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TORNIER INSTRUMENTATION
INSTRUCTIONS FOR USE

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.

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

Do not modify the instruments.

3. INSTRUMENT DELIVERED NON-STERILE
When the Tornier ancillary is not delivered in sterile condition, it is the responsibility of the healthcare establishment to proceed with the control, pre-disinfection, cleaning and sterilization of the ancillary, before its use, according to 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.
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 inventory 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, such as the 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 utilization cases, 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.

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. 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. All reusable devices must undergo immediate pre-disinfection or be immediately treated in a washer-disinfector.

Pre-disinfection is achieved by dipping 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 carefully 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.
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 neutral or slightly alkaline detergent used at a maximum of 60°C. 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 of 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. 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 (see Conditions 1 and 2 in the next table).
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.
The use of lubricants to optimize the use of the instruments is authorized. The products used shall be selected specifically for a medical use.

		Immersion			Rinsing 1	Rinsing 2	Drying
		Solution	Time (min)	T°C	Water	Water	
Condition 1	1. Pre-disinfection / Decontamination	MEDICLEAN 0.5% or ALKAZYME 0.5% pH10-11	15	Ambient	Tap water 30s to 1' in ambient temperature		
	2. Manual precleaning on ultrasonic bath	MEDICLEAN FORTE 2% pH10.4-10.8	5	20-30°C	Tap water 30s to 1' in ambient temperature	Purified water30s to 1' in ambient temperature	
	3. Automatic cleaning process	MEDICLEAN 0.6% pH 8.5-9.5	10	93°C	Softened water 20mn in ambient temperature		yes
Condition 2	1. Pre-disinfection / Decontamination	ALKAZYME 0.5% pH10-11	15	Ambient	Tap water 30s to 1' in ambient temperature		
	2. Manual precleaning on ultrasonic bath	CIDEX OPA 7.2-7.8	5	20-30°C	Tap water 30s to 1' in ambient temperature	Purified water30s to 1' in ambient temperature	
	3. Automatic cleaning process	Prolystica 0.7% pH1.2	10	93°C	Softened water 20mn 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.
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.
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 pre-disinfected, 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).

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.

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

Interpretation of terms and symbols

Do not reuse

Expiration date

STERILE R — Sterilized using irradiation

LOT — Batch code (sterilization)

SN — Serial number (manufacturing)

REF — Catalogue number

Caution, consult accompanying documents

Consult instructions for use

NON STERILE — Non-sterile

Do not use if package is damaged

Do not re-sterilize

LATEX — Not made with natural rubber latex

Manufacturer

The French text is the reference text.
The CE marking is only valid if it also appears on the external packaging label.

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CE = Reusable instrument

CE 0459 = Instrument depending on a source of electrical energy / single-use instrument