

INDICATIONS

The Precision Pro OA knee orthosis provides a corrective force to help reduce pain and joint degeneration.

Model #	Description	Size	Thigh Circumference*	Calf Circumference**
Precision OA brace Single upright (Lateral)				
PRECOAL-L1	OA Knee Brace Single Lateral Upright, Left	Sm/Md	15.5" - 21" (39 - 53.5 cm)	11.5" - 17" (29 - 43 cm)
PRECOAL-L2	OA Knee Brace Single Lateral Upright, Left	Lg-X-Lg	21" - 26.5" (53.5 - 67 cm)	17" - 22.5" (43 - 57 cm)
PRECOAL-R1	OA Knee Brace Single Lateral Upright, Right	Sm/Md	15.5" - 21" (39 - 53.5 cm)	11.5" - 17" (29 - 43 cm)
PRECOAL-R2	OA Knee Brace Single Lateral Upright, Right	Lg-X-Lg	21" - 26.5" (53.5 - 67 cm)	17" - 22.5" (43 - 57 cm)
Precision OA brace Single upright (Medial)				
PRECOAM-L1	OA Knee Brace Single Medial Upright, Left	Sm/Md	15.5" - 21" (39 - 53.5 cm)	11.5" - 17" (29 - 43 cm)
PRECOAM-L2	OA Knee Brace Single Medial Upright, Left	Lg/X-Lg	21" - 26.5" (53.5 - 67 cm)	17" - 22.5" (43 - 57 cm)
PRECOAL-R1	OA Knee Brace Single Medial Upright, Right	Sm/Md	15.5" - 21" (39 - 53.5 cm)	11.5" - 17" (29 - 43 cm)
PRECOAL-R2	OA Knee Brace Single Medial Upright, Right	Lg/X-Lg	21" - 26.5" (53.5 - 67 cm)	17" - 22.5" (43 - 57 cm)
Precision OA brace Double upright				
PRECOAD-L1	OA Knee Brace Double Upright, Left	Small	15.5" - 18.5" (39 - 47 cm)	11.5" - 14.5" (29 - 37 cm)
PRECOAD-L2	OA Knee Brace Double Upright, Left	Med	18.5" - 21" (47 - 53.5 cm)	14.5" - 17" (37 - 43 cm)
PRECOAD-L3	OA Knee Brace Double Upright, Left	Large	21" - 23.5" (53.5 - 60 cm)	17" - 19 1/3" (43 - 50 cm)
PRECOAD-L4	OA Knee Brace Double Upright, Left	X-Lg	23.5" - 26.5" (60 - 67 cm)	19 1/3" - 22.5" (50 - 57 cm)
PRECOAD-R1	OA Knee Brace Double Upright, Right	Small	15.5" - 18.5" (39 - 47 cm)	11.5" - 14.5" (29 - 37 cm)
PRECOAD-R2	OA Knee Brace Double Upright, Right	Med	18.5" - 21" (47 - 53.5 cm)	14.5" - 17" (37 - 43 cm)
PRECOAD-R3	OA Knee Brace Double Upright, Right	Large	21" - 23.5" (53.5 - 60 cm)	17" - 19 1/3" (43 - 50 cm)
PRECOAD-R4	OA Knee Brace Double Upright, Right	X-Lg	23.5" - 26.5" (60 - 67 cm)	19 1/3" - 22.5" (50 - 57 cm)

*Thigh sizing guide - measure 6" (15 cm) above the medial condylar plateau.

** Calf sizing guide - measure 5" (12 cm) below the medial condylar plateau.

APPLICATION

Warning: Do not modify the frame of knee brace except to shape it as instructed in this guide. It will void the warranty and can cause product failure.

Note: Recommended installation and use procedures must be followed for maximum safety and service life.

Precision Pro Double Upright OA

1. Locate knee center by palpating the superior angle of the medial tibial plateau. "Knee Center" is 1.9 cm (0.75") above this point (FIGURE 1).
2. Loosen all straps prior to applying brace on patient.
3. With the patient seated and the affected leg flexed between 10° and 15°, apply the orthosis to the leg, aligning the center of the knee joint to the knee center. Press tibia shell against leg.

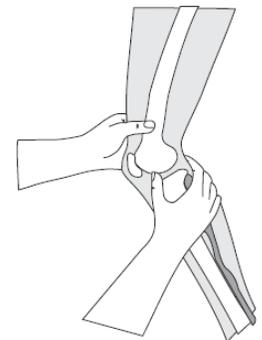


Figure 1. Find knee center



4. Tighten the straps in the following order:

- 1) Proximal posterior calf strap
- 2) Distal posterior calf strap
- 3) Distal posterior thigh strap
- 4) Proximal posterior thigh strap
- 5) Anterior tibia strap
- 6) Anterior thigh strap.

5. Have patient walk with brace checking for strap discomfort. Readjust strap if necessary.

6. To help maintain an appropriate fit, instruct the patient to only unfasten the posterior straps when removing the brace.

7. To adjust the angle of the knee joint, turn the screw (**shown in FIGURE 2**) located at the outer superior portion of the medial and lateral joints with the 3mm hex tool supplied in kit. Set the joint in the desired position. (There is up to 10° of correction in each direction, valgus or varus).

8. Allow the patient to ambulate to ensure that the correction is appropriate.

9. Setting of the flexion and extension stops requires the use of a screw driver. Remove screw and existing stop on outside of hinges and replace with desire stop. Anterior screw holds extension stops Posterior screw holds flexion stop. ***Be sure to have same degree setting on both sides of brace and that screws are snug.***

10. Provide the patient with the Patient Instructions for the Precision Pro OA knee orthosis.

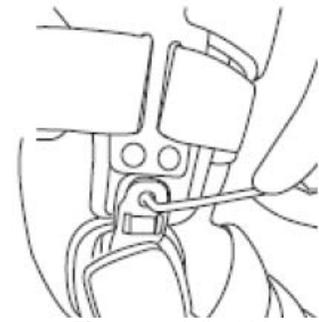


Figure 2. Adjust hinge

Precision Pro Single Upright OA

1. Locate knee center by palpating the superior angle of the medial tibial plateau. “Knee Center” is 1.9 cm (0.75”) above this point (**FIGURE 1**).

2. Loosen all straps prior to applying brace on patient.

3. With the patient seated and the affected leg flexed between 10° and 15°, apply the orthosis to the leg, aligning the center of the knee joint to the knee center. Press tibia shell against leg.

4. Tighten the straps in the following order:

- 1) Proximal posterior calf strap
- 2) Distal posterior calf strap
- 3) Distal thigh strap
- 4) Proximal posterior thigh strap.

5. Have patient walk with brace checking for strap discomfort. Readjust strap if necessary.

6. To adjust the angle of the knee joint, turn the screw (**shown in FIGURE 2**) located at the outer superior portion of the joint with the 3mm hex tool supplied in kit. Set the joint in the desired position. (There is up to 10° of correction in each direction, valgus or varus).

7. Setting of the flexion and extension stops requires the use of a screw driver. Remove screw and existing stop on outside of hinge and replace with desire stop. Anterior screw holds extension stops Posterior screw holds flexion stop.

QUESTIONS

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Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

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LIMITED WARRANTY

Trulife warrants that the Precision Pro O.A. Knee Brace will be free from defects in material and workmanship for the Precision Pro O.A. Knee Brace from the date of installation.

This warranty will not apply if the product has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that a Precision Pro O.A. Knee Brace has been modified/repared by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.