INSTRUCTIONS FOR USE - **EN**

**INSTRUMENTATION KIT CLEANING AND STERILIZATION**

IFU-7638 GLB EN Rev H

CE-Marking is only valid if it is also mentioned on the external package labeling.

2797


TORNIER

Tornier, Inc.
10801 Nesbitt Avenue So.
Bloomington, MN 55437
USA
Tel: (952) 921-7100
Fax: (952) 236-4007

EC REP

Tornier S.A.S
161 rue Lavoisier
38330 Montbonnot Saint Martin
France
Tel: 33 (0) 476 613 500
Fax: 33 (0) 476 613 533


| Symbol | Definition | ISO 15223-1* reference number |
|---|---|---|
| | Manufacturer | 5.1.1 |
| EC REP | Authorized Representative of the European Community | 5.1.2 |
| | Use By Date | 5.1.4 |
| LOT | Batch Code | 5.1.5 |
| REF | Catalog Number | 5.1.6 |
| SN | Serial Number | 5.1.7 |
| STERILE R | Sterilized using Irradiation | 5.2.4 |
| NON STERILE | Non-Sterile | 5.2.7 |
| 2 | Do Not Re-sterilize | 5.2.6 |
| | Do Not Use if packaging is damaged | 5.2.8 |
| | Do Not Reuse | 5.4.2 |
| or IFU.wright.com | Consult Instructions for Use | 5.4.3 |
| | Caution, Consult Accompanying Documents | 5.4.4 |
| Rx only | Caution: Federal Law (USA) restricts this device to sale by or order of a physician | N/A |
| LATEX | Not Made with Natural Rubber Latex | N/A |
| | Contains Hazardous Substances | N/A |
| MD | Medical Device | N/A |
| | Double Sterile Barrier System | N/A |
| | Importer | N/A |
| | Date of manufacture | N/A |
| UDI | UDI | N/A |
| MR | MR Conditional | N/A |

ISO 15223-1, Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied, Part 1: General requirements



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For additional information and translations please contact the manufacturer or local distributor.

The manufacturer recommends that all personnel responsible for handling and implanting the devices read and understand this information before use. The use of surgical instrumentation requires knowledge of anatomy, biomechanics, and reconstructive surgery of the musculo-skeletal system. Surgical instrumentation must be used only by a qualified surgeon operating in accordance with current information on the state of scientific progress and the art of surgery.
The user must ensure the adequate condition and function of surgical instrumentation before use.

## IMPORTANT:

When the hospital does not own the surgical instrumentation, it accepts invoicing and delivers payment in the following cases:

- When the instrumentation must be destroyed according to sanitary rules
- When the instrumentation has been damaged due to non-respect of Tornier instructions mentioned herein.

## 1. DESCRIPTION

The surgical instrumentation consists of ancillary instruments, packaging trays as well as containers. The instrumentation type is inscribed on the metal container or, if the instrument is delivered individually, on the packaging. The exact designation of each instrument is given on the instrumentation list supplied or, if the instrument is delivered individually, on the package label.
Symbols are sometimes used to identify instruments (labeling or marking) and they have the following meanings:
XS = Extra-small;
S or SM = Small;
S+ or SM+ = Small+;
M or ME = Medium;
M+ or ME+ = Medium+;
L or LA = Large;
L+ or LA+ = Large+;
XL = Extra-large;
2XL = Extra-extra-large;
3XL = Extra-extra-extra-large;
L = Left;
R = Right;
"-" = Short neck; "0" = Medium neck; "+" = Long neck.
Tornier surgical instrumentation has been specially designed to facilitate the implantation of Tornier implants and must be used solely for this purpose. It is important to refer to the technical documentation prior to the operation, or contact your Tornier representative for a more detailed description of how to use the instrumentation. Under no circumstance should an instrument be implanted. The selection of the appropriate instrumentation can be made by using the recommendation of the corresponding surgical technique.

**COMPATIBLE SYSTEMS:**
This device is intended for use in combination with other devices. For a list of compatible devices, please reference the corresponding surgical technique.

## 2. INTENDED USE:

The surgical instrumentation is intended to be used by surgeons for the implantation and explantation of implants in orthopedic surgery.
Do not modify the instruments.

**SIDE EFFECTS AND POSSIBLE COMPLICATIONS**

- Dissociation of components
- Component loosening or migration
- Dislocation
- Component breakage
- Component wear
- Instability of component
- Infection or any other event that could follow surgery
- Postoperative pain
- Surgical delay
- Metal sensitivity

## 3. INSTRUMENT DELIVERED NON-STERILE

When surgical instrumentation is delivered non-sterile, the hospital is responsible for its point-of-use processing, cleaning and sterilization prior to use, in accordance with validated methods. The following recommendations do not substitute for the sanitary rules in force: standards, guides, government notices, ministerial texts, etc…
Before any operation, it is necessary to remove wedging foam in the metal containers as well as plastic bags if the instrument is delivered individually.
Instruments made up of removable components must be dismantled before point-of-use processing and cleaning, in accordance with instructions provided in the inventory list. Articulated instruments must be opened in order to allow the cleaning of all interstices.

From a functional perspective, an inspection must be carried out prior to use to check for any burrs or debris that could damage tissue or personal protective equipment. Furthermore, the integrity of cutting tools and rotating tools must be verified. Any device deemed to be dull or non-functional in any manner should be returned to Tornier for maintenance or exchange.
The instructions hereafter must be followed in order to maintain optimal efficiency and safety of instruments:

- The use of metallic brushes, scrub pads and other articles likely to damage the instruments must be avoided.
- Chemicals such as chlorine or soda as well as organic or ammoniated acids or solvents (e.g. acetone) which are likely to damage the instruments must not be used.
- Chemicals including soda must not be used for metal containers.
- Phosphoric acid must not be used for the neutralization of alkaline residues after the cycle of automated machine cleaning on instrumentation packaging trays and on instruments made up of polymer pieces (example: polymer handle).

**Note:** Orthopedic procedures are not considered at risk in relation to NCTA (Non-Conventional Transmissible Agents). A complete cleaning using molar sodium (1N) or sodium hypochlorite with a concentration of 2% active chlorine should only be reserved for instruments that have been used on a patient with suspected or confirmed TSE (Transmissible Spongiform Encephalopaties) before the invasive procedure.
While Tornier performs routine inspections on instrument sets when receiving and distributing, the lifetime of non-sterile instruments is dependent upon a number of factors including, but not limited to, method and duration of use and handling of instruments between uses. Consequently, Tornier does not claim a maximum number of uses, but recommends thorough functional inspection, as previously cited, to verify the absence of wear/damage and to be sure of their efficacy.

## 3.1. STORAGE AND HANDLING:

Surgical instrumentation must be handled with care and stored in an appropriate, clean and dry location. It is recommended to remove instruments from plastic bags before storing them to avoid condensation. Instruments must not be stored in contact with or near products that may have a corrosive effect.

## 3.2. POINT-OF-USE PROCESSING

Point-of-use processing aims to make subsequent cleaning easier. It is also intended to protect staff while handling instruments and avoid contamination of the environment. All reusable devices must undergo immediate point-of-use processing or be immediately treated in a washer-disinfector.
Point-of-use processing is achieved by dipping instruments, for a minimum of 15 minutes, in a neutral or alkaline solution that does not contain aldehyde nor ethanol. The use of soft-bristled brushes is authorized to clean the parts from all soils that can potentially alter the action of detergents and decontaminants. Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils. The instruments should then be carefully rinsed in a controlled water to avoid interference between the cleaning solutions. It is important to refer to the instructions supplied by the manufacturer of these products.
**CAUTION:** Packaging trays and baskets must not be in contact with decontaminating solutions for a long time. Clean dirty areas and rinse immediately.

## 3.3. CLEANING:

The equipment is then thoroughly cleaned out of the container (the efficiency of parts cleaned inside their loading container is not ensured), after disassembly if assembly/disassembly instructions are provided. A cleaning process done out of qualification ranges can lead to sterility or toxicity issue. Cleaning eliminates contamination of the material. It must be performed in a washer-disinfector with a detergent equivalent to those listed in the next table. Refer to the manufacturers' labeling for instructions on how to use the washer-disinfector. The detergent shall be selected for medical applications and present no known residual toxicity for the patient. The use of a mechanical action through manual or ultra-sonic means is recommended. In case the process cannot be done automatically, a manual process shall be used by reproducing the conditions described in the cleaning recommendations. The cleaning cycle must include a final rinse with a controlled water. Time, water flow and rinsing volumes shall be sufficient to produce a low level of cleaning agent residues left on the product surface. Instruments should be carefully dried to avoid recontamination.
A thermal decontamination at 93°C is recommended. After cleaning, please inspect devices to ensure they are visually clean. If not, repeat the cleaning process until devices are visually clean. The correct operation of each instrument must be inspected thereafter per the specific product documentation supplied.
The cleaning conditions validated by Tornier can be found in this document.
For Europe only: In the case of patients with suspected or confirmed TSE, the cleaning procedure for the washer-disinfector shall be done after a decontamination process conform to the instruction DGS/RI3/2011/449.

| | Immersion | | | Rinsing 1 | Rinsing 2 | Drying |
|---|---|---|---|---|---|---|
| | Solution | Time (min) | T°C | Water | Water | |
| 1. Pre-disinfection/ Decontamination | MEDICLEAN, MEDICLEAN FORTE, or ALKAZYME 0.5% | 15 | Ambient | Tap water 30s to 1' in ambient temperature | | |
| 2. Manual precleaning on ultrasonic bath | MEDICLEAN FORTE 2% | 5 | 20-30°C | Tap water 30s to 1' in ambient temperature | Purified water 30s to 1' in ambient temperature | |
| 3. Automatic cleaning process | MEDICLEAN or MEDICLEAN FORTE 0.6% | 10 | 93°C | Purified or Deionized water in ambient temperature | | yes |

## 3.4. STERILIZATION:

Instruments, packaging trays and baskets are adapted for steam sterilization at a temperature not exceeding 140°C. Sterilization is mandatory for Tornier instruments, disinfection is not sufficient. It shall be done using the containers wrapped per the l'ANSI AAMI ST 79, Fig.6.In the USA, a FDA cleared wrap for sterilization should be used.
The instruments' function shall be controlled before the sterilization per the specific product check-lists supplied.
Generally speaking, the instruments must be sterilized when assembled, but certain instruments consisting of components that can be disassembled must be disassembled before pre-disinfection and cleaning if assembly/disassembly instructions are provided with the product check-list.
After sterilization, the wrapped trays shall be handled with care to the point of use to prevent any disrupture of the sterile barrier.
The sterilization conditions validated by Tornier can be found in this document. Instruments, packaging trays and baskets may be sterilized in their container.
The heaviest containers must be placed at the bottom of the autoclave.
Instrument trays must not be stacked together during sterilization.
In order to avoid residual water in containers after sterilization we advise that a folded paper or non-woven sheet is placed on the back of the container before sterilization, to improve vaporization during final drying.
Tornier recommends to sterilize through one of the 3 following method: (tables 1, 2, 3).

| Table 1* | Pre-vacuum method |
|---|---|
| T°C | 132°C (269.6°F) |
| Time | 4 min |
| Drying | 20 min |
| Wrapped | yes |

*Sterilization parameters recommended in North America

| Table 2 | Pre-vacuum method |
|---|---|
| T°C | 134°C (273.2°F) |
| Time | 18 min |
| Drying | 20 min |
| Wrapped | yes |

| Table 3** | Pre-vacuum method |
|---|---|
| T°C | 134°C (273.2°F) |
| Time | 3 min |
| Drying | 20 min |
| Wrapped | yes |

**Sterilization parameters recommended in the UK

## 3.5 AFTER USE:

After each use and before returning to Tornier, the instrumentation (entire box or isolated instrument) must be point-of-use processed, cleaned and sterilized according to the aforementioned recommendations. Instruments that appear to be non-functional must immediately be sent to Tornier for maintenance or exchange. The nature of dysfunction must be clearly indicated. The instrumentation must be correctly packaged before being returned, and the original positioning of the components in corresponding containers should be respected.
Instrumentation must be returned with the Count Sheet filled in and duly signed by authorized hospital personnel (with respect to position, qualification or authority).

**LIFETIME OF DEVICE**

The end of life for each device is determined when the device's characteristics or performance indicate that the health or safety of the patient or user may be compromised. The device's lifetime depends on many factors, including but not limited to, method and duration of use and level of reprocessing. Hence Tornier does not define the maximum number of uses. Careful inspection and functional testing should be completed. Examine the cutting edges, flutes, tip, shaft, handle, and features of the working end, as applicable, for dulling, chipping, warping, cracking, or other indications of material degradation or compromised structural integrity. If the device displays any of these signs of wear or other indications of malfunction, it is recommended to discontinue use and replace the device. Per the surgical technique, actuate moving parts and assemble mating devices to test for sticking or obstruction. If moving or mating parts display limited functionality, replace the device(s).
During the surgery, devices may experience a variety of forces which cannot be fully anticipated. Even with proper reprocessing, maintenance, and inspection, devices may reach the end of their lifetime during surgery. A replacement or alternative should be available to the surgeon.

## 4. CLOSED CONTAINER CLEANING AND STERILIZATION INSTRUCTIONS

Closed container validation has been completed with Aesculap Steril Container System. Ensure that the sterilization container is in proper working order prior to sterilization. The care and handling of these containers can be found at www.aesculapusa.com\ifu.
NOTE: THE STERILIZATION PARAMETERS WITHIN THE AESCULAP STERIL CONTAINER INSTRUCTIONS-FOR-USE DO NOT SUPERSEDE THE STERILIZATION PARAMETERS OUTLINED BELOW.
Only FDA cleared Aesculap Steril Containers, excluding JK744, are to be used. (e.g. Lid JK489, Base JK444, Filter US994 or Lid JK789, Base JK742, Filter US994)

| Table 4*** | Pre-vacuum method |
|---|---|
| T°C | 132°C (270°F) |
| Time | 4 min |
| Drying | 15 min |
| Wrapped | No |

***Sterilization parameters recommended for Aesuclap Steril Container in U.S. Only

## 5. SINGLE USE INSTRUMENT DELIVERED STERILE

### 5.1. PRECAUTIONS OF USE:

- **Never re-use an instrument designated for single-use, even if it appears to be in perfect condition, to prevent any risks of cross-contamination or a risk of reduced performances.**
- **Never re-sterilize an instrument designated for single-use.**

## 5.2. STORAGE AND HANDLING:

The instrumentation must be stored in an appropriate, dry and clean location to prevent any loss of sterility.
Instrumentations must not be exposed to direct sunlight, ionising radiation, extreme temperatures nor particular contamination. Instrumentations must be handled with care to preserve integrity of their packaging.
Instruments delivered sterile must be stored in their sealed packaging of origin.

## 5.3. PACKAGING AND STERILIZATION:

Instruments delivered sterile are sterilized by gamma irradiation. The expiration date for sterilization and integrity of the packaging must be checked.
An instrument whose packaging is open or damaged or whose expiration date has passed must not be used.
Every precaution must be taken to ensure sterility when opening the packaging of the instrument.

## REFERENCE DOCUMENTS


- French rule DGS/RI3/2001/449 of December 1st, 2011 updating recommendations to reduce the risk of transmitting non-conventional transmissible agents during invasive procedures and French Circular DGS/SD5C/DHOS/2005/435 of 23 September 2005 regarding recommendations for treatment of medical devices used on patients having received labile blood products retrospectively from donors that suffered suffering from a variant of Creutzfeld-Jakob Disease (CJD).
- Good Pharmaceutical Practice – 22 June 2001 French regulation.
- FD S 98-135 : April 2005 – Guide for the sterilisation of medical devices – Treatments applied to reusable medical devices.
- NF EN ISO 17664 – August 2004 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- "Recommended practices for sterilization in perioperative practice settings," in *Standards, Recommended Practices, and Guidelines* (Denver: AORN, Inc, 2007) 673 – 677.
  Comprehensive guide to steam sterilization and sterility assurance in health care facilities - ANSI/AAMI ST79-2010.
  AAMI TIR12 : Designing, testing, and labelling reusable medical devices for reprocessing in health care facilities : a guide for medical device manufacturers.
  AAMI TIR30 : A compendium of processes, materials, test methods, and acceptance criterias for cleaning reusable devices.
- "Health Technical Memorandum 2010" – Part 2: design considerations – Sterilization – London: HMSO – NHS Estates
- NF EN ISO 17665-1: November 2006: Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices