaces.

After Use

- Detach the Cement Cable(s) from the Cement Transducer(s) by disconnecting from the handpiece.
- Remove the Sleeve from the Grip on the Cement Handpiece. Detach the Handpiece from the Cement Transducer by pulling the Transducer and the Handpiece apart.
- Detach the Cement probe from the Cement Transducer using BOTH supplied spanners.
- Replace the Transducers, Cables, reusable Probes and spanners back into the autoclave tray, preferably within its original wrap to reduce drying of soil while it is returned to the cleaning facility.

Single Use Items

- Dispose of the Cement Handpiece Grip and Sleeve and the Cleaning Cell, [and the opened/used probes](#) as per hospital protocols.

Reusable Items

Manual Cleaning

- Prepare enzymatic cleaning solution (e.g. Gigazyme Plus) to manufacturer's instructions.
- Soak soiled instruments in enzymatic solution for 5 minutes.
- When cleaning, fully submerge the instruments in the cleaning solution. Brush with soft non-metallic bristle brush or cloth to remove all traces of blood and debris, concentrating on any crevices, seams, or other surface discontinuities. Clean holes and recesses using an appropriate brush ensuring that the full depth of the feature is reached. Ensure instruments are visibly clean before progressing to the next step.
- Rinse instruments thoroughly with clean running water for 2 minutes. Ensure that blind holes and recesses are repeatedly filled and emptied with running water.
- Dry instruments immediately after final rinse. Do not exceed 140°C (285°F)

Automated Cleaning

- Instruments may require manual cleaning prior to automated cleaning to improve the removal of adherent soil. Brush with a non-metallic bristle brush in enzymatic cleaning solution.
- Load instruments such that crevices, seams, surface discontinuities, holes and recesses can drain.
- Clean using the "Instruments" cycle in a validated washer disinfecter and a pH neutral cleaning agent intended for use in automatic cleaning (e.g. Getinge Enzymatic Detergent). The cleaning cycle should incorporate pre-rinse, wash, rinse, thermal rinse and drying steps. The duration and temperature of the steps may vary between different washing systems/devices but any washer/disinfecter cycle which is validated to ISO 15583-1 & ISO 15883-2 is suitable for processing the TORS device(s). Do not exceed 140°C (285°F).
- An alkaline cleaning solution such as, for example, Serchem pH Plus Detergent, with a pH up to 13.2 may be used instead of, or in addition to, an enzymatic solution.

Cleaning Inspection

- Inspect all instruments prior to sterilization or storage to ensure the complete removal of soiled surfaces.
- Visually inspect instruments, if soil is still present clean instruments again.
- Inspect cables for wear and damage, ensuring that no cracks, tears, or other damage is found.
- Check to see that Probes are free of scratches.
- Report any damage found to the Radley Scientific representative.

Wrapping

- Double wrap in accordance with local procedures, using standard procedures wrapping techniques such as those described in ANSI/AAMI ST46-1993
- Label contents of wrapped tray using indelible marker or other sterilization compatible label system.

Sterilization

- Sterilization is best achieved on the day preceding the surgery, but must be at least one hour prior to use to allow the equipment to cool and stabilize.
- ⚠ Transducers are NOT to be submerged in water to expedite cooling.
- ⚠ Do NOT sterilize the Generator or Footswitches
- These components have been validated for sterilization by the following method in a vacuum autoclave. The parameters for this being 270°- 277°F for a minimum of 3 and a maximum of 4 minutes.
- Next Use - After decontamination, the Transducers, Cement cables, probes and spanners can be re-sterilized as above.

Drying Time

After sterilization at 270°F the validated drying time is 30 minutes.

End of Life Management

TORS generator and all reusable accessories (including Transducers) should be recycled. Contact RSL for return instructions - see end page of this IFU.

A valid decontamination certificate must accompany each returned Transducer, Probe or Cement cable.

Opened in Error

In the event of a Single Use Handpiece being unwrapped in error, it may not be re-sterilized.

Care should be taken to ensure that the cables are not kinked during sterilization as this can produce cracks in the cable and reduce cable life.

Cleaning the Generator

The TORS Generator may be cleaned as follows:

- i. Dilute a neutral pH detergent according to the manufacturer's directions.
- ii. Using above solution, lightly moisten a soft, clean cloth. Wipe surfaces of the Generator.
- iii. Using tap water, lightly moisten a soft, clean cloth. Wipe surfaces of the Generator.
- iv. Dry Generator surfaces with a soft clean cloth.

Cleaning the Footswitch

The TORS Footswitches may be cleaned as follows:

- i. Dilute a neutral pH detergent according to the manufacturer's directions.
- ii. Using above solution, lightly moisten a soft, clean cloth. Wipe surfaces of the Footswitch.
- iii. Using tap water, lightly moisten a soft, clean cloth. Wipe surfaces of the Footswitch.
- iv. Dry Footswitch surfaces with a soft clean cloth.
- v. Do not allow any water to enter into the air-hoses.
- vi. Do not detach the air hoses from the Footswitch.