

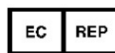
Qualität und Funktion

Gebrauchsanweisung
Instruction Manual

OR05 Becker Spinal Orthosis



Becker Orthopedic
635 Executive Drive
Troy, MI 48083 United States



Acorn Regulatory
Knockmorris Cahir
Co. Tipperary
Ireland, E21 R766



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

1. Intended Use

Sagittal postural realignment and pain reduction

2. Technische Daten

REF

Order No.	Back-Pad	xxx	Article No.
OR05-S	„Extra wide“	S	4 506 020 02 00 000
OR05-M	„Extra wide“	M	4 506 020 01 00 000
OR05-L	„Extra wide“	L	4 506 020 03 00 000

3. Indication/ Contraindicationen

Indicationen:

- Conservative treatment of vertebral compression fractures with stable posterior wall
- Lumbar adolescent kyphosis with compensating thoracic hyperextension
- After vertebral fractures
- Postoperatively
- Osteoporosis

Contraindicationen

- None

4. Side effects

- Improperly fitted brace may cause cardiorespiratory discomfort

5. General Instructions



- This medical products is single patient multiple use.
- Fitting/service of the medical devise is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the devise to the user.

5.1 Information for orthopedic professional

When you deliver the completed orthosis, please discuss basic maintenance procedures with your patient and give him/her this IFU.

Please write in product model and lot number information below. This section should be signed by the patient as proof he/she has been given maintenance instructions. Make a copy of this page and then attach it to your patient file.

Model #:

LOT #:

Date:

Patient Signature:

(Please attach to patient file)

5.2 Information for patient

- When not in use, your orthosis should be stored away from open flame or direct sunlight. Metal parts can conduct heat and plastic can deform or deteriorate prematurely due to heat effects.
- As a daily donning routine, you should perform the following safety check:
 - Inspect for dents, scratches or cracks.
 - Straps should be secure and have no tears.
 - Make sure all rivets and screws are tight.
- If you have any problems, notice any undue wear, or observe any unsafe or unusual condition in the orthosis, contact your orthotist **immediately**.

Orthotist:

Phone:



6. Cleaning



To clean, wipe with a damp cloth with mild detergent.

7. 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/ or *Becker Orthopedics* as well as to the competence European Authority.

8. Warranty an Guarantee

- One year limited warranty for defects in workmanship

9. Disposal

Dispose of in accordance with local laws and regulations for aluminum and leather.

Please direct any questions to:

Customer Service: + 49 (0) 36628-66-33 70

Fax: + 49 (0) 36628-66-33 77

E-mail: export@uniprox.de