

CyMedica Orthopedics

e-vive™ KNEE BRACE USER'S MANUAL

with Trimmable Straps

Read this manual carefully before operating the e-vive™
knee brace

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Rev. C

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1 INTRODUCTION

The CyMedica Orthopedics e-vive post-operative knee brace provides protection and support for knee function after knee ligament reconstruction surgeries including, but not limited to, Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL).



Read this User's Manual carefully before using the device. Pay attention to the Safety Information.

2 INTENDED USE

The e-vive post-operative knee brace is an externally applied orthopedic apparatus intended to support, align, and improve knee function post knee ligament reconstruction surgery.

EXPLANATION OF SYMBOLS

The following symbols are used in this user manual, on the device packaging, or on the device or accessory labeling. Refer to the e-vive User's Manual (CY-0090-019 and CY-0090-020) for a glossary of the symbols.



Reference number; part number



Lot number



Manufacturing date



Manufacturer name and address



Follow instructions for use



Consult instructions for use

3 SAFETY INFORMATION

3.1 WARNINGS & CAUTIONS

- Carefully read fitting instructions and warnings prior to use. To ensure proper performance of the brace, follow all instructions. Failure to properly position the brace and fasten each strap will compromise performance and comfort.
- This device will not prevent or reduce all injuries. Proper rehabilitation and activity modification are also an essential part of a safe treatment program. Consult your licensed health care professional regarding safe and appropriate activity level while wearing this device.
- For single patient use only.
- The slide lock and extension/flexion limits are designed to keep the leg positioned properly and are not designed to support the patient's weight. Applying full body weight to the lock and limits may break the brace and lead to injury.

3.2 **e-vive Knee Brace**

The e-vive knee brace is used with e-vive knee conductive garment, refer to e-vive NMES System User's Manual for information related to the conductive garment.

The following picture shows the e-vive knee brace and the main components. The hinge can be locked out at full extension or a specific angle, or adjusted to limit knee range of motion.



3.3 Instructions for Applying the Knee Brace

Position the Brace:

Sit on the edge of a stable chair

With the straps undone, place the brace behind the knee

Position the hinge brace bars to the midline of the knee

Center the hinges with the knee cap

Secure the Brace:

Be careful to maintain the lateral and medial positions of the hinge bars.

Starting with brace strap A, feed strap through its associated loop and attach so the brace is snug against the leg.

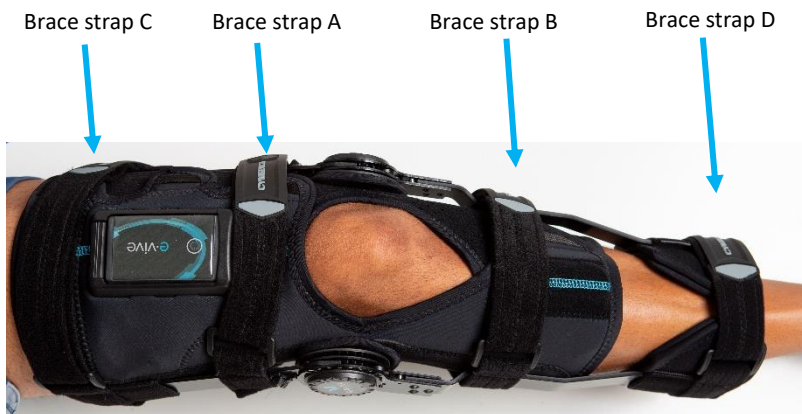
Attach remaining brace straps in order:

Brace strap B

Brace strap C

Brace strap D

Verify that the brace bars are aligned along with the midline of the leg.



The brace should fit snug to the leg.

Clinician may trim excess material as needed. The Alligator strap tabs enable easy strap trimming.

To Trim the Straps:

Remove Alligator tab from strap ends by pulling up on the fabric adjacent to the rubber logo tab on both sides of the strap.

Trim excess material starting from the end of the strap– take care to not cut too short.

Replace Alligator tab by re-attaching the fabric onto both ends of the strap with the hook-and-loop material facing down.

Secure straps.

Using the lock out feature of the e-vive knee brace:

The e-vive knee brace can be locked out at 0° (extension) via the slide lock to prevent knee motion.

Locking the knee brace in extension:

To lock out the brace in extension, fully extend your leg and align the slide lock between the two white lines on the hinge. When positioned, move the slide lock towards your foot to secure. Ensure that the slide lock is fully seated into its mating slot on the hinge. Repeat for both knee brace hinges. Confirm the slide lock is fully seated on each hinge.

Unlocking the knee brace:

With your leg fully extended, move the slide lock on both brace hinges towards your thigh. Carefully, retract the slide lock to ensure it is completely removed from the mating slot on the hinge.



Knee brace with slide lock engaged



Knee brace with slide lock disengaged

3.4 Instructions for Operating the e-vive Knee Brace

The e-vive knee brace can be used to limit or lock out the flexion and extension range of motion of the knee. Each brace has an independent hinge on both sides of the knee joint. The hinge dial is used to adjust the extension and flexion range of motion of its associated hinge. The extension limit can be set to -15° (hyperextension) or from 0° to 90° in 15° increments. The flexion limit can be set from 15° to 135° in 15° increments.

NOTE: The knee brace hinge dials on both sides should always be adjusted to the identical settings prior to use.

Setting the e-vive knee brace extension and flexion limits:

Removing the extension limit:

Rotate the hinge dial towards the EXTENSION setting until the locking disc pops out and releases the extension limit.

Setting the extension limit:

Rotate the hinge dial to the desired EXTENSION setting and push in the locking disc firmly until seated.

Removing the flexion limit:

Rotate the hinge dial towards the FLEXION setting until the locking disc pops out and releases the flexion limit.

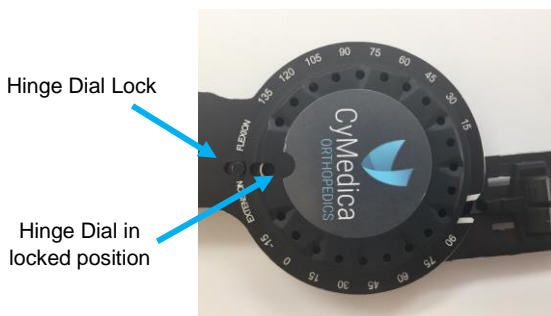


Using the Locking Disc to set Extension Limit at 30°

Using the Locking Disc to set Extension Limit at 90°

Locking the Hinge Dial

Once the desired EXTENSION and FLEXION Limits have been set, the hinge dial should be rotated to the LOCK position to prevent unintentional rotation of the hinge dial.



NOTE: To lock the hinge at any setting (in 15° increments), set the extension and flexion limits to the same number. To accomplish this, set flexion limit first, then set the extension limit. To unlock, disengage the extension first, and then the flexion limit.

3.5 Instructions for Detaching the e-vive Knee Brace

Your doctor may request to use the knee brace for a period of weeks. The knee brace may be removed from the e-vive conductive garment. To do this, detach the straps and remove from the associated loops. Then, peel the brace bars, straps, and pockets away from the sides of the conductive garment. The parts removed may be discarded or stored as desired.



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