Reusable Instrument Care Manual
**Balanced Knee® System, BKS® TriMax, Balanced Knee® Revision System, and BKS® Uni**

Manufacturer
Ortho Development® Corporation
12187 South Business Park Drive
Draper, UT 84020
Phone 801-553-9991
Fax 801-553-9993
www.odev.com

## INSTRUMENT CARE

### Considerations

• This guide includes processing instructions for all Ortho Development® (ODEV) reusable instruments only.
• New and used instruments must be thoroughly cleaned per these instructions prior to sterilization and use.

### Warnings and Precautions

• Universal precautions should be observed by all hospital personnel that work with contaminated medical devices. Caution should be exercised when handling devices with cutting edges or sharp points.
• Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated devices. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
• Do NOT place heavy instruments on top of more delicate instruments.
• Do NOT use metal brushes or scouring pads during manual cleaning. These will damage the surface and finish of instruments. Only soft-bristled, nylon brushes and pipe cleaners should be used.
• Do NOT allow contaminated instruments to dry prior to reprocessing. All subsequent cleaning is facilitated by not allowing blood, body fluid, bone and tissue debris, saline or disinfectants to dry on used instruments.
• Saline, and cleaning/disinfection agents containing active chlorine, aldehyde, bromide, bromine, chloride, mercury, iodine or iodide are corrosive and should NOT be used.
• Mineral oil or silicone lubricants should not be used because they are difficult to remove, prevent direct contact of the surface with steam during sterilization and coat microorganisms.

### Limitations and Restrictions

• Automated cleaning using a washer/disinfector alone may not be effective for cleaning orthopedic instruments. A thorough manual or combination manual/automated cleaning process is recommended.
• Neutral pH enzymatic and cleaning agents are recommended.
• Instrument trays, cases and lids must be cleaned separately. Non-sterile, single use implants are an exception as they may remain in the tray or caddy for reprocessing.
• Repeated processing has minimal effect on Ortho Development reusable instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended use and not reprocessing.
• Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Reverse Osmosis (RO) or Deionized (DI) water should be used for final rinsing of the instruments.

## CLEANING INSTRUCTIONS

### Point of Use

• Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a tray of distilled water or cover with damp towels.
• Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
• Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

**Preparation Before Cleaning**

• All cleaning agents should be prepared according to the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of manufacturer recommended temperatures is important for optimal performance of the cleaning agents

•NOTE: Fresh cleaning solutions should be prepared when the existing solutions indicate the presence of visual debris or visual soils (turbid and/or bloody).

Table 1: Cleaning/Disinfection Options

| Method | Description |
|---|---|
| Manual (Table 2) | Enzymatic soak and scrub followed by sonication. |
| Combination Manual/Automated (Table 3) | Enzymatic soak and scrub followed by an automated washer/disinfector cycle. |

**Manual Cleaning/Disinfection Procedure**

**Table 2: Manual Cleaning Steps**

| | |
|---|---|
| Step 1 | Use a lint-free cloth dampened in tap water to remove visual debris, or soil. While wiping, actuate the instrument(s) through the full range of motion. |
| Step 2 | Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water. |
| Step 3 | Fully immerse the instruments in the detergent and soak for a minimum of 20 minutes. While soaking, the instrument(s) should be actuated to ensure complete penetration of the detergent. Using a soft bristled brush (e.g. M16) and as necessary, lumen brushes (e.g. 45-541, 45-545), remove all visible soil paying attention to crevices and hard to reach areas. |
| Step 4 | Rinse the instrument(s) under running RO/DI water for a minimum of 3 minutes to remove detergent residue. While rinsing actuate the instrument through its/their full range of motion. |
| Step 5 | Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water in an ultrasonic cleaner. |
| Step 6 | Fully immerse the instrument(s) and sonicate for a minimum of 10 minutes. |
| Step 7 | Rinse the instrument(s) under running RO/DI water for a minimum of 5 minutes to remove all evidence of detergent residue. While rinsing actuate the instrument through its/their full range of motion. |
| Step 8 | Visually inspect the instrument for soil. Dry using a clean, soft cloth and filtered pressurized air (<40psi). If soil is visible, repeat the process. |

NOTE: Use of a sonicator at 45-50 kHz will aid in thorough cleaning of the devices.

NOTE: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

**Table 3: Combination Manual/Automated Cleaning Steps**

| | |
|---|---|
| Step 1 | Use a lint-free cloth dampened in tap water to remove visual debris, or soil. Actuate the instrument(s) through the full range of motion. |
| Step 2 | Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water. |
| Step 3 | Fully immerse the instruments(s) in the detergent and soak for a minimum of 20 minutes. While soaking, the instrument(s) should be actuated to ensure complete penetration of the detergent. Using a soft bristled brush (e.g. M16), remove all visible soil paying attention to crevices and hard-to-reach areas. |
| Step 4 | Rinse the instrument(s) under running RO/DI water for a minimum of 3 minutes to remove detergent residue. While rinsing actuate the instrument(s) through its/their full range of motion. |
| Step 5 | Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water in an ultrasonic cleaner. |
| Step 6 | Fully immerse the instrument(s) and sonicate for a minimum of 10 minutes. |

| | |
|---|---|
| Step 7 | Rinse the instrument(s) under running RO/DI water for a minimum of 5 minutes to remove all evidence of detergent residue. While rinsing actuate the instrument(s) through its/their full range of motion. |
| Step 8 | Place instrument(s) into the associated tray, then place into a washer/disinfector with the cover and upper tray(s) separate from the lower tray and main case. Refer to a-e for cycle information. |
| | a) Pre-Wash; Cold Softened Tap Water; 1 minute |
| | b) Enzyme Wash; Hot Softened Tap Water; 1 minute |
| | c) Detergent Wash; Hot Softened Tap Water (66°C set point); 2 minutes |
| | d) Rinse; Hot Softened Tap Water; 1 minute |
| | e) Hot Air Dry (115°C); 7 minutes |
| Step 9 | Remove from the washer and visually inspect for visible soil. If soil is visible, repeat the process. |

NOTE: Use of a sonicator at 45-50 kHz will aid in thorough cleaning of the devices.
NOTE: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

**Inspection, Maintenance and Testing**

- Carefully inspect each instrument, and all instrument trays, to ensure all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts to ensure smooth operation throughout the full range of motion.
- Hinged, rotating or articulating instruments should be lubricated with a water-soluble product intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. Manufacturer's expiration dates should be adhered to for both stock and use-dilution concentrations.

**STERILIZATION INSTRUCTIONS**

Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wrap, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Inner Trays that are removable from their outer cases may be sterilized in Aesculap Full Size Solid Bottom SterilContainer JK442 (6") or JK444 (8") and lid JK489 as appropriate. Outer cases (with or without corner bumpers) do not fit in these full-size SterilContainers and should not be placed inside. Trays that have not yet been validated for use with SterilContainers are listed in the Exceptions section. Detailed information on use and appropriate filters is found at www.aesculapusaifus.com. The manufacturer's instructions for use of these containers should be followed.

NOTE: Areas designated for specific instruments shall contain only instruments specifically intended for these areas.
NOTE: These validated reprocessing instructions are not applicable to Ortho Development trays that include devices that are not manufactured and/or distributed by Ortho Development. Instrument trays and cases without defined, preconfigured layouts or containing undefined universal spaces or compartments should only be used under the following conditions:

1. All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact.
2. Instrument cases are not to be stacked during the sterilization cycle.
3. The user must ensure that the instrument case is not tipped or the contents shifted once the instruments are arranged in the case. Silicone mats may be used to keep instruments in place.
4. Only instruments manufactured and/or distributed by Ortho Development should be included in Ortho Development instrument trays. Ortho Development validated reprocessing instructions are not applicable to Ortho Development trays that include devices that are not manufactured and/or distributed by Ortho Development.

**Sterilization**
All instruments, and all instrument trays, should be thoroughly cleaned prior to sterilization. Below are the recommendations for sterilization of Ortho Development instrument sets.

**Table 4: Recommended Sterilization Parameters Balanced Knee® System, BKS® TriMax, Balanced Knee® Revision System, and BKS® Uni (Wrapped and Aesculap SterilContainers)**

| Cycle Type | Minimum Sterilization Exposure Temperature | Sterilization Exposure Time (minutes) | Minimum Dry Time (minutes)* |
|---|---|---|---|
| Prevacuum | 132°C (270°F) | 4 | 30 |

*A thirty minute cooldown on a rack outside the autoclave should be included. When applying dry times to Ortho Development's cases, dry times outside of the standard healthcare prevacuum parameters may be required. The current recommended dry times for Ortho Development cases can range from a standard 30 minutes to an extended time of 60 minutes. The dry time is most often influenced by the presence of polymer based plastic materials; therefore, changes such as elimination of silicone mats and/or change in sterile barrier system (e.g. heavy grade to light grade wrap or the use or rigid sterilization containers) can reduce the necessary dry time. If polymer-based plastic cases/trays are used in conjunction with heavy duty nonwoven sterilization wraps, dry times may need to be altered. Variable dry times may also be required based on: differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. Certifiable methods (e.g. visual inspections) should be employed to confirm adequate drying.

**Exceptions**

**Wrapped Cases**
**Table 5: Exceptions to Recommended Wrapped Sterilization Parameters Based on Kit Description/Kit Number**

| Kit Number | Kit Description | Cycle Type | Minimum Sterilization Exposure Temperature | Minimum Sterilization Exposure Time (minutes) | Minimum Dry Time (minutes)* |
|---|---|---|---|---|---|
| 265-9301 | BKS Femoral 1 | Prevacuum | 132°C (270°F) | 6 | 45 |
| 261-9301 | | | | | |
| 261-9304 | BKS Tibial 1 | Prevacuum | 132°C (270°F) | 5 | 50 |
| 261-9304A | | | | | |

**Aesculap SterilContainers**
The following cases with removable trays **have not been validated** for use with Aesculap SterilContainers.

265-9301 BKS Femoral 1

661-9403 BKS Revision Femoral Augments

**Cases with brackets in the outer tray bottom have also not been validated for use with Aesculap SterilContainers.**

**Immediate Use Steam Sterilization**
Steam sterilization for immediate use of BKS instruments should only be performed on an emergency basis and AAMI or AORN guidelines should be followed. Instruments must be cleaned and disassembled according to Table 1 prior to sterilization.

Steam sterilization should be performed with a prevacuum cycle according to the parameters listed in Table 4 or Table 5 as applicable, without the indicated dry and cool down times. Instruments sterilized without dry time and cool down time should not be stored under any circumstances and should be used immediately.
Instrument **261-0017 Notched I/M Alignment Guide** should use the **BKS Femoral 1** parameters from Table 5 and **262-0101 Tibial Alignment Guide** should use the **BKS Tibial 1** parameters from Table 5.
Instruments in IUSS cycles may be sterilized in Aesculap JK series SterilContainers.

**General Precautions**

• The hospital is responsible for in-house procedures for the reassembly, inspection and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilization penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.

• Moist heat/steam sterilization is the preferred and recommended method for Ortho Development orthopedic instrument sets. Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.

•The hospital should also ensure that cycle and dry times are appropriate for all instrument sets being processed in accordance with these instructions. The hospital should have procedures in place to ensure sterilization has occurred and should perform visual inspections to ensure adequate drying has occurred. The methods for cleaning and sterilization described in these instructions have been validated by Ortho Development. Methods for cleaning and sterilizing Ortho Development reusable instruments outside of these instructions should be validated by the hospital. Ortho Development® Corporation is not liable for problems arising from a lack of cleanliness or sterility of instrument sets provided by Ortho Development that were sterilized outside the parameters established by Ortho Development.

Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces. Ethylene oxide or gas plasma sterilization methods should not be used unless package inserts for the applicable product specifically provide instructions for sterilization using these methods. Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.

**Storage**

• Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

**Hospital Responsibilities for Ortho Development Loaner Instruments**

• Orthopedic instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper case should be returned to Ortho Development to be discarded. Notify your Ortho Development representative of any instrument problems.

• Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Ortho Development. Documentation of decontamination should be provided with instruments being returned to Ortho Development.

**Important Notice**

The instructions provided have been validated by Ortho Development as being capable of preparing orthopedic instruments for use. It is the responsibility of the hospital to ensure that the reprocessing is performed using the appropriate equipment and materials and the personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.