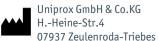
Qualität und Funktion

Gebrauchsanweisung Instruction Manual

Torsion Orthosis/ Pelvic Band 0B100, 0B101, 0B102







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Please read the IFU carefully before fitting. Only correct usage will warrant the function.

1. Intended use

The Torsion Orthosis is a rotation-rod-orthosis for dynamic torsion of the full leg.

2. Technical data

2.1 OB100, OB101 Torsion Orthosis

- The torsion rod connectors are made of aluminium, the rods are made of Vulkolan, a homogeneous elastomer
- An adjustable continues torque is created to correct an existing rotation defect
- Calf belt is made of leather



With Calfbelt

| Order No. | Ø Torsion rod | Lenght | Article No. |
|-----------|---------------|---------|---------------------|
| 0B100-08 | 8 mm | 700 mm | 4 518 010 00 00 008 |
| 0B100-10 | 10 mm | 800 mm | 4 518 010 00 00 010 |
| OB100-12 | 12 mm | 1000 mm | 4 518 010 00 00 012 |
| 0B100-16 | 16 mm | 1000 mm | 4 518 010 00 00 016 |

Without Calfbelt

| Order No. | Ø Torsion rod | Lenght | Article No. |
|-----------|---------------|---------|---------------------|
| 0B101-08 | 8 mm | 700 mm | 4 518 020 00 00 008 |
| OB101-10 | 10 mm | 800 mm | 4 518 020 00 00 010 |
| 0B101-12 | 12 mm | 1000 mm | 4 518 020 00 00 012 |
| 0B101-16 | 16 mm | 1000 mm | 4 518 020 00 00 016 |

2.2 OB102 Pelvic Band

Artificial leather band with formable aluminium core (removable)



| Order No. | Circumference | Article No. |
|-----------|---------------|---------------------|
| 0B102-45 | 40 – 45 cm | 4 518 001 05 00 045 |
| 0B102-50 | 45 – 50 cm | 4 518 001 05 00 050 |
| 0B102-55 | 50 – 55 cm | 4 518 001 05 00 055 |
| 0B102-60 | 55 – 60 cm | 4 518 001 05 00 060 |
| 0B102-65 | 60 – 65 cm | 4 518 001 05 00 065 |
| 0B102-70 | 65 – 70 cm | 4 518 001 05 00 070 |
| 0B102-75 | 70 - 75 cm | 4 518 001 05 00 075 |
| 0B102-80 | 75 – 80 cm | 4 518 001 05 00 080 |

2.3 Optional accessory

| Order No. | Description | Article No. |
|-----------|-------------|---------------------|
| E-0B13 | Shoe clamp | 4 518 001 04 00 008 |

2.4 Service parts

| Order No. | Description | Article No. |
|--------------|--|---------------------|
| E-0B01 | Torsion rod f.torsion orthosis, Ø 8 mm, length 700 mm | 4 518 001 01 00 008 |
| E-0B02 | Torsion rod f.torsion orthosis, Ø 10 mm, length 800 mm | 4 518 001 01 00 010 |
| E-0B03 | Torsion rod f.torsion orthosis, Ø 12 mm, length 1000mm | 4 518 001 01 00 012 |
| E-0B04 | Torsion rod f.torsion orthosis, Ø 16 mm, length 1000mm | 4 518 001 01 00 016 |
| E-0B05 | Proximal attachment, straight, with connector, Ø 8 mm | 4 518 001 02 00 008 |
| E-0B06 | Proximal attachment, straight, with connector, \emptyset 10 mm | 4 518 001 02 00 010 |
| E-0B07 | Proximal attachment, straight, with connector, \emptyset 12 mm | 4 518 001 02 00 012 |
| E-0B08 | Proximal attachment, straight, with connector, Ø 16 mm | 4 518 001 02 00 016 |
| E-0B09 | Distal attachment, curved, with connector, Ø 8 mm | 4 518 001 03 00 008 |
| E-0B10 | Distal attachment, curved, with connector, \emptyset 10 mm | 4 518 001 03 00 010 |

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| Order No. | Description | Article No. |
|-----------|--|---------------------|
| E-0B11 | Distal attachment, curved, with connector, Ø 12 mm | 4 518 001 03 00 012 |
| E-0B12 | Distal attachment, curved, with connector, Ø 16 mm | 4 518 001 03 00 016 |
| E-0B14 | Torsion rod guide, Ø 8 mm | 4 518 001 07 00 008 |
| E-0B15 | Torsion rod guide, Ø 10 mm | 4 518 001 07 00 010 |
| E-0B16 | Torsion rod guide, Ø 12 mm | 4 518 001 07 00 012 |
| E-0B17 | Torsion rod guide, Ø 16 mm | 4 518 001 07 00 016 |
| E-0B18 | Torsion rod connector, Ø 8 mm | 4 518 001 08 00 008 |
| E-0B19 | Torsion rod connector, Ø 10 mm | 4 518 001 08 00 010 |
| E-0B20 | Torsion rod connector, Ø 12 mm | 4 518 001 08 00 012 |
| E-0B21 | Torsion rod connector, Ø 16 mm | 4 518 001 08 00 016 |
| E-0B22 | Proximal attachment, straight | 4 518 001 09 00 000 |
| E-0B23 | Distal attachment, curved | 4 518 001 10 00 000 |
| E-0B24 | Joint nut, M4 | 4 518 001 11 00 000 |
| E-0B25 | Joint screw M4 | 4 518 001 12 00 000 |
| E-0B26 | Washer | 4 518 001 13 00 000 |
| E-0B27 | Hexagon socket screw M4x4 | 4 518 001 14 00 000 |
| E-0B28 | Joint screw, set | 4 518 001 15 00 000 |
| E-0B29 | Buckle, 30 mm | 4 518 001 16 00 000 |
| E-0B30 | Calf band complete for torsion rod Ø 8 mm, circumference 15 – 20 cm | 4 518 001 06 00 008 |
| E-0B31 | Calf band complete for torsion rod Ø 10 mm, circumference 20 – 25 cm | 4 518 001 06 00 010 |
| E-0B32 | Calf band complete for torsion rod Ø 12 mm, circumference 20 – 25 cm | 4 518 001 06 00 012 |
| E-0B33 | Calf band complete for torsion rod Ø 16 mm, circumference 25 – 30 cm | 4 518 001 06 00 016 |
| E-0B34 | Calf band complete for torsion rod Ø 8 mm, circumference 30 – 35 cm | 4 518 001 06 01 016 |

3. Indication/ Contraindication

Indication:

• Pathological internal tibial and foot rotation

Contraindication:

• Pathological antetorsion of the femoral neck

4. Side effects

There are no known side effects.

5. General safety instructions





- This medical product is designed for: single patient, multiple use.
- Fitting/service of this medical device is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the devise to the user.
- The OB100 and OB101 torsion orthotics are semi-finished products and are made by the orthopaedic technician into individual aid fittings according to the doctor's prescription.
- The torsion orthosis is worn according to the information in these instructions for use for the listed areas of application.
- In case of hypersensitivity of the skin, known contact allergies and pressure sensitivity, a textile should be worn under the torsion orthosis.
- Do not make any improper changes to the product. Non-observance may impair the function of the product. Product liability is excluded in the event of improper use.
- If the patient notices any unusual changes in him/herself (e.g. increase in complaints), he/she must consult his/her attending physician or the orthopedic technician.
- A combination with other products must be discussed with the treating physician beforehand.

6. Adaptation



The torsion orthosis is not a finished product, but an aid that must be individually adapted to the patient's needs.



6.1 Mounting the straight torsion connector on the pelvic belt

The pelvic belt is selected according to the circumference. The embedded aluminum brace is taken out of the padding and should be adapted to the patient. Then the "torsion connector straight" corresponding to the diameter of the torsion bar is attached to the aluminum brace as follows:

- The connector is fixed on the aluminum brace in a flexion of approx. 10°, so that the physiological movement of the leg and orthosis harmonizes.
- If the "torsion connector straight" is correctly aligned and the mechanical pivot point of the connector and the anatomical pivot point of the hip joint match, the "torsion connector straight" is fixed to the aluminum brace with two iron rivets (3 mm).



6.2 Mounting the curved torsion connector on the shoe

A ready-made shoe can be used for mounting the connection. The following points must be taken into account:

- The mechanical pivot point of the "torsion connection bent" and the anatomical pivot point of the ankle joint must match.
- For shoes with a heel, the shoe stirrup is arranged in front of the heel; for shoes
 with a flat sole, the "torsion connection bent" is set sufficiently deep into the sole
 so that it does not come into contact with the ground during weight.
- The "torsion connection bent" is fixed with two rivets (4 mm) with the steel spring integrated in the ready-made shoe or an additionally inserted metal reinforcement plate beneath the leather insole to the ready-made shoe.



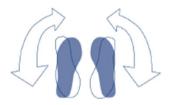
6.3 Longitudinal adjustment

The length dimension from the ankle joint to the hip joint is transferred accordingly to the torsion bars with their connectors. The following points must be taken into account:

- The calf strap corresponding to the diameter of the torsion bar is slid onto the torsion bar after removing the "torsion connection bent" and fixed with two hexagon socket screws.
- After shortening the torsion bar, it must be pushed as far as it will go into the "torsion connection straight" or in the "torsion connection bent" and fastened accordingly with the 4 hexagon socket screws. This allows the length to be adjusted during growth spurts (maximum 20 mm per torsion connection).
- When fastening the hexagon socket screws, make sure that the two screws located one below the other are visible on the lateral orthosis side.

6.4 Adjustment of the torsional stress

The shoe with the fixed "torsion connection bent" is placed on the torsion bar in such a way that the tip of the shoe points in the opposite direction to the leg malposition. This position is then fixed with the hexagon socket screws.



7. Maintenance and Cleaning

The function of the torsion orthosis must be checked at intervals of no more than 12 months by an orthopedic technician and should be corrected if necessary. If required, the torsion bar can be replaced in case of abrasion.



Cleaning

- Can be washed off with soap and water
- Use commercially available disinfectants for disinfection



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8. CE- Conformity

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to Uniprox and the competence European Authority.

9. Warranty and Guarantee

The duration of use depends on the intensity of the application or the duration of therapy.

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

10. Storage and Disposal

The torsion rod must be protected from direct sunlight and must not be bent sharply or kinked during storage.

The product is disposable with standard household garbage.

Please direct any questions to:

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E-mail: export@uniprox.de