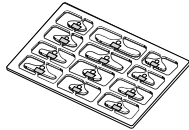
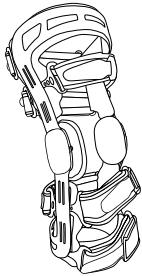




DUALIGN OA

KNEE ORTHOSIS



ANGLE ADJUSTMENT SET



CONDYLE PAD



ADJUSTMENT TOOL



ALLEN WRENCH



ALLEN SCREW



MEDICAL DEVICE



SINGLE PATIENT- MULTIPLE USE



CAUTION



Manufactured for:

Aspen Medical Products, LLC
6481 Oak Canyon, Irvine, CA 92618-5202 USA
aspenmp.com • +1-800-295-2776 • +1-949-681-0200
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ENGLISH

1. FITTING THE BRACE

- Before fitting the brace, ensure all brace fasteners are open by pressing the button on the side of the fastener.
- While sitting, bend the knee joint slightly (approximately 30°).
- Position the brace on the side of the leg so that the center of the hinge lines up with the center of the patella.
- Close fasteners starting with the lower shin strap labeled 1. Adjust and tighten the strap so that it is comfortable for the patient and prevents the brace from migrating. Continue closing the fasteners following the order sequence 2, 3, 4 adjusting the straps at each step.
- Use the adjustment tool to set the appropriate degree of unloading. Clockwise decreases unloading and counterclockwise increases unloading. While the patient is sitting, turn the adjustment screw 1/8 to a 1/4 turn at a time and evaluate patient before adjusting further.

Note: adjust and tighten straps 4&5 and 3&6, so that the hinge is centered and the straps are snug and comfortable. The back calf strap is important in providing purchase over the calf muscle, preventing the brace from migrating.

2. REMOVING THE BRACE

- To remove the brace, press and release the fasteners until all straps are released.
- To reapply, simply click the fasteners in place in the same order as listed above.

3. ADJUSTING THE RANGE OF MOTION

If required, flexion / extension limits can be set. Remove the condyle pad and remove the screw for the limit stop. Remove the extension limit stop from the hinge and insert the required angular degree. Secure the inserted limit stop with the screw. Repeat on the opposite hinge.

Limits available are:

-Extension: 0°, 5°, 15°, 20° and 25°

-Flexion: 0° (180°), 30°, 45°, 60°, 75° and 90°

IMPORTANT: Both hinges must be set to the same extension and/or flexion settings. For 0° extension limiting, 0° extension stops must be used to mitigate the risk of hyperextension.

TO CHANGE AN EXTENSION STOP:

Unscrew from the front of the hinge cap. Remove the extension stop. Insert another extension stop into the front of the hinge and replace the screw. Repeat for the opposite hinge.

TO INSERT A FLEXION STOP:

Insert a flexion stop into the back of the hinge and use the extra screw that is attached to the flexion/extension tree to secure. Repeat for the opposite hinge.

4. STRAP LENGTH ADJUSTMENT

To determine the required length, open the strap pad, open the end of the binding strap, separate the hook and loop material and the binding strap, cut to the required length, and then attach the pad back to the end of the binding strap.

INTENDED USE

To provide medial or lateral forces on the knee joint.

INDICATIONS

Osteoarthritis, medial or lateral compartment of the knee.

CONTRAINDICATIONS

Hypersensitivity or allergies to any of the materials from which the brace is made. Swelling of the lymphatic tissue caused by circulatory disorders. Patients who are not allowed to wear a brace according to medical instructions.

PRECAUTIONS

READ INSTRUCTIONS BEFORE USE. Proper training in the use of this device should take place before it is applied. These directions are guidelines only and are not offered as medical recommendations. If you suffer from a serious medical condition, we strongly suggest that you consult with a licensed health care professional before using this product. Proper fitting is required for this product to be effective. Under some circumstances, this product may be prescribed by a physician. Please see the limited warranty for further information.

CARE INSTRUCTIONS

Hand wash only at 30° C; Wash with mild detergent; Air dry; Do not use bleach or other chemicals.

MATERIALS

Acetel, Polyester, Steel, Aluminum, UBL, EVA, Nylon, Polyurethane.

NOT MADE WITH NATURAL RUBBER LATEX.

DISPOSAL

Product may be safely disposed in accordance with local laws.

LIMITED WARRANTY

Aspen Medical Products, LLC, Irvine, CA 92618, warrants to the user who originally purchases this product that it is free from defects in material and workmanship. The sole obligation of Aspen Medical Products, LLC in the event of breach of warranty shall be to repair or replace the defective product or part(s).

Aspen Medical Products, LLC shall have no obligation under this limited warranty in the event:

- The product was not purchased from Aspen Medical Products, LLC or through its authorized channels of distribution;
- The product is altered;
- Any parts not supplied by Aspen Medical Products, LLC are inserted into the product; or
- The product is not used in accordance with the Aspen Medical Products, LLC Instructions for Use.

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A listing of authorized distributors in your area is available upon request.