



OrthoStride[®]

Ultra OA Knee Brace



Instruction For Use

Please read these instructions carefully before application.

OrthoStride®

Ultra OA Knee Brace

GENERAL DESCRIPTION

Ultra OA Knee Brace provides targeted relief for mild to moderate uni-compartment osteoarthritis (OA) and ligament injuries. Its adjustable height and range of motion control ensure a personalized fit. The 3-point pressure system reduces joint stress, improves comfort, and helps stabilize and realign the knee.

INTENDED USE

Ultra OA Knee Brace is designed to provide pain relief, stability, and offloading for uni-compartment osteoarthritis (OA). It supports post-surgical recovery and helps individuals with moderate ligament instability. The brace features adjustable Range of Motion (ROM) control to regulate flexion and extension, aiding in optimal rehabilitation. Its universal size and height adjustability ensure a customized fit for a wide range of users.

INDICATIONS FOR USE

- Mild to moderate uni-compartment knee osteoarthritis (OA)
- Moderate ligament instability/ injuries

CONTRAINDICATIONS

- Skin disorders or injuries in the relevant area
- Numbness/Paraesthesia
- Severe varicose veins
- Impaired lymphatic drainage

PATIENT POPULATION

- Patients suffering from uni-compartment knee osteoarthritis (OA)
- Patients recovering from sports injuries, moderate ligament injuries/ instabilities

INTENDED USERS

Patients prescribed or guided by a Healthcare Professional (HCP) for intended use.

SIZE CHART

- Universal Left/Right

INSTRUCTION FOR APPLICATION

Detach all straps before applying the brace.

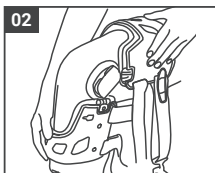
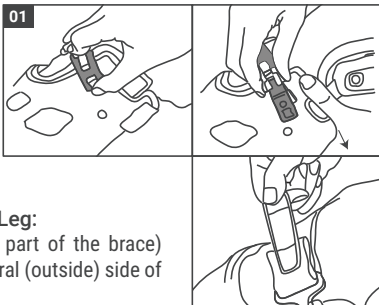
Step 1-

Detach all buckles

- Press the button on the buckle to open it.
- Slide the buckle out of its slot to detach it.
- Loosen all straps as much as possible.

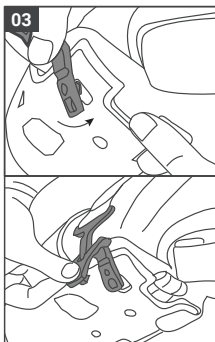
Position the Brace on Your Leg:

- Align the hinge (the moving part of the brace) with the knee joint on the lateral (outside) side of the leg.



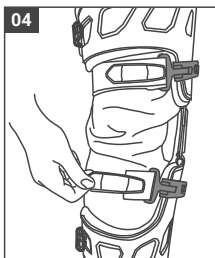
Step 2: Put on the Brace

- Place the knee brace with the patient seated on a chair with the knee joint flexed at 90°.



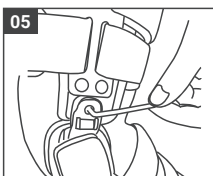
Step 3 - Fasten the Straps

- Start by securing the top strap around the thigh, ensuring a snug and proper fit.
- Insert the buckle into the designated slot and press the button to lock it securely.
- Adjust the strap length to achieve a firm and comfortable fit without excessive pressure.
- Fasten the remaining three straps using the same method, maintaining even tension for optimal support.
- Secure straps firmly but avoid excessive tightness to prevent restricted circulation, numbness, or swelling.



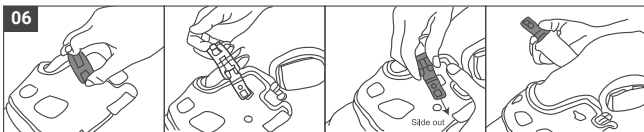
Step 4 - Check the Fit:

- Have the patient stand and ensure the straps securely hold the brace in place.
- Instruct the patient to walk around to assess comfort and ensure the brace does not cause discomfort or exacerbate pain.
- If the brace causes discomfort or pain, have the patient sit, adjust the straps, and reassess the fit.



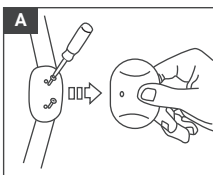
Step 5: Varus/ Valgus Adjustment (if needed)
Use the Hex Wrench (Allen Key) provided with the device to make precise varus/valgus adjustments, optimizing fit, alignment, and offloading pressure from the affected knee compartment for improved support and pain relief.

Step 6: Make It Easy to Use Later:

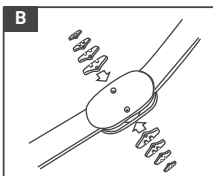


- Once the straps are properly adjusted to fit, use the quick-release buckle for easy application and removal of the brace during future use.
- Place the brace around your knee, ensuring proper alignment.

HOW TO SET THE HINGE (FOR RANGE OF MOTION CONTROL)

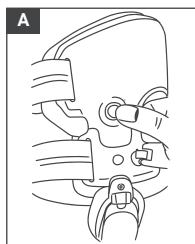


- **Remove the Screws:** Use the screwdriver provided with the device to detach the screws from the hinge.
- **Replace the Stops:** Replace the existing pair of stops with new ones from the adjustment kit provided, setting the desired flexion (bending) or extension (straightening) angle.
- **Secure the Screws:** Reinsert and tighten the screws firmly to ensure stability.

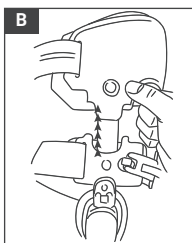


Important: Only a healthcare professional should adjust the brace, with regular follow-ups to ensure proper alignment and effectiveness.

HEIGHT ADJUSTMENT



- **Locate the Height Adjustment Button:** Find the button positioned above the hinge joint of the brace.
- **Release the Lock:** Press and hold the button to unlock the height adjustment mechanism.



- **Adjust the Height:** While holding the button, gently pull the brace to extend it to the desired height.
- **Ensure Proper Fit:** Adjust to the optimal size for maximum comfort and support.

BRACE ACCESSORIES

- Strap pads
- Hex Wrench (Allen Key)
- Screwdriver
- Flexion Stops 
- Extension Stops 

REMOVAL INSTRUCTIONS

- Sit in a comfortable position.
- Gradually unfasten all straps.
- Gently open and remove the brace.
- Inspect for any signs of wear or damage.

WASHING INSTRUCTIONS

- Only the cushions and straps are washable.
- Wash in cold water using a mild soap.
- Do not dry clean, tumble dry or use bleach.
- Air dry in a well-ventilated area and do not expose to any heat sources or direct sunlight.

DISPOSAL

Dispose of the knee brace according to local waste management guidelines.

WARNINGS & PRECAUTIONS

- **Fit & Adjustment:** Ensure proper fit for effective support. Only healthcare professionals should adjust varus/valgus alignment and ROM settings.
- **Monitoring & Discomfort:** Discontinue use and seek medical attention if pain, tingling, or increased swelling occurs.
- **Activity Restrictions:** Avoid high-impact or strenuous activities unless approved by a healthcare professional.
- **Inspection & Maintenance:** Regularly check for loose screws, worn-out straps, or structural damage. Keep the brace clean and dry to prevent infections or skin irritation.
- **Application Over Wounds:** Do not apply the brace over open wounds.
- **Follow-Up Assessments:** Periodic medical reviews by healthcare professionals are essential to assess fit, function, and therapeutic effectiveness.

Caution: Discontinue if allergies or discomfort occur and consult a healthcare professional. Do not use continuously for more than 24 hours.

ADVERSE EFFECTS

- Prolonged usage may cause skin irritation, discomfort, or pressure sores, and sensitivity to materials may cause allergic reactions.
- Excessive tightening can lead to poor circulation, numbness, or swelling, and improper fit may increase pain or discomfort.

STORAGE CONDITIONS

- Store at room temperature, away from sunlight and moisture.
- Avoid placing heavy objects on the brace to prevent damage.
- Ensure the brace is clean and completely dry before storing.

MR COMPATIBILITY

Ultra OA Knee Brace is not MR compatible.

REPORTING OF ADVERSE EVENTS

In case of any event please notify to 'care@orthoheal.com' or to the competent authority of the respective member state.

INSTRUCTION FOR PATIENTS

Do's:

- Wear as instructed by your Healthcare Professional.
- Ensure a comfortable snug fit.
- Keep clean and dry.
- Follow prescribed ROM settings, if applicable.
- Remove if discomfort, swelling, or numbness occurs.
- Keep the brace away from heat and moisture.

Don'ts:

- Do not wear without medical advice.
- Avoid excessive strap tightening.
- Do not use over wounds or irritated skin.
- Avoid wearing while sleeping.
- Do not engage in high-impact activities unless approved.
- Do not share; the device is for personal use only.
- Keep out of reach of children and pets.

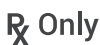
RECOMMENDATION

This product is intended for use only under the supervision of a qualified medical professional. In the event of a serious incident related to the device, it must be reported to the manufacturer and the relevant regulatory authority in the jurisdiction where the user and/or patient is located.

SYMBOL GLOSSARY



Medical Device



Caution: Federal law restricts this device to sale by or on the order of a HCP



Single patient multiple use.



Do not use if package is damaged and consult instructions for use



Non-sterile



Consult instructions for use.



Device is not made with natural rubber latex.



Keep away from sunlight.



Manufacturer



Date of Manufacture



Catalogue Number / Reference code



Batch code / Lot Number



Unique device identifier



Authorised representative in the European Union

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FDA
LISTED



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MADE IN INDIA

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