Cleaning, Disinfection and Inspection of Non-sterile Integra® Devices

Description and Intended Use
Integra LifeSciences Corporation reusable surgical device sets consist of various configurations of orthopedic devices in cases or trays. The sets are constructed from durable metal and/or plastic materials. The reusable surgical devices are intended for use in orthopedic surgical procedures according to the Instructions for Use and Surgical techniques that accompany Integra® implants. Reusable devices are to be cleaned, inspected, disinfected and sterilized between uses.

Inspection Before Use
Reusable Devices can be used indefinitely if not damaged or worn. Device systems should be cleaned and then inspected between uses. DO NOT use broken or damaged devices. Contact Integra for repair or replacement of damaged items. If damage or malfunction is detected, the device should not be used.
Disposable Devices should be disposed of according to hospital procedure and any applicable laws.

Preparation/General Guidance for Cleaning and Disinfection
Verify that all instruments required for use are present in the case. In addition, it is not recommended to use chloride containing cleaning solutions since its use has been linked to corrosion of metallic instruments, especially stainless steel.

Please also note the following:

- Disinfect and clean devices immediately after use in order to avoid device encrustations.
- Solutions used for cleaning must always be prepared in accordance with the manufacturer's instructions.
- Never use metal brushes or metal sponges for manual cleaning.
- Use a suitably sized non-metallic bristle brush for cleaning lumens, cannulations, blind holes, and cavities, making sure that every part of the inner surface can be properly accessed.
- Clean jointed instruments in closed as well as open positions.
- Disassemble instruments as far as possible before cleaning.
- Be sure to arrange the items so that the water can easily flow out of cannulations, blind holes, and cavities.
- For instruments with long or narrow lumens, standard processing should be used only if the disinfectant can flow easily through the lumens and safe rinsing is guaranteed.
- The cases/trays used for cleaning must always be loaded correctly to ensure proper cleaning.
- After cleaning, check instruments for cleanliness (visible dirt). This especially applies to cannulated instruments or those with blind holes and crevices.
- To ensure proper instrument functioning, verify that all movable parts have been thoroughly cleaned.
- Pay special attention to slots, ratchets, joints and box locks, narrow lumens, blind holes, and other areas that are hard to access.
- Deionized or distilled water should be used for the final rinse.

Automated Cleaning and Disinfection Procedure
The following steps should be completed in sequence. Please note that all instructions provided are as validated by Integra LifeSciences. The disinfection validation protocols were performed in accordance with *ISO 15883-1: 2009 Washer-disinfectors, Part 1; General requirements, terms and definitions and tests.*

a) Prepare an enzymatic detergent using lukewarm deionized water as per the manufacturer's recommendation.

b) Fully immerse the devices and allow to soak for a minimum of two (2) minutes.

c) Following the soak time, flush any lumens of the device using a syringe.

d) Rinse the devices under lukewarm running deionized water for a minimum of one (1) minute, while agitating the devices. Agitation includes actuating all movable parts, such as opening and closing hinges and moving the devices around under the running water.

e) Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of device components. Use a syringe to flush any lumens.

f) Place the devices back into the designated locations of the case/tray, and load the case/tray set into an automated washer disinfector (Steris 444 or equivalent).

g) The washer disinfector cycle parameters are as follows:

Phase	Recirculation Time (Min.)	Water Temperature (Min.)	Detergent
Pre-Wash	02:00	Cold Water	NA
Enzyme Wash	01:00	Hot Water	Enzymatic Cleaner
Wash	02:00	60°C	Neutral Detergent
Thermal Rinse	10:00	82°C*	NA

* Note: The highest grade of water available should be used during the final rinse cycle, distilled or deionized is recommended.

h) After washing and disinfecting, dry the devices using a clean lint free cloth and visually examine to determine if all adherent visible soil has been removed.

i) Repeat the cleaning and disinfection procedure if visible debris is detected.

Inspection After Cleaning

Following cleaning and disinfection, the instruments must be macroscopically clean, i.e. free from visible dirt or deposits. All movable parts, working tips and blades (scissors) should be inspected with particular care. In addition, the instruments must be sterilized prior to use as per the noted reprocessing instructions referenced below.

Non Sterile Device Sets Validated for Use	Associated Reprocessing Instructions for Use (IFU)
Cadence® Total Ankle Trials, Insertion, and Removal Instruments	LC-04-1020-0006
Cadence® Total Ankle Resection Instruments	
Cadence® Flat Cut Instruments	
Cadence® Flat Cut Instruments, Alternate	
Ti6® Internal Fixation System Low Profile Screw Set	LC-04-0000-0004
Ti6® Internal Fixation System Solid Screw Tray[1]	
Ti6® Internal Fixation System Base Instrument Set	
Ti6® Internal Fixation System Headless/Quicksnap Screws	
Ti6® Internal Fixation System Digital Fusion Screws[1]	
Total Foot System 2[1]	LC-04-0000-0013
Titan™ Modular Shoulder System, 2.5 Glenoid Tray	
Titan™ Modular Shoulder System, 2.5 Humeral Tray I	
Titan™ Modular Shoulder System, 2.5 Humeral Tray II	
Titan™ Reverse Shoulder System	
Titan™ Reverse Shoulder System-S [1]	
Titan™ Modular Shoulder System, 2.5 Monoblock Sounder Instrumentation	

[1] This system does not have a registered CE mark.

Manufacturer:

Ascension Orthopedics, Inc.
11101 Metric Blvd
Austin, TX 78758 ▪ USA
Phone: 1 (800) 654-2873
Fax: 1 (888) 980-7742
integralife.com

Authorized Representative:

EC REP

Integra LifeSciences Services (France)
Immeuble Sequoia 2
97 allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest–France
Telephone: +33 (0) 4 37 47 59 10

CE
2797