

ORTHIOS INNOVATIONS
The Weight Bear®



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

DEVICE DESCRIPTION: The Orthios Weight Bear® (part number OI-200) and optional Accessory Wedge (OI-50) allows the physician to effectively orient the foot of a patient in a simulated weight-bearing position and maintain that position for images to be taken. The device allows for different angulations of the foot for simulated weight-bearing when desired by the physician.

The Weight Bear® is intended to be used in operating rooms, radiology departments, and/or orthopedic offices. The device is radiolucent, foldable, sterilizable, and reusable.

There are metal strips embedded and hidden in the foot plate, parallel to the surface. These metal strips provide a reference for the patient's foot during imaging.

One or more optional Accessory Wedges (OI-50) can be attached to the Weight Bear® to change the angulation of the patient's foot.

INTENDED USE: The Orthios Weight Bear provides a simulated weightbearing position and maintains the orientation of the foot for images to be taken. Weight Bear is intended to be used in operating rooms, radiology departments, and/or orthopedic offices.

Features:

- Autoclavable
- Radiolucent with radiopaque positioning strips
- Quick and easy loading
- Lies flat as a working surface
- Portable/easily moveable
- Comfortable elevated position
- Hands-free during imaging
- Reproducible imaging in both A/P and Lateral positions
- Adjustable footpad angle

CONTRAINDICATIONS:

- Local infection or open wound that would be in contact with the Weight Bear.
- Material sensitivity. If sensitivity is suspected, the device should not be used.

PRECAUTIONS:

- It is the responsibility of each physician using the device to consider the clinical and medical status of each patient. For safe and effective use, the device should only be used by trained foot and ankle surgeons and radiologists.
- The device should not be used to force the patient's anatomy into any unnatural position for their condition.
- No component of this instrument is designed for implantation.
- The Weight Bear is provided non-sterile and must be sterilized prior to surgical use.
- Follow the provided cleaning instructions and sterilization parameters in between each use.

MR SAFETY INFORMATION: The Weight Bear has not been evaluated for safety and compatibility in the MR environment. The system has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Weight Bear in the MR environment is unknown. Scanning a patient while utilizing this device may result in potential injury.

FOR SURGICAL USE OF THE WEIGHT BEAR

DIRECTIONS FOR USE (Surgical):

Surgical procedure for use of the Weight Bear:

1. Clean and sterilize the Weight Bear and accessory wedge according to the instructions below.
2. Remove the sterile barrier material.
3. The Weight Bear can be moved by using the handle only when the foot plate is in its stored position and the latches are moved to the upper position.
4. Drape the surgical table as required and place the Weight Bear on top of the surgical drapes where the affected foot will be positioned. Ensure that the Weight Bear remains in full contact with the surgical table.
5. Position the affected foot with the heel in the heel cup opening of the calf pad. A folded surgical towel (or towels) may be positioned between the heel and the Weight Bear to aid in positioning the foot.
6. The optional Accessory Wedges can be positioned below the base of The Weight Bear to change the elevation and angulation of the lower leg. The Accessory Wedges will snap into The Weight Bear, or into each other. Detach the Accessory Wedges by gently pulling or by pressing the snaps that are engaged.
7. To position for loading of the foot, pull the foot plate out of the base by grasping the handle and withdrawing it horizontally from the stored position.
8. When the foot plate fully exits the stored position, it can then be rotated into any of multiple positions.
9. Raise the foot plate up and push it toward the patient's affected foot so that the foot plate side wedges engage with the locking slots at the desired angle.
10. Ensure that the plantar aspect of the affected foot is in contact with the foot plate.
11. The foot may be strapped to the foot plate with a sterile strap through the strap slots if desired.
12. Perform the surgical procedure or radiographic imaging in a loaded position as required (Note: there are radiopaque indicators that should be aligned to confirm a true lateral position for lateral imaging).
13. To return to the storage position (nested), remove foot straps from the foot and foot plate if they were used.
14. Pull the handle radially away from the base to disengage the foot plate side wedges from the locking slots.
15. Using the handle, move the foot plate down to a nearly horizontal position.
16. Start pushing the foot plate into the base.
17. Continue to push the foot plate into the base until it stops.
18. The previous steps may be repeated as frequently as required during the surgical procedure.
19. When surgery is completed and all radiographic images have been taken, the Weight Bear must be returned to its storage position with the foot plate returned to its position within the base. The latches can be moved to the upper position to hold the foot plate in place.
20. The Weight Bear can be removed from the surgical table and transported using the handle.
21. The Weight Bear must be cleaned and re-sterilized before its next use.

OTHER SUPPLIES AND EQUIPMENT NEEDED (Surgical Use):

- Standard OR equipment used in patient preparation and surgical exposure.

STORAGE AND HANDLING (Surgical Use):

- After sterilization, the instruments should be stored in such a way as to maintain their sterile condition, in accordance with the procedures defined by the health facilities.

CLEANING (Surgical Use):

1. **Preparation for Cleaning:**
 - Prior to cleaning, unlatch the device and fully extend the foot plate to expose all internal and external surfaces.
 - If cleaning the Accessory Wedge (OI-50), proceed to Step 2.
2. **Initial Rinse:**
 - Rinse all surfaces of the device with warm tap water (35–40 °C) for a minimum of two (2) minutes to remove gross contamination.
3. **First Enzymatic Soak and Cleaning:**
 - Soak the device in a freshly prepared pH-neutral enzymatic detergent solution, prepared and used in accordance with the detergent manufacturer's instructions (e.g., ASP Enzol or equivalent), for fifteen (15) minutes.
 - While immersed, scrub all internal and external surfaces using a soft brush and/or pipe cleaner for a minimum of three (3) repetitions.
 - Flush all holes, crevices, and hinged areas a minimum of three (3) times using a syringe filled with the detergent solution.

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4. **Rinse:**
 - Rinse all surfaces with warm tap water (35–40 °C) for a minimum of two (2) minutes.
5. **Second Enzymatic Soak and Cleaning:**
 - Repeat Step 3 using freshly prepared detergent solution.
6. **RO/DI Rinse:**
 - Rinse all surfaces with reverse osmosis/deionized (RO/DI) water for a minimum of two (2) minutes.
7. **Ultrasonic Cleaning:**
 - Sonicate the device for a minimum of ten (10) minutes in freshly prepared pH-neutral enzymatic detergent solution, prepared and used per the manufacturer's instructions.
8. **Final Rinsing:**
 - Rinse thoroughly with tap water.
 - Perform a final rinse/flush with RO/DI water for a minimum of two (2) minutes.
9. **Drying:**
 - Dry all surfaces using clean compressed air or a soft, lint-free cloth.
10. **Inspection:**
 - Visually inspect all internal and external surfaces for cleanliness.
 - If any visible soil remains, repeat the cleaning process until visibly clean.

Note: Examples of suitable detergents include pH-neutral enzymatic cleaners such as ASP Enzol. Equivalent detergents may be used if they are intended for medical device cleaning and used in accordance with the manufacturer's instructions.

STERILIZATION AND DRYING (Surgical Use):

1. **Device Configuration Prior to Sterilization:**
 - The Weight Bear® shall be placed in the fully stowed (nested) configuration prior to packaging and sterilization.
 - Ensure the foot plate is fully inserted into the base and secured in the stored position.
 - Accessory Wedges (OI-50), if used, should be attached together (back-to-front) to form a rectangular configuration prior to packaging. Accessory Wedges (OI-50) should be wrapped separately from the Weight Bear (OI-200).
2. **Packaging:**
 - The device was validated using a single-wrapped configuration with FDA-cleared sterilization wrap (e.g., Halyard H200) using the technique in accordance with AAMI ST79.
 - Equivalent FDA-cleared sterilization wraps may be used, provided they allow effective steam penetration and drying.
 - Use of alternative packaging systems (e.g., rigid containers or pouches) has not been validated and may require adjustment of cycle parameters.

3. **Steam Sterilization Parameters:**

Cycle Type	Exposure Temperature	Exposure Time	Minimum Dry Time
Prevacuum	270 °F (132 °C)	4 Minutes	30 Minutes

4. **Drying and Post-Cycle Handling:**
 - The validated cycle includes a minimum drying time of 30 minutes.
 - Drying performance may vary depending on packaging system, sterilizer performance, load configuration, and facility conditions.
 - After completion of the cycle, allow the device to cool at ambient conditions prior to handling.
 - Visually inspect the device and packaging for residual moisture.
 - If visible moisture is present on the device or within the packaging, the device should be reprocessed or additional drying time applied in accordance with facility procedures.

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FOR NON-SURGICAL USE OF THE WEIGHT BEAR

DIRECTIONS FOR USE (Non-Surgical):

1. If necessary, clean the Weight Bear with a neutral detergent and hot water or a single use universal surface disinfection and cleaning wipe.
2. The Weight Bear can be moved by using the handle only when the foot plate is in its latched position
3. Place the Weight Bear on the examination table in the desired location on top of the provided non-slip mat.
4. Position the patient on the table with a cushion or pillow beneath the lower back so that they are in an elevated inclined position.
5. Position the affected foot with the heel on the heel cup opening of the calf pad with the plantar aspect of the foot in position to fully contact the foot plate. A folded surgical towel (or towels) may be positioned between the heel and the Weight Bear to aid in positioning the foot. Support may be placed under the knee if desired. The affected leg may be strapped to the calf pad utilizing the slots in the base of the device.
6. To position for loaded imaging, disengage the handle locking latches and pull the foot plate out of the base by grabbing the handle and raising it slightly.
7. When the foot plate is fully extended, raise the foot plate up and push it toward the patient's affected foot so that the positioning tabs engage with the positioning slots at the desired angle.
8. Ensure that the plantar aspect of the affected foot is in full contact with the foot plate.
9. The foot may be strapped to the foot plate with a strap through the strap slots if desired.
10. Perform imaging as required.
11. When all images have been taken, the Weight Bear must be returned to its flat position
12. To return the foot plate to the flat position (nested), remove foot straps from the foot and foot plate if they were used.
13. Pull up vertically on the handle to disengage the positioning tabs from the positioning slots.
14. Using the handle, move the foot plate down to a nearly horizontal position.
15. Start pushing the foot plate into the base.
16. Continue to push the foot plate into the base until it stops.
17. Engage the handle locking latches.
18. The Weight Bear can be removed from the examination table and transported using the handle.
19. The Weight Bear must be cleaned before its next non-surgical use.

OTHER SUPPLIES AND EQUIPMENT NEEDED (Non-Surgical Use):

- Straps, if desired, for affixing the patient to the Weight Bear.
- A non-slip mat that can be placed under the Weight Bear.

STORAGE AND HANDLING (Non-Surgical Use):

- The Weight Bear should be stored with the foot plate in its latched position, in a dry location

CLEANING (Non-Surgical Use):

1. Unlatch the device, extend the footpad, and angle the calf plate away from the base, so as to expose internal surfaces.
2. Wash all surfaces of the device with warm (35-40 °C) tap water and a neutral detergent for a minimum of two (2) minutes to remove visible contamination, or wipe with a single use universal surface disinfection and cleaning wipe.
3. Allow all surfaces to dry.

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SYMBOLS

Symbol	Title of Symbol	Description
	Prescription Device	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult instructions for use (Ref. #5.4.3)	Indicates the need for the user to consult the instructions for use.
	Quantity in package	Indicates the number of units in the package
	Reference number (Ref. #5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Lot number (Ref. #5.15)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Non-sterile (Ref #5.2.7)	Indicates a medical device that is not provided sterile and that needs to be sterilized prior to use.
	Unique Device Identifier (Ref #5.7.10)	Indicates a unique number assigned to each device
	Manufacturer (Ref. #5.1.1)	Indicates the medical device manufacturer

* ISO 15223-1:2021 *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*