

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 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.

INTENDED USE: The Orthios Weight Bear device 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.

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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 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.
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 accessory wedges can be positioned below the base of The Weight Bear to change the elevation and angulation of the lower leg.
7. To position for loading of the foot, pull the foot plate out of the base by grabbing the handle and raising it slightly.
8. When the positioning pins contact the distal end of the base, raise the foot plate slightly so that the pins will rise over the base and continue to pull the foot plate until it stops.
9. Raise the foot plate up and push it toward the patient's affected foot so that the positioning pins 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 up vertically on the handle to disengage the positioning pins 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 and ensure that the locking pins are seated into appropriate slots in the base.
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.
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. Unlatch the device and extend the footpad, so as to expose internal surfaces.
2. Rinse all surfaces of the device with warm (35-40 °C) tap water for a minimum of two (2) minutes to remove gross contamination.
3. Soak the device in ASP Enzol pH neutral enzymatic detergent solution* for fifteen (15) minutes.
4. While in the detergent, scrub all interior and exterior surfaces of the device at least three (3) repetitions with a soft brush and/or pipe cleaner; repeatedly flush any holes, crevices, and pinned or hinged areas at least three (3) repetitions with the same detergent solution using a syringe.
5. Rinse all surfaces of the device with warm (35-40 °C) tap water for a minimum of two (2) minutes.
6. Soak the device in freshly prepared ASP Enzol pH neutral enzymatic detergent solution* for fifteen (15) minutes.
7. While in the detergent, scrub all interior and exterior surfaces of the device at least three (3) repetitions with a soft brush and/or pipe cleaner; repeatedly flush any holes, crevices, and pinned or hinged areas at least three (3) repetitions with the same detergent solution using a syringe.
8. Rinse all surfaces of the device with reverse osmosis deionized (RO/DI) water for a minimum of two (2) minutes.
9. Sonicate the device for a minimum of ten (10) minutes in freshly prepared ASP Enzol pH neutral enzymatic detergent* solution.
10. Rinse all surfaces of the device thoroughly with tap water
11. Rinse all surfaces of the device thoroughly /flush with RO/DI water for a minimum of two (2) minutes.

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12. Dry all surfaces of the device with clean compressed air or a soft, lint free, clean cloth.
13. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, reclean until it is visibly clean.









* - A pH neutral enzymatic detergent solution equivalent to ASP Enzol may also be used.

STERILIZATION AND DRYING (Surgical Use):

1. Double wrap the device in an FDA cleared wrap.
2. Autoclave according to the following parameters:

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 °F (132 °C)	Exposure Temperature	270 °F (132 °C)
	Exposure Time	8 minutes
	Dry Time	60 minutes

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*