DONJOY®

VersaROM® Hip

CLINICIAN APPLICATION

BEFORE USING THIS DEVICE, PLEASE READ THE FOLLOWING INSTRUCTIONS COMPLETELY AND CAREFULLY. CORRECT APPLICATION IS VITAL TO THE PROPER FUNCTIONING OF THE DEVICE.

INTENDED USER PROFILE:

The user should be able to:

- Read and understand the directions, warnings and cautions.

INTENDED USE/INDICATIONS:

Post-Op use following minimally invasive hip procedures; Labral repair; with or without gluteus medius repair; ROM control following primary or hip revision surgery; Post-op use following proximal hamstring repair.

CONTRAINDICATIONS:

Pulmonary, cardiovascular or skeletal conditions which have risk to be made worse as a result of compression and/or pressure, unstable, displaced fractures.

WARNINGS AND PRECAUTIONS:

If you experience any pain, swelling, sensation changes, or any unusual reactions while using this product, consult your medical professional immediately.

CLEANING INSTRUCTIONS:

Hand wash in water (86°F/30°C) using mild soap. Air dry.
NOTE: If not rinsed thoroughly, residual soap may cause irritation and deteriorate material.

Do NOT wash.

Do NOT iron.

Do NOT tumble dry.

Do NOT bleach.

MATERIAL CONTENTS:

Mesh: Nylon; **Spacer:** Polyester; **Binding:** Poly/Cotton

WARRANTY:

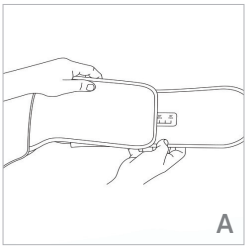
DJO, LLC will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of six months from the date of sale. To the extent the terms of this warranty are inconsistent with local regulations, the provisions of such local regulations will apply.

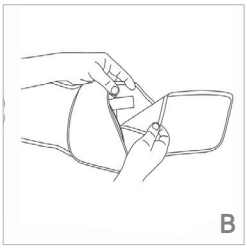
RX ONLY.

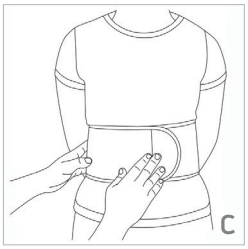
INTENDED FOR SINGLE PATIENT USE.

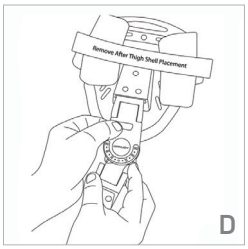
NOT MADE WITH NATURAL RUBBER LATEX.

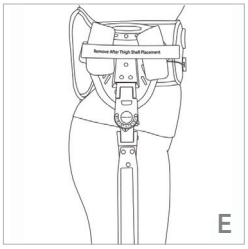
NOTICE:
WHILE EVERY EFFORT HAS BEEN MADE IN STATE OF THE ARTTECHNIQUES TO OBTAIN THE MAXIMUM COMPATIBILITY OF FUNCTION, STRENGTH, DURABILITY AND COMFORT, THIS DEVICE IS ONLY ONE ELEMENT IN THE OVERALL TREATMENT PROGRAM ADMINISTERED BY A MEDICAL PROFESSIONAL. THERE IS NO GUARANTEE THAT INJURY WILL BE PREVENTED THROUGH THE USE OF THIS PRODUCT.

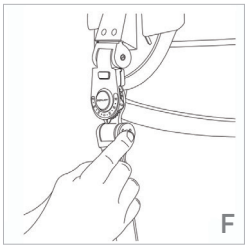


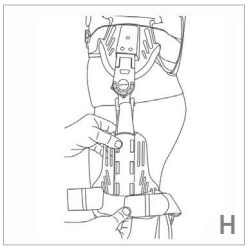


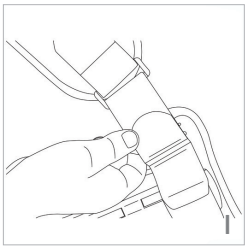


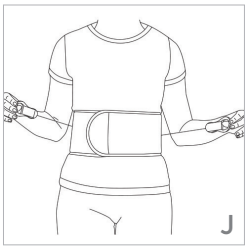


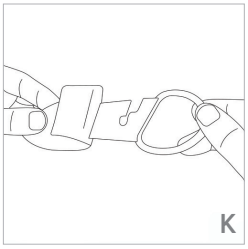


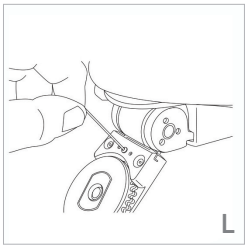


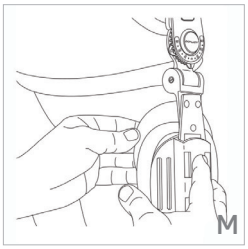












Application Information

Fort best results, fit patient prior to surgery.

SIZING: The VersaROM® Hip fits most waists 25"-53" (64cm-135cm)

1. Measure the waist at the level of the navel.
2. Align the edge of the rear belt components to a mark on the measurement strip corresponding to the waist measurement taken. Fully reengage both components. *(Figure A)*
3. For patients with a waist UNDER 34" (<86cm): Disengage the side wings from the rear belt components. Remove & discard the side wings *(Figure B)*. Reattach the modified belt component to the rear belt component. If the waist belt is trimmed, locate the two black, hook and loop adapters in the packaging. Attach the hook and loop adapters to the rear belt to cover any exposed hook and loop area.
   Note: For patients with a waist over 53" (>135cm) an extension belt is included in the packaging.

APPLICATION INSTRUCTIONS:

4. Wrap the waist belt approximately 1" (2.5cm) above the widest part of the hips and secure the hook and loop attachment on the front side of the patients. *(Figure C)*
5. Prepare pelvic shell and hinge assembly for placement. Set the flexion and extension stops by pressing the center button on the face of the hinge and moving each respective tab to the desired postiions. *(Figure D)*
   NOTE: Make sure the center button returns to a fully locked position. A click sound may be heard and the center button protrudes when locked.
6. DO NOT remove the "peel away" red tab on the pelvic shell or the red (protective strip" found on the thigh component. Position the pelvic shell and hinge assembly so it is centered laterally with the top aligned just below the top edge of the belt assembly, reposition if necessary. *(Figure E)*
   NOTE: There are two pivot changes. Once pivot change is located above the range-of-motion and other is located below the range-of-motion. Pushing the recessed buttons at the center of each pivot, changes the abduction/adduction angles, allowing for the desired angle with the least amount of hinge protrusion. *(Figure F)*
7. Once the pelvic component is positioned correctly, peel away the red tab from the pelvic shell and fully engage the hook-and-loop wings. *(Figure G)*
8. Slide the thigh component up and down the distal bar to the desired position. Be sure to leave enough clearance for knee movement. Reposition as necessary without removing the red protective strip. Once the thigh component is in the desired position remove the red protective strip exposing the aggressive hook-and-loop underneath. Press the shell firmly against the distal bar to fully engage the hook-and-loop. *(Figure H)*
9. Wrap thigh strap around leg and adhere hookand loop tab.
   NOTE: To adjust the thigh strap, peel open the shiny tab to expose the strap ends. Cut the strap and reapply the hook tab. Please be careful not to cut the strap too short. *(Figure I)*
10. Pull the pull tabs around and attach to the front of the waist belt. *(Figure J)*

ADJUSTING PULL TAB LENGTH (OPTIONAL)

11. Remove lace spool from the pull tab pocket and wind lace around the spool to shorten the length of the pull tab. Unwind lace from the spool to lengthen the pull tabl. *(Figure K)*

LOCKING THE BRACE (OPTIONAL)

12. If desired, the clinician can lockout the flexion/extension range-of-motion of the hip joint. Locate the screw found on the interior side of the pelvic shell and tighten it down using the provided tool.. *(Figure L)*

EXTRA PADDING

13. If so desired, attach the mid thigh pad as shown. *(FIgure M)*

BRACE REMOVAL

14. To remove the hip brace, detach the pull tabs on the side of the waist belt then, unfasten the belt and thigh cuff. Remove hip brace.

DJO®

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