

ENGLISH

Description of symbols

MD Medical Device

PRODUCT OVERVIEW (FIGURE 1)

- a. Sling
- b. Shoulder Strap
- c. Immobilizer Strap
- d. Offloading Strap
- e. Exercise Ball
- f. Abduction Pillow
- g. External Rotation Pillow

INDICATIONS FOR USE

For shoulder conditions that may benefit from shoulder immobilization and/or abduction and/or external rotation, such as:

- Post-operative
- Soft tissue repairs/strains
- Shoulder instabilities/injuries

CONTRAINDICATIONS

None known.

WARNINGS AND PRECAUTIONS

This sling is supportive only and is not intended or guaranteed to prevent injury.

This product is designed to be worn, in part, directly on the skin. Inspect your elbow, arm, hand and shoulder, and this product before and after each use.

If you have any questions as to how the product applies to your own specific condition, consult your healthcare professional.

This product is for single patient use only.

If there is a change in loss of device functionality or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact a healthcare professional.

FITTING INSTRUCTIONS

Application with Abduction and External Rotation (Fig. A)

1. Attach the quick release buckle of the Immobilizer Strap to the Abduction Pillow (Fig. 1).

2. Position the Abduction Pillow above the hip and the quick-release buckle towards the front.

Secure the Abduction Pillow in place using the Immobilizer Strap, with the quick-release buckle at the front, and the d-ring at the back (Fig. 2). If the Immobilizer Strap is too long, remove alligator clip, trim strap to length, and re-attach alligator clip.

3. Using the double-sided hook, attach the External Rotation Pillow to the Abduction Pillow (Fig. 3).

4. Place the forearm into the Sling at a 90° angle, seating the elbow snugly in the elbow pocket and the hand in the thumb loop (Fig. 4). The thumb loop can be repositioned, and the installed elbow pillow can be removed, if necessary, to improve the fit and comfort.

5. Close the top flap to secure the Sling (Fig. 5). Note: Right arm application is shown in the figure. For left arm application, the flap will fold towards the body.

6. Locate the pocket on the side of the Sling facing towards the body and ensure buckle is placed within the pocket (Fig. 6).

DEUTSCH

MD

Medizinprodukt

PRODUKTBÜRSCHT (ABBILDUNG 1)

- a. Schlinge
- b. Schultergurt
- c. Ruhigstellungsurt
- d. Entlastungsgurt
- e. Gymnastikball
- f. Abduktionsschlüssel
- g. Außenrotationskissen

INDIKATIONEN

Bei Gelenkerkrankungen, die einer Ruhigstellung der Schulter und/oder Abduktion und/oder Außenrotation profitieren können, wie z. B.:

- Postoperativ
- Weichteilekonstruktionen/-zerrungen
- Schulterinstabilitäten/-verletzungen

KONTRAINDIKATIONEN

Keine bekannt.

WARNUNGEN UND VORHALTEMASNAHMEN

Diese Orthese dient nur zur Unterstützung und wurde nicht zur Verbeugung von bswm. als Garantie gegen Verletzungen entwickelt.

Dieses Produkt wurde entwickelt, um teilweise direkt auf der Haut getragen zu werden. Untersuchen Sie vor und nach jedem Gebrauch Ihren Ellbogen, Arm, Ihre Hand und Ihre Schulter sowie dieses Produkt.

Wenden Sie sich an Ihren Arzt, wenn Sie irgendwelche Fragen hinsichtlich der spezifischen Verwendung dieses Produkts haben.

Die Orthese ist nur für individuelle Anwendungen am einzelnen Patienten bestimmt.

Wenn sich die Funktionsweise der Orthese verändert, die Funktion beeinträchtigt ist oder wenn die Orthese Anzeichen von Beschädigung oder Verschleiß aufweist, darf der Anwender die

7. Place the adjustable Shoulder Strap over the opposite shoulder and fasten it to the Sling via the quick-release buckles (Fig. 7). Position the shoulder strap pad where it is most comfortable.

8. Position the Sling against the outer surface of the External Rotation Pillow and hold in place using the double-sided hook strip. If necessary, adjust the Shoulder Strap from the front (Fig. 8) or the back (Fig. 9). If any strap is too long, trim strap to length, and re-attach alligator clip.

9. A correctly applied device (Fig. 10).

Offloading strap (Fig. 8)

To use the Offloading Strap, feed the Offloading Strap through the O-ring behind the opposite shoulder, pull back in the opposite direction and fasten it snugly to itself with the alligator clip (Fig. 11).

10. Pass the Offloading Strap through the O-ring behind the opposite shoulder and secure using the O-ring above the affected wrist (Fig. 12). Position the strap pad where it is most comfortable.

11. A correctly applied device using the Offloading Strap (Fig. 15).

CLEANING AND CARE

Hand wash using a mild detergent and 30°C (86°F) cold water. Hang to dry.

The cover from the pillowcase may be removed for washing.

Do not put the device in a washing machine or dryer.

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3. A correctly applied device using the Offloading Strap (Fig. 15).

ACCESSORIES AND REPLACEMENT PARTS

- a. Axilla Pillow
- b. External Rotation Pillow
- c. Airplane Accessory

REPORT A SERIOUS INCIDENT

Report a serious incident to your employer or patient must report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

LIAIBILITY

Össur does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

INSTRUCTIONS OF ADJUSTMENT

Colocation with abduction and rotation extrema (Fig. A)

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12. Place the adjustable Shoulder Strap over the opposite shoulder and fasten it to the Sling via the quick-release buckles (Fig. 7). Position the shoulder strap pad where it is most comfortable.

13. A correctly applied Orthese mit Entlastungsgurt (Abb. 15).

REINIGUNG UND PFLEGE

Reinigen Sie die Orthese von Hand mit einem kleinen Reinigungsmittel und 30 °C kaltem Wasser. Zum Trocknen aufhängen.

Der Bezug von den Kissen kann zum Waschen entfernt werden.

Nicht in der Waschmaschine waschen oder in einem Trockner trocken.

ZUBEHÖR UND ERSATZTEILE

- A. Schultergurt
- B. Außenrotationskissen
- C. Flugzeuggekörbchen

MELDUNG SCHWERWIEGENDER VORFÄLLE

Wichtigster Hinweis für Europa anlässliche Anwender und/oder Patienten:

Der Anwender und/oder Patient muss dem Hersteller und der zuständigen Behörde des Mitgliedstaats, in dem der Anwender und/oder Patient ansässig ist, jeden schweigenden Vorfall melden, der im Zusammenhang mit dem Produkt auftritt.

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Position the strap pad where it is most comfortable.

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14. Legen Sie den Unterarm im 90° Winkel in den Hebegurt, wobei der Ellbogen fest in der Ecktasche des Hebegurts und der Daumen in der Daumenschlaufe sitzt (Abb. 5).

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SIGNALER UND INCIDENT GRAVE

Avis importante aux utilisateurs et/ou patients établis en Europe :

Le patient doit être informé de l'incident grave que se présente en relation avec le dispositif ou à la suite de l'application de ce dispositif.

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