

Instructions for use

Mbrace shoulder orthosis

Please read this manual carefully. If you have any questions, please contact your physician or supplier.

Intended use

This medical device relieves and supports the shoulder without restricting functional movements of the arm. The orthosis is intended for the shoulder only. Use the orthosis as directed.

Indications

Chronic, post-traumatic or post-operative painful shoulder. Indications must be determined by a physician.

Contraindications

The following indications require consultation with a physician:

- Skin conditions/injuries (including allergic or inflammatory reactions) in the application area of the orthosis.
- Sensory and circulatory disorders in the area of the arm and hand.
- Impaired lymph drainage, including soft tissue swellings of uncertain origin distal to the orthosis.
- Vein occlusion in the arm.

Important notes

Discuss the use of the shoulder orthosis with your physician. Please closely observe the specifications in these instructions for use. Only use it according to your indication and any additional instructions given by a medical specialist. This medical aid is to be used by one patient only..



Do not make any changes to the product. Modifications to the product and/or improper use of the product exempt the manufacturer from product liability .



Do not use in case of intolerance to one or more of the materials used.

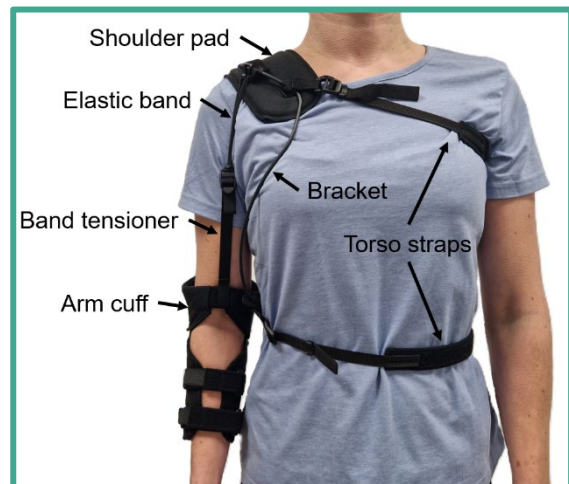


Only use with other products after consultation with your physician.



If you notice any changes or an increase in symptoms while wearing the product, stop any further use and contact your physician or medical retailer.

Product overview



Manual Mbrace

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Preparation for first-time use

When you start using the Mbrace for the first time, follow the following steps to properly adjust the Mbrace.

1. Adjustment of torso strap length
2. Adjustment of upper part arm cuff
3. Selection and attachment of elastic bands

1. Adjustment of torso strap length

The length of the torso straps can be shortened for a better fit.

1. Put the arm through the bracket (Fig. 1).
2. Let the shoulder pad rest on the shoulder, close to the neck.
3. Attach the upper torso strap by securing the plastic hook to the loop on the front of the bracket (Fig. 2).
4. Wrap the torso strap around the torso just below the armpit. At the back of the torso, cut the strap to the desired length (Fig 3).

5. If necessary, tighten the torso strap further by pulling on the loose end of the torso strap.
6. Repeat steps 3 through 5 for the lower torso strap.

2. Adjustment of upper part arm cuff

The upper part of the arm cuff can be adjusted to fit the size of the upper arm.

1. Measure the largest circumference of the user's upper arm while contracting the biceps.
2. The upper arm cuff should fit loosely around the upper arm and should not obstruct blood flow, even when the biceps is contracted. Consider (thick) clothing as well. As a general guideline, add 2 cm to the measured circumference. Cut off the excess from the band (Fig. 4).
3. Close the Velcro and slide the triangular sections over the strap to cover the Velcro (Fig. 5).

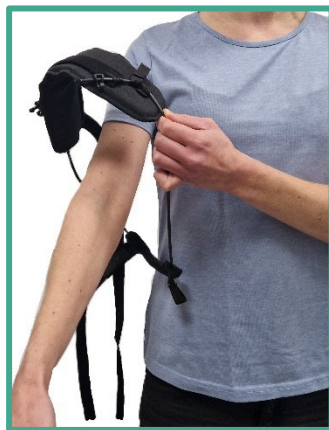


Fig. 1

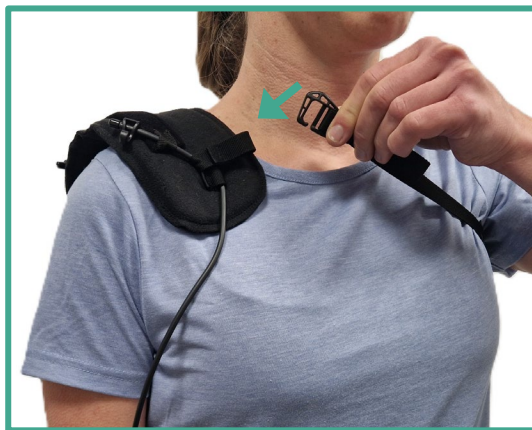


Fig. 2



Fig. 3



Fig. 4



Fig. 5

3. Selection and attachment of elastic bands

Depending on preference, the number of elastic bands can be adjusted to change the degree of support the Mbrace provides to the arm. It is recommended to start with one or two bands per side. More elastic bands provide more upward force and therefore more support to the arm. Two sizes of elastic bands come with the Mbrace: small and large. The small bands offer more support than the wide bands. Both can be used.



For the best results, place an equal number of elastic bands at the front and back of the shoulder.

Attachment of the selected elastic bands:

1. Pass the elastic bands through the plastic opening of the band tensioners.
2. Make a knot by passing one end of the elastic band through the other end of the same elastic band (Fig. 6).
3. Put on the arm cuff (Fig. 7).
4. Attach the elastic bands to the hooks, both on the front and the back (Fig. 8).



Fig. 6



Fig. 7



Fig. 8

Putting on orthosis

1. Put the arm through the bracket and arm cuff (Fig. 9).
2. Align the two metal D-rings of the arm cuff with the elbow rotation axis (green dotted line) and close the Velcro (Fig. 10).
3. Check the correct positioning of the arm cuff and test for free movement of the elbow.
4. Let the shoulder pad rest on the shoulder, close to the neck.
5. Wrap the upper torso strap around the torso and attach the plastic hook to the upper loop at the front of the bracket (Fig. 11).
6. Pull on the loose end of the torso strap, to ensure that the strap is tight and the brace stays in place (Fig. 12).
7. Repeat steps 5 and 6 for the lower torso strap.
8. Tighten the elastic bands by pulling the band tensioners down as far as possible (Fig. 13).



Regularly check the elastic bands for wear, especially around the attachment points.



Regularly check the integrity of the arm cuff, torso straps and bracket before using the orthosis.



The pressure applied to the shoulder area after tightening the straps should be comfortable. If you experience discomfort in the shoulder area, reduce the tension of the elastic bands.



Avoid closing the Velcro too tight (risk of obstructing blood flow) or too loose (arm cuff slides up during use).



Fig. 9



Fig. 10



Fig. 11



Fig. 12



Fig. 13

Taking off orthosis

1. Reduce the tension of the torso straps.
2. Release the (upper and lower) torso straps by lifting the plastic hooks out of the loops (Fig. 14).
3. Loosen both Velcro straps of the arm cuff.
4. Take off the orthosis (Fig. 15).
5. Reduce the tension of the elastic bands by loosening the band tensioners.



Close the Velcro of the arm cuff after use to prevent damage to clothing.



Fig. 14



Fig. 15

Manufacturer information

Material composition

Polyamide, Steel, Softshell fabric (90% Polyester, 2% Elastane, 8% Polyurethane), Synthetic polyisoprene (non-latex rubber).

Cleaning instructions

The fabric parts of the orthosis can be washed by hand. The torso strap(s) and arm cuff can be detached from the bracket and washed separately if required.

1. Close all Velcro to avoid damage to other laundry items.
2. Hand wash the orthosis in warm water (30°C) with a mild detergent.
3. Rinse well.
4. Allow to air dry.



Do not bleach, do not tumble dry, do not iron, do not dry clean.

Warranty

The legal requirements of the country of purchase apply. Warranty is excluded if:

- The product has not been used according to the indication.
- The instructions for use were not followed.
- Unauthorized modifications have been made to the product.

All products are subject to product inspection as part of our quality management system. Please first contact the retailer from whom you obtained the product directly in the event of a potential claim under the warranty.

Reporting requirement

Due to local regulations, you are required to immediately report any serious incident related to the use of this medical device to both the manufacturer and the responsible authority in your country.

Disposal

Upon termination of use, the product must be disposed in accordance to local regulations.

Declaration of conformity

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE Declaration of Conformity can be downloaded from the manufacturer's website.

Medical device | One patient - multiple use

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