



OrthoStride®

360 OA Knee Brace



Instruction For Use

Please read these instructions carefully before application.

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GENERAL DESCRIPTION

360 OA Knee Brace provides support and stability for mild to moderate knee osteoarthritis (OA) and ligament injuries. It aids in pain relief by partially unloading the joint through a dual 3-point pressure system, limiting mobility in specific axes, and ensuring controlled movement with adjustable range of motion settings.

INTENDED USE

360 OA Knee Brace is a knee orthosis designed to provide partial medial/lateral offloading and support in the setting of multi-compartment osteoarthritis (OA), ligament injuries, and post-surgical rehabilitation of the knee. It is intended to aid in pain reduction and functional improvement. The brace should be prescribed and adjusted according to patient requirements by a healthcare professional.

INDICATIONS FOR USE

- Mild to moderate multi-compartment knee osteoarthritis (OA)
- Combined ligamentous instability
- Post surgical rehabilitation

CONTRAINDICATIONS

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

PATIENT POPULATION

- Patients with mild to moderate multi-compartment knee osteoarthritis (OA) requiring joint offloading and enhanced stability.
- Individuals with severe ligament instability or injuries needing controlled stabilization, protection, and assisted recovery.
- Post-surgical patients requiring restricted mobility and joint support during rehabilitation.

INTENDED USERS

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

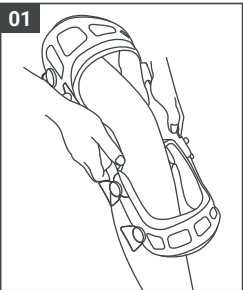
SIZE CHART

- Thigh Measurement: Measure 15 cm (6 inches) above the medial condylar plateau.
- Calf Measurement: Measure 12 cm (5 inches) below the medial condylar plateau.

Size	Thigh Circumference	Calf Circumference
2	39-47 cm	29-37 cm
3	47-54 cm	37-43 cm
4	54-60 cm	43-50 cm
5	60-67 cm	50-57 cm

SIDE: LEFT OR RIGHT

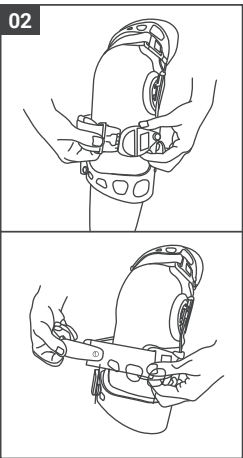
INSTRUCTION FOR APPLICATION



Detach all straps before applying the brace.

Step 1- Position the brace

- Apply the knee brace with the patient seated on a chair with the knee joint flexed at 80°-90°.
- Place the hinge joint in line with the knee joint as shown in the image.



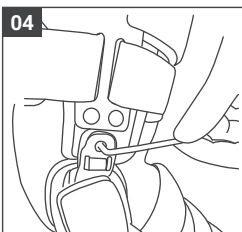
Step 2: Secure the Straps

- Press the brace firmly against the leg.
- Fasten strap 1 behind the calf, adjusting it for a snug fit using the hook and loop closure.
- Wrap and secure strap 2 around the lower calf muscles, ensuring it stays in place without causing discomfort.
- Fasten straps 3, 4, 5 and 6 in the correct order, following the same method as strap 1.
- Secure straps firmly but avoid excessive tightness to prevent restricted circulation, numbness, or swelling.



Step 3 - 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.

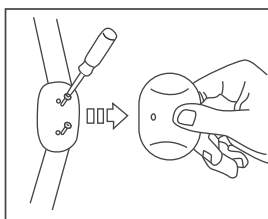


Step 4 - Making Varus/ Valgus Adjustments:

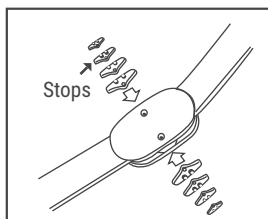
Use the Hex Wrench (Allen Key) provided with the device to make precise varus/valgus adjustments, optimizing fit, alignment, and offloading pressure from the affected knee compartment for improved support and pain relief.

HOW TO SET THE HINGE

(FOR RANGE OF MOTION CONTROL)



STEP: 1



STEP: 2

- **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.
- **Check Both Sides and Verify Symmetry:** It is mandatory to set the flexion stops and extension stops on both the medial (inner) and lateral (outer) hinges to the same angle for proper alignment and balanced support.

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

BRACE ACCESSORIES

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

REMOVAL INSTRUCTIONS

- Ensure the patient is seated in a comfortable position.
- Unfasten the straps sequentially from 6 to 1, following the strap numbering.
- Gently open the brace and remove it carefully.
- Inspect the brace for any signs of wear or loose components before storage.

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

360 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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