Optimotion™ Blue Total Knee System

Reusable Instrument Manual/Automated Cleaning and Steam Sterilization Instructions

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Before using this product, read the following information thoroughly.

Product Description:

The Optimotion Implants Blue Total Knee Arthroplasty (TKA) System instruments and instrument cases are generally composed of aluminum, stainless steel, and/or polymeric materials. The instrument cases are single-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases are perforated to allow steam to penetrate these various materials and components. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing a sterilization and drying cycle that has been validated by the Optimotion Implants. Use of the instrument cases should be limited only to this device system. **Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared Sterilization Wrap per AAMI or equivalent method to maintain sterility.**

Materials

Aluminum

Stainless Steel

Polymeric Materials

DISCLAIMER

The Optimotion Implants Blue TKA System instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. The Optimotion Implants Blue TKA System has verified through laboratory testing that its instrument cases are suitable for the specific sterilization methods and cycles for which they have been tested.

CARE AND HANDLING OF INSTRUMENTS

General

Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising their exacting performance. To minimize damage and risk of injury, the following should be done:

- *Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned.*
- *Instruments in need of repair should be set aside for repair service or returned to Optimotion Implants (Instruments returned to Optimotion Implants or its distributors should be cleaned and sterilized prior to shipment.*
- *ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for return or contact Optimotion Implants or your distributor for further instruction).*
- *Only use an instrument for its intended purpose.*
- *When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.*

Product Reuse Life

The useful life of Optimotion Implants Blue TKA System instruments depends on many factors including the method and duration of each use, and the handling between uses. Careful visual inspection and functional tests of the instrument is the recommended method to determine the end of serviceable life for an instrument.

- *Check all instruments for smooth function of hinges, ratchets, sleeves, etc.*
- *Visually inspect all instruments for any signs of corrosion, pitting, discoloration, cracking, etc.*
- *Verify all cutting instruments are sharp and do not contain any nicks, gouges or pits on the cutting surfaces.*
- *Verify all lumens and slots are free from inclusions and obstructions.*
- *Any instrument not meeting these criteria should be returned to Optimotion Implants.*

RESPONSIBILITIES OF THE USER

General

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance.

Cleaning/Decontamination

The health care facility is responsible to ensure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance.

Sterility

Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved and that specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. ANSI/AAMI ST33 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities covers the selection and use of reusable rigid sterilization container systems. Guidelines are provided by this standard for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

WARNINGS AND PRECAUTIONS

- *When handling sharp instruments use extreme caution to avoid injury.*
- *Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.*
- *Unless otherwise indicated, instrument sets are NOT sterile and must be thoroughly cleaned and sterilized prior to use.*
- *Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided.*
- *NOTE: Unwrapped instrument cases DO NOT maintain sterility.*

STORAGE AND SHELF LIFE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument cases based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

CLEANING AND DECONTAMINATION

Optimotion Implants Blue TKA System instruments and cases have been validated in accordance with best practices for cleaning utilizing AAMI TIR 30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. The cleaning instructions below are intended for all instruments contained in the instrument cases. Ensure the instrument cases are thoroughly clean prior to placing all cleaned instruments back in the instrument cases for steam sterilization cycle. Visually inspect the instrument cases for any visible soil or contamination and repeat the cleaning if any remaining soil is observed.

Preparation for cleaning

After use (within a maximum of 2 hours post-operatively):

- *Remove gross soil using absorbent paper wipes.*
- *Intensive rinsing of the reusable instruments with fluent water or transfer of the medical devices into a bath with an aldehyde-free disinfectant solution is highly recommended.*
- *Prior to cleaning, all instruments must be disassembled, if applicable.*

Manual Cleaning – Validated as minimum Cleaning Requirement.

1. Prepare an enzymatic detergent according to the manufacturer's recommendations.
2. Completely submerge instruments in the enzymatic detergent solution and gently shake to remove trapped bubbles. Actuate all moving parts of the device while submerged to ensure contact with enzymatic cleaning solution. Lumens, blind holes and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces.
3. Soak instruments for a minimum of 10 minutes.
4. Scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Particular attention should be given to crevices, roughened surfaces, cutting features, hinged joints, sharp edges, box locks, and areas with small components or springs.
5. Lumens, blind holes and cannulas should be cleaned using a long narrow nylon bristle brush/pipe cleaner. Insert a snug fitting long narrow brush/pipe cleaner into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times.
6. **Note:** All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.
7. Remove the instruments from the enzymatic solution and rinse in tap water for a minimum of two (2) minutes. Actuate all moveable and hinged parts while rinsing.
8. Visually inspect the instruments for any visible soil or contamination and repeat the cleaning steps above if any remaining soil is observed. If the soil or contamination cannot be removed the instrument should be appropriately disposed and not re-used.
9. Dry instruments with a clean, absorbent non-shedding wipe. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.

Automated Cleaning – This step is supplemental to the Manual Cleaning

10. Place instruments in a suitable validated washer. Follow the washer manufacturer's instructions for loading the instruments for maximum cleaning exposure; e.g. open all instruments, place concave instruments on their side or upside down, use baskets and trays designed for washers,

place heavier instruments on the bottom of trays and baskets. If the washer is equipped with special racks use them according to the manufacturer's instruction.

Treatment	Time (MM:SS)	Temperature	Cleaning Solution
Pre-wash	Minimum 02:00	Cold Water	N/A
Wash 1	Minimum 01:00	Hot Water (heated to a minimum of 43°C/109.4° F)	Enzymatic Detergent diluted per manufacturer's instructions
Rinse 1	Minimum 00:15	Cold Water	N/A
Wash 2	Minimum 02:00	Hot Water (heated to a minimum of 43°C/109.4° F)	Neutral pH Detergent diluted per manufacturer's instructions
Rinse 1	Minimum 01:00	High Purity Water (reverse osmosis, deionized or distilled) (heated to a minimum of 43°C/109.4° F)	N/A
Dry	Minimum 05:00	Minimum 104.4°C/220°F	N/A

11. Confirm the water supply meets the specifications in Table 1 of AAMI TIR 34. If this cannot be confirmed, then manually final rinse the instruments in high purity water (reverse osmosis or distilled) for a minimum of one (1) minute or until there is no sign of residue detergent or biologic soil. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas.
12. Visually inspect the instruments for any visible soil or contamination and repeat the cleaning steps above if any remaining soil is observed. If the soil or contamination cannot be removed the instrument should be appropriately disposed and not re-used.
13. Allow instruments to drain and dry with a clean, absorbent non-shedding wipe.
14. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas, and difficult to access areas.

STERILIZATION

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use. Optimotion Implants Blue TKA System instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using Optimotion Implants Blue TKA System instruments or instrument cases, please bring this to Optimotion Implants or Optimotion Implants distributor's attention when you return them. (Instruments returned to Optimotion Implants distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provide guidelines for return or contact Optimotion Implants or your distributor for further instruction).

Unless supplied sterile, all instruments must be thoroughly cleaned and sterilized prior to surgical use.

Individual users must validate the cleaning and autoclaving procedures used on-site. Surgical instruments may be autoclaved using a full cycle. Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended.

STERILIZATION METHOD

All instruments and associated containers must be dry prior to packaging for sterilization.
Note: Do not stack instrument cases during sterilization.

*Prevacuum Sterilizer (Full Cycle)**

Temperature:	270°F (132° C)
Wrap:	Double wrapped single ply using FDA cleared Sterilization Wrap per AAMI or equivalent method
Exposure Time:	4 minutes
Dry Time:	30 minutes
Maximum Weight:	<25 lbs.

* Validated by Optimotion Implants under laboratory conditions; however, if end user utilizes different sterilization parameters or methods, then those different parameter and methods should be validated and verified.

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by, or on the order of, a physician.

Comments regarding the use of this device can be directed to
Attn: Customer Service, Optimotion Implants, LLC. 6052 Turkey Lake Road, Suite 170
Orlando, Florida 32819, USA; support@optimotionimplants.com

SYMBOL LABEL KEY

 Manufacturer	 Date of Manufacture	 Do not use if package is damaged	 Do Not Reuse	 Batch Code	 Catalog Number
 Non-Sterile	 Caution, consult Accompanying documents	 Use by YYYY-MM-DD	 Consult Instructions for Use	 Sterilized using Ethylene Oxide	 Sterilized Using Radiation

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