AEQUALIS™ ADJUSTABLE REVERSED INSTRUMENTATION

INSTRUCTIONS FOR USE

IFU-5035 REV A

The use of instrumentation requires knowledge of anatomy, biomechanics, and reconstructive surgery of the musculo skeletal system. The instrumentation can only be used by a qualified surgeon who operates in accordance with current information on the state of scientific progress and the art of surgery.
The user must verify the condition and functioning of the instrumentation before using it.

IMPORTANT: When the hospital does not own the instrumentation, it accepts invoicing and makes payment in the following cases:
- when the instrumentation is to be used in conditions of suspected contact with Transmissible Non Conventional Agents (TNCA) on a patient affected or suspected of Creutzfeld-Jakob disease;
- when the instrumentation must be destroyed in relation to the observation of sanitary rules
- when the instrumentation has been damaged due to non-respect of Tornier instructions mentioned in these instructions for use.

1. DESCRIPTION

The instrumentation is made up of the instruments (ancillary material), packaging trays and baskets as well as a container. The instrumentation type is written on the metal container or if need be, on the packaging (if the instrument is delivered individually). The exact designation of each instrument is given on the instrumentation list supplied with the instrumentation.
The Tornier instrumentation has been specially designed to facilitate the implantation of Aequalis™ Adjustable Reversed implants. For a more detailed description of how to use the instrumentation, it is necessary prior to the intervention to refer to the technical documentation or if need be, to your Tornier representative.

2. INSTRUMENTS DELIVERED NON-STERILE

When the Tornier instrumentation is not delivered sterile, it is the responsibility of the hospital to pre-disinfect, clean and sterilize the instrumentation before use, by validated methods. The following recommendations cannot substitute for the sanitary rules in force (standards, guides, government notices).
Before any intervention, it is necessary to remove wedging foam from the metal containers as well as the plastic bag if the instrument is delivered individually.
Instruments made up of removable components must be dismantled before pre-disinfection and cleaning. Articulated instruments must be opened in order to allow the cleaning of all interstices.
In order to preserve optimal efficiency and safety of the instruments, the following instructions must be applied:
- 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 (ex: acetone) which are likely to damage the instruments must not be used.
Pre-disinfection and cleaning must be performed before sterilization.

2.1. STORAGE AND HANDLING

The instrumentation must be stored and handled with care. To avoid condensation, it is recommended to remove instruments from plastic bags before storing them. The storing of instruments must be performed with care in an appropriate, dry and clean location. They must not be stored in contact with or near products which may have a corrosive effect.

2.2. PRE-DISINFECTION

Pre-disinfection aims at reducing the micro-organisms population and making subsequent cleaning easier. It is also intended to protect staff while handling instruments and it avoids contamination of the environment. After use of the instrumentation, pre-disinfection must be performed as promptly as possible.
Pre-disinfection is obtained by dipping the instruments for a minimum of 15 minutes in an alkaline deterging/pre-disinfecting bactericidal and fungicidal solution containing didecyl ammonium chloride combined with proteolytic enzymes. The solution is diluted to 0.5% and must not contain aldehyde. It is strongly recommended to soak the instruments in an ultrasonic bath. The instruments should then be carefully rinsed in order to avoid any interference between the pre-disinfection and cleaning solutions. The pre-disinfection solution must be changed after each use to avoid its saturation.

CAUTION: Packaging trays and baskets must not be in contact with this pre-disinfecting solution for extended periods of time: clean the dirty area and rinse immediately.

2.3. CLEANING

Cleaning eliminates organic and mineral materials which will stick to the surface of instrumentation. It must be performed in a washer-disinfector with adapted cleaning solutions (the directions for use given by the supplier must be followed). The cleaning cycle must incorporate a final rinse at a temperature between 70°C and 95°C in order to make the drying easier. Then carefully dry the instruments to avoid any recontamination.
The proper operation of each instrument must be controlled appropriately.

2.4. STERILIZATION

Instruments, containers, packaging trays and baskets are adapted to steam sterilization at a temperature not exceeding 140°C. Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used and your internal sterilization procedures. Instrument trays must not be stacked together during sterilization. Alternative sterilization methods may be used if they have been validated by the hospital.
Flash sterilization is not recommended.

RECOMMENDED USA STERILIZATION PARAMETERS[1]

Items should be packaged so sterility can be achieved and maintained to the point of use. We recommend wrapping of trays or baskets.
The sterilization may be performed using the following method.

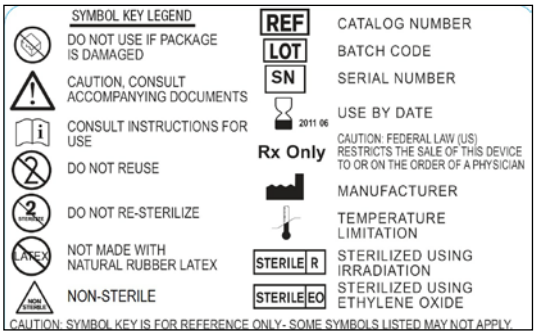
Practice	Type of sterilizer	Temperature	Cycle time	Dry Time
Preferred method in US	Pre-Vacuum (wrapped)	270° F (132°C)	8 minutes	75 minutes

CAUTION: Before returning to the Tornier Company, the instrumentation (entire box or isolated instrument) must be pre-disinfected, cleaned and sterilized according to above mentioned recommendations and be correctly packaged. Respect the positioning of the instrumentation (instruments, packaging trays and baskets) in the corresponding container.
Moreover it must be returned with the Count Sheet filled in and signed by a person duly authorized (in function of his/her quality, qualification or authority) by the hospital.

NOTES

1. "Recommended practices for sterilization in perioperative practice settings," in *Standards, Recommended Practices, and Guidelines* (Denver: AORN, Inc, 2005) 459 – 469.
2. Association for the Advancement of Medical Instrumentation, *Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use,* ANSI/AAMI ST37-1996 (Arlington, Va: Association for the Advancement of Medical Instrumentation, 1996) ix, x.

SYMBOL KEY



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