INSTRUCTIONS FOR USE - **EN**

Tornier Instrumentation
UTBI GLB EN Rev 211

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

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

Symbol	Definition
	Manufacturer
EC REP	Authorized Representative of the European Community
	Use By Date
LOT	Batch Code
REF	Catalog Number
SN	Serial Number
STERILE R	Sterilized using Irradiation
NON STERILE	Non-Sterile
2	Do Not Re-sterilize
	Do Not Use if packaging is damaged
	Do Not Reuse
or	Consult Instructions for Use
	Caution, Consult Accompanying Documents
Rx only	Caution: Federal Law (USA) restricts this device to sale by or order of a physician
LATEX	Not Made with Natural Rubber Latex
	Contains Hazardous Substances
MD	Medical Device
	Double Sterile Barrier System
	Importer
	Date of manufacture
UDI	UDI
	MR Conditional

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

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 packed according to ISO 11607-1 with tray, basket or basket lid delivered in a container or are packed individually in pouches. 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.

2. INTENDED USE:

The surgical instrumentation is used by surgeons for the implantation and explantation of implants in orthopedic surgery.

The patient target group and the claimed performances depend on the range of product used with those instrumentations. Please refer to specific implants instructions for use.

The following side effects, complications and residual risks may happen after use of Tornier SAS instruments:

- Pain
- Loosening of the device implanted
- Local adverse tissue reaction
- Osteolysis
- Infection
- Minor surgical delay
- Dissociation
- Dislocation
- Poor Joint Mechanics
- Injury to user

Do not modify the instruments.

3. INSTRUMENT DELIVERED NON-STERILE

All Tornier SAS reusable instruments delivered non-sterile must be controlled, predisinfected, cleaned and sterilized before its use in the operating room, according to validated methods described in §3.1 to 3.6 of this document. 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.

3.1.Visual and functional control:

All reusable instruments must be inspected visually, in order to detect any traces of dirt/impurities or corrosion. Special attention must be paid to placements that could trap dirt or debris.

Instruments made up of removable components must be dismantled before pre-disinfection and cleaning, in accordance with instructions provided in the assembly/disassembly check-list articulated instruments must be opened in order to allow the cleaning of all interstices.

On a functional level, an inspection must be carried out to check for the absence of chips or debris that could damage the tissue or personal protection. The cut of cutting tools must be verified. The integrity of rotating tools must be controlled. The healthcare establishment must control the assembly of modular instruments and verify that the mobile components articulate correctly.

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 polymere 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.

Even though Tornier carries out regular controls on its instruments when sending them out or accepting them back after loan periods, the lifetime of instruments delivered in a non-sterile condition depends on numerous factors, including but not limited to, method and duration of each use, as well as the handling of the instruments between two cases of use. Consequently, Tornier does not claim a maximum number of use or number of reprocessing cycle, but recommends that meticulous controls be carried out, as previously cited, in order to verify the absence of wear and damage to the instruments and therefore to be sure of their efficacy. If the device displays any signs of wear or other indications of malfunction, it is recommended to discontinue use and replace the device. Per the functional check-list, 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). The signs of degradation should be verified in accordance with the instrumentation set check-list delivered with the instrumentation set.

3.2. STORAGE AND HANDLING: Surgical instrumentation must be handled with care and stored in an appropriate, clean and dry location in order to avoid damage, minimize time before cleaning and avoid drying of soil prior to cleaning. 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.

3.3. PRE-DISINFECTION: Pre-disinfection aims to reduce the population of micro-organisms and to make subsequent cleaning easier. It is also intended to protect staff while handling instruments and avoid contamination of the environment. Tornier SAS recommends the use of a washer disinfector according to ISO 15883-1 and 5 for all reusable devices. The washer-disinfector must be used by qualified healthcare people trained by the automated equipment manufacturer. All reusable devices must undergo immediate pre-disinfection or be immediately cleaned according to the cleaning process steps, specified in section 3.4

Pre-disinfection is achieved by soaking instruments, for a minimum of 15 minutes, in a neutral or alkaline decontaminant/disinfectant bactericidal, fungicidal and possibly virucidal solution that does not contain aldehyde nor ethanol. The use of brushes is authorized to clean the parts from all soils that can potentially alter the action of detergents and decontaminants. The instruments should then be thoroughly rinsed in a controlled water to avoid interference between the decontaminant/disinfectant and cleaning solutions. It is important to refer to the instructions supplied by the manufacturer of these products.

Find below, the pre-disinfection condition validated by Tornier SAS.

CAUTION: Packaging trays and baskets must not be in contact with decontaminating/disinfectant solutions for a long time. Clean dirty areas and rinse immediately.

Manual pre-disinfection						
Stage	*Product*	*Type*	*Conc.*	*pH (at the condition of use)*	*T(°C)*	*Time*
Pre-disinfection Soaking Brush if there are stains	Anios'Clean Excel D	Pre-disinfectant cleanser	0,5%	7,4	Cold or warmwater (<45°C)	>15 min
Rinse	Tap water	NA	NA	NA	Room temperature	>1 min

3.4. CLEANING:

Tornier cleaning validation has been performed on unpackaged parts and does not recommend the use of boxes, trays or baskets for the cleaning process. While using packaging trays, baskets and boxes may be appropriate, the responsibility for validation and evaluation of the cleaning of instruments in those articles would be on the end-user. If an assembly/disassembly instruction is provided for a device, then they must be disassembled before pre-disinfection ste. A cleaning process done out of qualification ranges can lead to sterility or toxicity issue.

The cleaning reduces contamination of the instruments. It must be performed in a washer-disinfector with a neutral or slightly alkaline detergent used at the washer-disinfector manufacturer recommended temperature. The selected detergent must be usable for medical applications and must not have known toxic effect for the patient. The cleaning cycle must include a final rinse with an osmosis water or distilled water. Time, water flow and rinsing volumes shall be sufficient to produce a low level of cleaning agent residues left on the product surface.

At the final rinse, a thermal decontamination at 93°C for 3 minutes minimum is recommended. The material must be carefully dried to avoid recontamination.

Find below, the cleaning condition validated by Tornier SAS.

Manual pre-cleaning (Only for complex geometries)						
Stage	*Product*	*Type*	*Conc.*	*pH (at the condition of use)*	*T(°C)*	*Time*
Pre-cleaning by swabbing or wiping	Neodisher® MediClean forte	Alkaline enzymatic	2% (V/V)	~10,4-10,8	Room temperature	5 min
Rinse soaking	Purified water	NA	NA	NA	Room temperature	1 min

Automatic cleaning						
Stage	*Product*	*Type*	*Conc.*	*pH (at the condition of use)*	*T(°C)*	*Time*
Cleaning 1	Tap or purifiedwater	NA	NA	NA	Room temperature (<45°C)	≥2 min
Cleaning 2	Neodisher® MediClean forte	Alkaline enzymatic	0,5% (V/V)	10,4-10,8	55±5°C	10 min
Rinse 1	Tap or purifiedwater	NA	NA	NA	≥ Room temperature (<45°C)	≥2 min
Rinse 2	Osmosis water or distilled water	NA	NA	NA	Increase to 93 ° C	≥15 min With a minimum of 3 min at 93°C
Drying	NA	NA	NA	NA	80±5°C	≥20 min

NOTE: The recommended quality for water used in final rinsing steps is a water exempt of mineral residues as well as high contamination with microorganisms and endotoxin.

Typically, a water quality as purified water defined by European Pharmacopeia is suitable.

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 and 29CFR1910.1030.Each instrument must then be inspected to verify its operation according to the specific documentation of the product supplied.

3.5. STERILIZATION: The process parameters shown in this paragraph are validated in accordance with EN ISO 17665, ANSI AAMI ST 79 and recommended for autoclave/steam sterilization.

It is recommended to wrap instruments placed in their packaging trays, baskets, with basket lids according to the process validation performed. Instruments, packaging trays and baskets are adapted for steam sterilization at a temperature not exceeding 140°C. Sterilization is mandatory for Tornier reusable instruments, disinfection and cleaning are not sufficient. It shall be done using the containers wrapped per the l'ANSI AAMI ST 79, Fig.6.

Despite some devices must be disassembled according to assembly/disassembly checklists for the cleaning step, they must be assembled for sterilization step.

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 describing sterilization conditions validated (tables 1, 2, 3):

Table1: Sterilization parameters

Table 1	**Pre-vacuum method**
T°C	134°C (273.2°F)
Time	18 min
Drying	20 min
Wrapped	yes

Table 2: Sterilization parameters recommended in North America

Table 2	**Pre-vacuum method**
T°C	132 °C (269,6 °F)
Time	4 min
Drying	20 min
Wrapped	yes

Table 3: Sterilization parameters recommended in the UK

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

After sterilization, the wrapped trays shall be handled with care to the point of use to prevent any disruption of the sterile barrier.

3.6 AFTER USE:
At the point of use, Tornier SAS recommends achieving the soaking of all reusable instruments immediately after use. After each use and before returning to Tornier, the instrumentation (entire box or isolated instrument) must be pre-disinfected, cleaned and sterilized according to the aforementioned recommendations. To avoid mechanical damage during the transport to processing area, the user must ensure that heavy devices do not get mixed with delicate ones. Transport the reusable instruments to the point where cleaning is to be performed as soon as practical. 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).

4. SINGLE USE INSTRUMENT DELIVERED STERILE

4.1. 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.**

4.2. 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.
4.3. 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.

5. INSTRUMENT BREAKAGE

DURING AN OPERATION, THERE IS A RISK OF BREAKAGE OF METAL INSTRUMENTS. NORMAL WEAR AND TEAR, INTENSE USE, OR EXCESSIVE FORCE ARE THE MAIN CAUSES OF INSTRUMENT BREAKAGE. TO LOCATE A METAL INSTRUMENT OR INSTRUMENT FRAGMENT, TORNIER RECOMMENDS USING X-RAY MEDICAL IMAGING EQUIPMENT.

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 – December 2017 – 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

- EN ISO 15883-1: September 2009: Washer-Disinfectors – Part 1: General requirements, terms and definitions and tests.

- EN ISO 15883-5: November 2005 – Washer-Disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

- EN ISO 11607-1: January 2018: Packaging for terminally sterilized medical devices