# Instructions for use
## Mbrace Shoulder Support

Please read the instructions for use carefully. If you have any questions, please contact your physician or medical retailer.

## Intended purpose

This medical device relieves and supports the shoulder without restricting functional arm movements. The orthosis is intended exclusively for orthotic fittings of the shoulder. The orthosis must be used in accordance with the indications.

## 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 disorders/ 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.

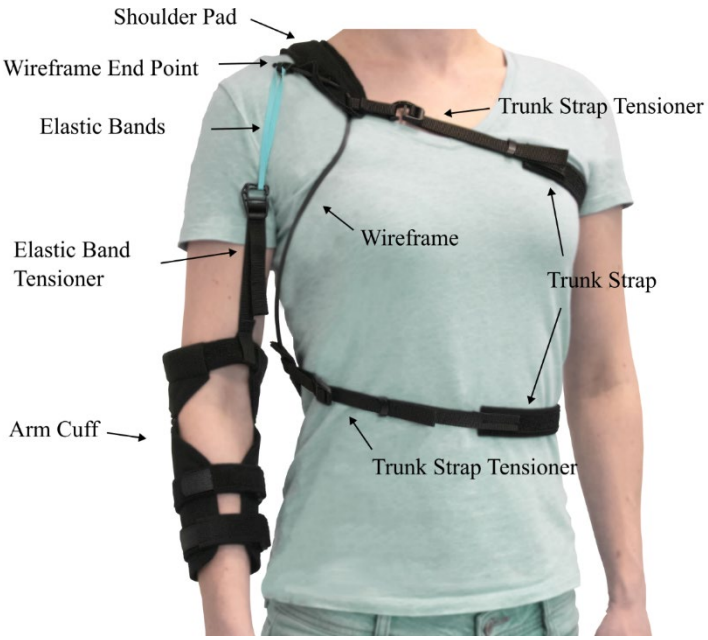
Do not make any changes to the product. Modifications to the product and/or improper use of the product exempt the manufacturer from product liability.

Do not use in case of intolerance of one 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.

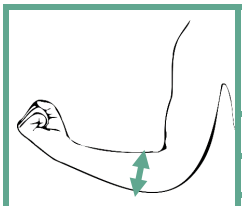
## Product overview




## Preparation for first-time use

### Mbrace size selection

1. Measure the largest circumference of the forearm.
2. Determine the Mbrace arm cuff size according to the table below.



| Size | Forearm circumference (cm) |
|---|---|
| S | 21 – 25 |
| M | 25 – 29 |
| L | 29 – 35 |

**Upper arm cuff adjustment**

The upper part of the Arm Cuff can be adjusted to match the size of the upper arm.

1. Measure the upper arm circumference of the user while flexing the biceps (Fig. 1).
2. The upper arm cuff should fit loosely around the upper arm, and not constrict the blood flow even when the biceps is flexed. Also, take into account (thick) clothing. As a general guideline, add 2 cm to the measured circumference and cut the excess of the strap (Fig. 2).
3. Close the Velcro and slide the triangular parts over the upper Arm Cuff strap to cover the Velcro (Fig. 3).

**Trunk strap adjustment**

The length of the trunk straps can be cut to fit around the trunk of the user.

1. Put the arm through the Arm Cuff and Wireframe. (Fig. 4)
2. Let the Shoulder Pad rest on the shoulder, close to the crease of the neck region. (Fig. 5)
3. Fasten the upper Trunk Strap by attaching the plastic hook to the loop at the front side of the Wireframe. (Fig. 6)
4. Slightly tension the trunk strap by pulling on the Trunk Strap Tensioner.
5. Wrap the Trunk Strap around the trunk just below the arm pit.
6. At the back of the body, cut the strap to the desired length. (Fig. 7)
7. Secure the strap to the Velcro of the Wireframe.
8. Test if the strap can be fastened sufficiently before reaching the end of the adjustment range. Otherwise, cut more from the length of the strap.
9. Repeat the same procedure for the bottom Trunk Strap. Make sure the strap is kept horizontally, before cutting the strap to the desired length.

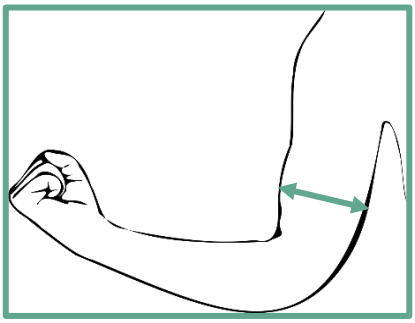


Fig. 1

Fig. 2

Fig. 3

Fig. 4

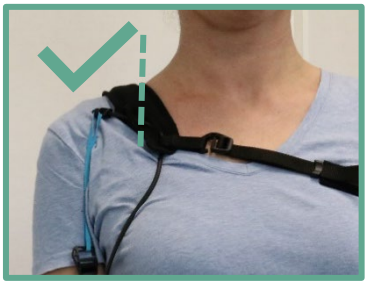


Fig. 5

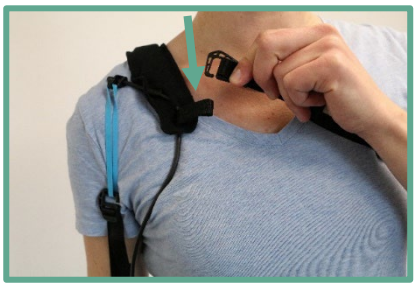


Fig. 6

Fig. 7

### Wireframe adjustment

The Wireframe is available in a left- and right-handed version.

The Wireframe End Points (A and B) should be modified such that they do not restrict the functional range of motion of the user. For the best result, the attachment points should be positioned as showing in Fig. 8 with respect to the center of rotation (orange circle) of the shoulder joint when viewed from the side.

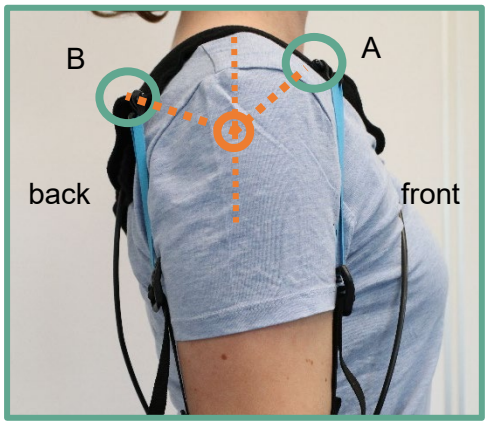


Fig. 8

Note that attachment point A is higher than point B to prevent limitations during forward movement of the arm. Test the functional range of motion of the user by asking the user to perform maximum shoulder flexion and maximum shoulder extension.

Additionally, the shape of the wireframe can be modified if it does not follow the contours of the user, or causes pressure points on the body. For this, the wireframe should be bent with appropriate tools. Make sure the tools do not damage the metal of the wireframe or other parts of the orthosis.

### Elastic bands selection

The elastic bands are attached between the elastic band tensioner hooks and the hook at the end of the wireframe. Based on individual preferences, the number of elastic bands can be changed to alter the amount of weight relief provided by the Mbrace to the arm. **More elastic bands** provide **more upward force** to the arm. Two sizes of elastic bands are provided with the Mbrace: small and large. Both can be used.

> ⚠ For the best results, put equal number of elastic bands at the front and at the back of the shoulder.

## Putting on orthosis

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

> ⚠ Regularly check the Arm Cuff, Trunk Straps and the Wireframe for integrity before orthosis use.

1. Put the arm through the Wireframe and Arm Cuff. (Fig. 9)
2. Align the metal D-rings of the Arm Cuff with the elbow rotation axis (green dashed line) and close the Velcro straps. (Fig. 10)

> ⚠ Prevent tensioning the straps too much (risk of constricting blood flow) or too little (arm cuff slides up during use).

3. Verify the correct positioning of the Arm Cuff and test if the elbow can move freely. (Fig. 11)
4. Let the Shoulder Pad rest on the shoulder, close to the crease of the neck region. (Fig. 12)
5. Wrap the Trunk Straps around the trunk and attach the plastic hook to the loop at the front side of the Wireframe. (Fig. 13)
6. Tension the Trunk Straps by pulling on the loose end of the strap. (Fig. 14)
7. Tension the Elastic Bands by pulling the strap of the Elastic Band Tensioners down. (Fig. 15-16) For the best result, pull the tensioner strap all the way to the bottom end and make sure the Elastic Bands at the front and back side are tensioned equally. (Notice the change in length between Fig. 15 and 16).

8. If required, multiple Elastic Bands can be used. It is advised to start with one or two bands per side.

> ⚠ The pressure applied to the shoulder region after tensioning the straps should be comfortable. If the user experiences discomfort in the shoulder region, lower the tension that is provided by the elastic bands.

## Removal of orthosis

1. Release the tension of the elastic bands by slightly lifting the plastic hook at the front of the orthosis. Repeat this procedure for the elastic bands at the back.
2. Loosen the trunk straps by slightly lifting the plastic hooks.
3. Unhook the Trunk Strap from the Wireframe.
4. Loosen both Velcro closures of the arm cuff. (Fig. 17)

Fig. 9

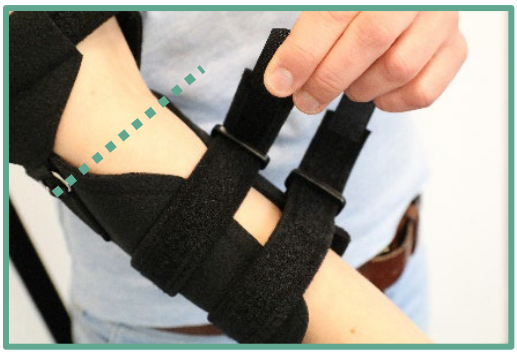


Fig. 10

Fig. 11

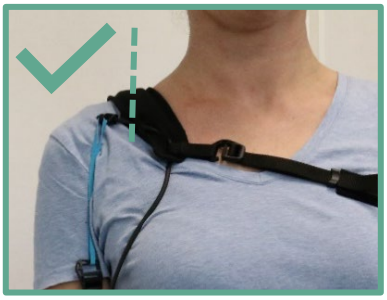


Fig. 12

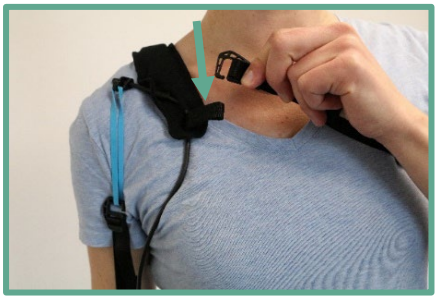


Fig. 13

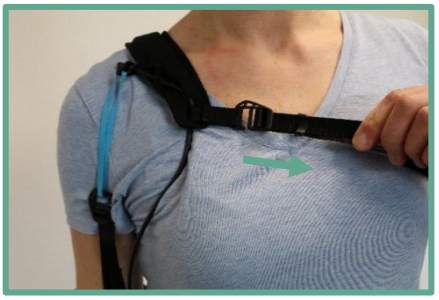


Fig. 14


Fig. 15

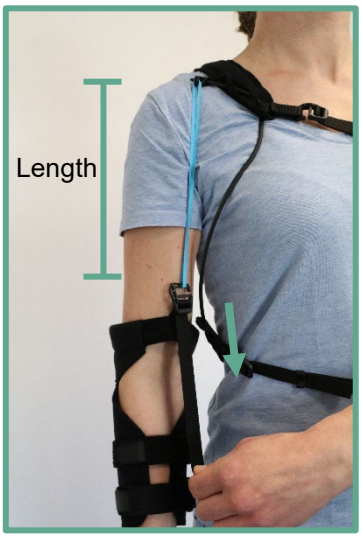



Fig. 16

Make sure to close the Velcro hooks of the Arm Cuff again after loosening, as otherwise damage to clothes may occur.

5. Slide the Wireframe and Arm cuff away from the body. (Fig. 18)

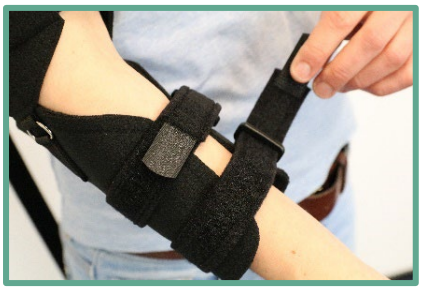


Fig. 17

Fig. 18

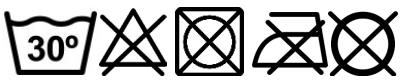
## Material composition

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 hand washed. The Trunk Strap(s) and Arm Cuff can be detached from the orthosis Wireframe and washed separately if required.

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




Do not bleach, do not dry in a tumble dryer, do not iron, do not clean chemically.

## Warranty

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

- The product was not used according to the indication.
- The instructions for use were not followed.
- Unauthorized modifications were applied 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.

## Duty of notification

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

## Disposal

Upon the termination of use, the product must be disposed of in accordance with 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.

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Medical device | Single patient – multiple use

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