

General information



Side effects:

Provided that the orthosis is used in a proper way there are none known to date. If the orthosis is too tight, this can cause local pressure sores, or in rare cases, constrain blood vessels or nerves.

Contraindications:

Skin diseases or lesions in those areas where the orthosis is to be used, especially in areas with inflammatory phenomena, scar tissue with swelling, redness and/or hyperthermia and/or lymphoedema.

Disposal:

The product may be safely disposed in accordance with the local laws.

Warranty:

Legal requirements apply. Product warranty is suspended immediately due to improper or diverted use of the product. Always follow the safety instructions and advice included in the instruction for use.

Intended patient population:

This medical device should only be used by patients who received an instruction by a qualified health professional. The medical device should only be used by adolescent and adult patients aged 12 to 99+.

Material composition:

Polypropylene, Aluminium, Polyester

Precautions:

The necessary stability for the supply area can only be guaranteed if the orthosis is fitted tightly to the body. The orthosis is not flameproof and should not be worn next to an open fire.

If there are signs of hyposensitivity, local pressure sores or pain, the orthosis must be refitted. If there are signs of wear or damaged components, the orthosis should be replaced.

Inform the patient to not wear the orthosis on bare skin. We suggest wearing a thin and breathable shirt underneath it, so moisture can be transported away from the skin.

We urge you to inform us about any serious incidents involving this medical device.



Manufacturer:

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Technical information - ErgoSpine Pro

Posterior panel



Version 1.0 / 06.2022

ErgoSpine Pro

Description:

Thoracic lumbar sacral orthosis

Components:

- ErgoBasic
- ErgoSpine Pro posterior panel
- Anatomic side parts



Intended purpose:

Thoracic lumbar sacral orthosis for relief and/or correction of the lumbar/thoracic spine and reduction of movement in the frontal-, rotational- and sagittal plane.

Supply area: TH5-S1

Indications:

- Stable vertebral fractures
- Scheuermann's disease
- Postoperative stabilization
- Spondylitis
- Spinal tumor

Mode of operation:

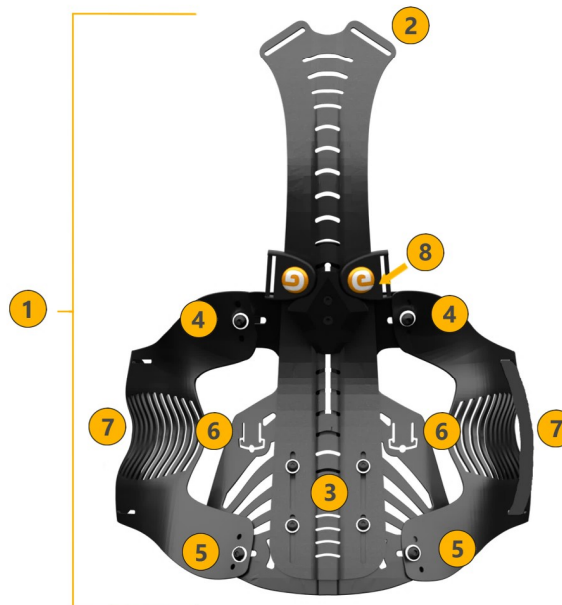
- Straightening and stabilization of the spine in the sagittal- and frontal plane with restriction of rotation

Features:

- Removable parts
- Height-adjustable Titan-Aluminium panel
- Adaptive fit
- Unilateral pull
- Pulley system, mounted on bearings
- Ergo Smart system

Assembling:

Shoulder straps, Smart Adapter, posterior panel and pads are pre-assembled. The anatomic side parts are assembled after fitting of the posterior panel.



Fitting of the posterior panel:

After measuring the patient's back length (C7-L5) the right size of the posterior panel (1) should be chosen. Then the posterior splint (2) can be fitted to the curvature of the patient's spine by cold-forming.

To adjust the connecting panel, loosen its screws (3) and shift the panel downwards or upwards until it is in the right position.

Assembling of the side parts:

The side parts should be connected to the posterior panel after it is fitted to the patient's spine.

Use the provided screws and pay attention to the labeling for right/left and upper side.

First, the screws (4) and (5) should just be tightened loosely, so that the side parts can be shifted. Fit the side parts to the patient, by pushing them close to the patient's body and tighten the screws while the orthosis is held in the correct position. It is possible to adjust the side parts again.

Connecting with the corset:

After the posterior panel is fitted, it should be connected to the corset. Therefore, remove the pad from the connecting panel. The elastic straps on the inside of the corset are now drawn through the slots (6).

To prevent the straps from sliding out, they are secured with the provided bolts. Pull the free ends of the corset through the loops (7) of the side parts.

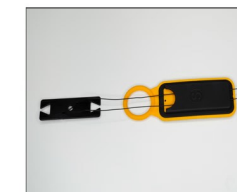
Adjusting the Smart Adapter:

The Smart Adapter (8) should now be positioned and screwed on tightly.

Shortening the shoulder straps:

The shoulder straps each have a Y-hook-and-loop-fastener at one of their ends. The other end is fixed to the strap-coupling of the Smart Adapter. Remove the Y-hook-and-loop-fastener and shorten the straps as required. Reattach the Y-fastener to the shoulder strap and secure it again.

Adjustment of the pulley:



The length of the pulley-system should be adjusted to the patient's circumference by the orthopedic technician. This is necessary to achieve optimal stability.

General process:

The ErgoSpine Pro is a preassembled orthosis, which should be fitted to the individual anatomy of each patient.

Material composition:

Anatomic side parts: Polypropylene - thermoplastic formable at 160 degrees Celsius - can be fitted through mechanical work

Connecting panel: Polypropylene - thermoplastic formable at 160 degrees Celsius

Posterior splint: Aluminium - cold formable