

DONJOY®

X-ACT FIT™ SHOULDER

Clinician quick start guide

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

INTENDED USER PROFILE:

The X-Act Fit shoulder brace provides support and immobilization of the shoulder, elbow, wrist and hand following surgery and other shoulder conditions. Rotator cuff repairs; Bankart and capsular shift procedures; Soft-tissue strains; Shoulder dislocation/subluxation; Non or minimally displaced proximal humerus fractures; Pectoral tendon rupture and distal biceps rupture; AC-Joint instabilities; Proximal biceps tenodesis, SLAP-Repairs; ORIF clavicle fractures; Humeral shaft fractures; Scapular fractures; SC joint separation, UCL recon of the elbow and other elbow fracture indications; Non- and Post-surgical rehabilitation.

Application:

Step 1. Prepare the brace

Remove brace from packaging. Set aside arm sling. Remove stress ball and waist belt closure mitt. (Fig A) NOTE: Do not remove plastic sleeve until Step 3.

Step 2. Position Waist Band & Size Waist Belt

1. (Right Shoulder shown) Place the malleable WAIST BAND on the affected side of body approximately 2.5 cm (1") above the belly button. (Fig B)
2. Wrap the WAIST BELT around the torso and attach the BELT CLOSURE STRAP to FRONT PANEL of WAIST BAND. (Fig C)
3. Tighten WAIST BELT using the BELT ADJUSTMENT STRAP as needed for secure fit. The ARM REST BAR should be pointing forward and in a neutral position. NOTE: Excess WAIST BELT may be trimmed or folded (Fig. D,E), as needed. Remove the Y-tab on the WAIST BELT, trim or fold belt and re-apply Y-tab. Secure WAIST BELT to WAIST BAND.
4. Movable HIP PAD may be positioned on inside of WAIST BELT on unaffected side to provide additional comfort & support. (Fig. G)

Step 3. Adjusting for Abduction /ER/IR Positions

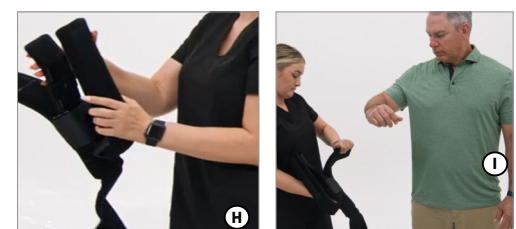
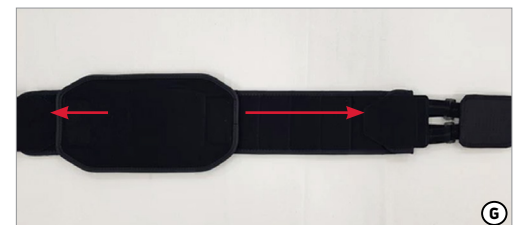
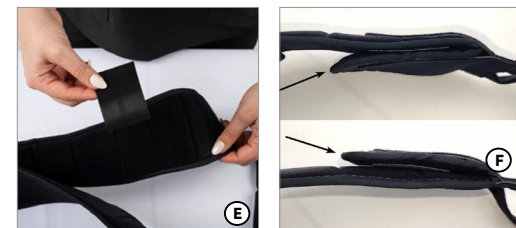
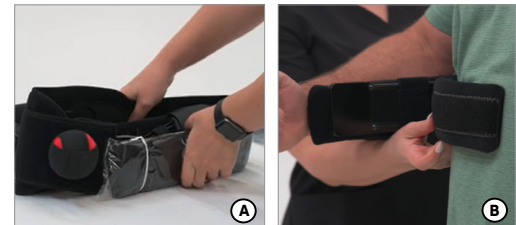
The X-Act Fit Shoulder is packaged and configured in a neutral abduction position.

UP TO 45 DEGREES OF ABDUCTION OR ER/IR

1. Remove Plastic Sleeve on ARM REST BAR.
2. Shape the malleable ARM REST BAR into the desired arm position for up to 45 Abduction or for External/Internal Rotation. Secure the AB STRUT under the ARM REST BAR. (Fig H)

45-TO-90-DEGREE ABDUCTION

1. Remove Plastic Sleeve on ARM REST BAR.
2. Locate the button on the EZ AXIS HINGE plate on the WAIST BAND. Push in the BUTTON and pull away from WAIST BAR to rotate the ARM REST BAR so it's at a 90-degree angle to WAIST BAND. Push down on EZ AXIS HINGE plate and make sure there is an AUDIBLE CLICK locking the ARM REST BAR in place. NOTE: ARM REST BAR should be pointing down toward patient's hip.
3. Form the ARM REST BAR to desired level of Abduction.
4. Remove the CINCH STRAP around the AB BAR. Detach AB EXTENSION and position along AB STRUT for optimal support of ARM REST BAR. Tightly secure the CINCH STRAP around the AB STRUT & EXTENSION. The hook on the top of the AB EXTENSION should be securely attached to the ARM REST BAR. The AB STRUT 'lip' may be formed if desired, to be flush with AB Extension. NOTE: For some patients, the WAIST BAND may need to be placed slightly higher on patient's torso to obtain 90-degree abduction.



Step 4. Sizing & Application of Arm Sling

1. Remove the thumb, forearm, and biceps straps from arm envelope. (Fig. J)
2. Open both quick release buckles at the front of arm envelope. (Fig. K)
3. Place forearm into arm envelope with elbow as far back as possible. (Fig. L)

ADJUST ARM SLING LENGTH:

1. Remove sling from patient, detach both the hook and loop closure pads and buckles. (Fig. M)
2. Fold the envelope inwards and adhere hook and loop at desired length. (Fig. N)
3. Re-attach buckles ensuring that the buckles are positioned above top of arm envelope. (Fig. O)
4. Place arm in ARM ENVELOPE. (Fig. P)

SHOULDER STRAP APPLICATION:

1. Place shoulder strap over the opposite shoulder. Connect shoulder strap QUICK RELEASE BUCKLES to its mate on front of ARM ENVELOPE. (Fig. Q) Trim and tighten straps as needed. (Fig. R)
2. Secure THUMB STRAP between the thumb and forefinger at front of sling. Then secure FOREARM and BICEP STRAPS at desired locations. (Fig. S)

NOTE: Final trimming of straps should be completed AFTER abduction bar is positioned.

ATTACH SLING TO ARM REST BAR:

Position ARM SLING ENVELOPE along the hook and loop strip of the ARM REST BAR with elbow a few inches behind the bend on the ARM REST BAR. Make sure the ARM ENVELOPE is firmly attached to the ARM REST BAR. (Fig. T) Adjust and trim shoulder strap, front and back, as needed. (Fig. U)

Optional Shoulder Ring Application:

1. Remove the standard shoulder strap from the ARM ENVELOPE. (Fig. V)
2. Lengthen FRONT and BACK SHOULDER STRAPS to their longest length for first time fitting. (Fig. W)
3. Attach the posterior strap to the O-ring on back of the ARM SLING ENVELOPE. (Fig. X)
4. Open the SHOULDER RING and wrap under unaffected arm, then over top of shoulder. (Fig. Y)
5. Secure SHOULDER RING with hook and loop closure (Fig. Z). Make sure the hook and loop closure of SHOULDER RING is away from patient with WIDEST ENDS over top of shoulder. Trim and/or adjust the SHOULDER RING circumference as needed. (Fig. AA)

POSITIONING OF SWIVEL D-RING STRAP TABS:

1. Adjust the front and back SWIVEL D-RING STRAP TABS on SHOULDER RING so they are approximately 2.5 - 5 cm (1 - 2") from top of shoulder (Fig. AB). Placement of the SWIVEL D-RING STRAP TABS on the shoulder ring helps to maintain straps and arm in proper position. (Fig. AC)
2. Secure SHOULDER STRAP with Quick Release Buckles to front of sling. (Fig. AD)
3. Adjust and Trim excess SHOULDER STRAP as needed. (Fig. AE)

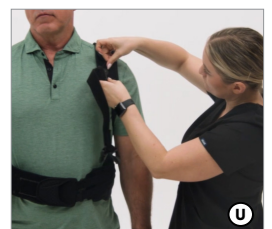
CLEANING INSTRUCTIONS

Separate the rigid components from the soft goods prior to cleaning. Hand wash in water (30°C/86°F) using mild soap. Air dry.

RX ONLY

WARNINGS AND CAUTIONS:

- Device is supportive only and does not guarantee or intend to prevent injury.
- If you have skin disorders/injuries in the relevant part of the body, the product should be fitted and worn only after consultation with a medical professional.
- Do not use over open wounds.
- If pain, swelling, changes in sensation or other unusual reactions occur while using this product, you should contact your doctor immediately.



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