

# Positive effects of the spinal orthosis Spinomed® in patients with osteoporotic vertebral fractures scientifically proven

## Guideline-based therapy

## Spinomed® - recommended in the S3 Guideline "Prophylaxis, Diagnostic, and Therapy of Osteoporosis"

The Dachverband der Deutschsprachigen Wissenschaftlichen Osteologischen Gesellschaft (DVO) recommends early mobilisation after minor traumatic stable vertebral fracture to avoid complications, which might occur following immobility (pneumonia, pulmonary embolism and functional deficits).

## The guideline recommends the use of a spinal orthosis for painless mobilisation.

The guideline commission evaluates the recommendations to the orthoses

- ✓ with a high class of recommendation "should be considered"
- ✓ with the highest to high level of evidence (following the SIGN levels of evidence: 1++ and 2++)
- ✓ with the highest consensus (strong consensus)



**Guideline recommendations** 

are based on these two studies

## Source

Source

S3 Guideline "Prophylaxe Diagnostik und Therapie der Osteoporose bei postmenopau-salen Frauen und bei Männern"; AWMF-register number: 183 - 001; Status: 31/12/2017. Published online at: https:// www.awmf.org/leitlinien/ detail/ll/183-001.html (Last access 23/08/2021).

Pfeifer M et al. Am J Phys Med Rehabil 2004;83(3):177-186.

Pfeifer M et al. Am J Phys Med Rehabil 2011;90(10):805-815.

# Clinical Trials – Scientific Evidence

## Summary of the most important study results

Wearing the spinal orthoses Spinomed or Spinomed active for the duration of six months led to

- → Increases of back extensor and abdominal flexor strength of 73 % and 65 %, respectively
- → Decrease of kyphotic angle up to 11 %
- → Reduction of body sway up to 25 %
- → Pain relief up to 47 %
- → Improvements in well-being up to 18 %
- → Improvements in respiratory function up to 19 %
- → Avery high patient therapy adherence due to an optimal profile of efficacy and tolerability

Using the spinal orthosis **Spinomed** for the duration of six months led to

- → Increase in muscle strength up to 50 %
- → Pain relief of 37 %
- → Therapy adherence of 90 %

Effects of the Spinomed orthosis compared to a rigid 3-point-spine-orthosis after three months:

- → Significant pain relief
- → Significant improvement of respiratory function
- → Noticeably less complications

Wearing the Spinomed orthosis for six months led to similar effects regarding the increase in back muscle strength compared to physiotherapeutic intervention. Therefore, the use of a spinal orthosis represents an alternative training method - especially in elderly patients.

Application after kyphoplasty

The use of the spinal orthosis Spinomed after kyphoplasty had a positive effect on long-term vertebral straightening and therefore on spine alignment in the sagittal plane.

Meccariello L et al. Aging Clin Exp Res 2017;29(3):443-449.

Dionyssiotis Y et al. Prosthet Orthot Int 2015;39(6):487-495.

Kaijser Alin C et al. Arch Osteoporos 2019;14(1):5.

Schupfner R et al. Ortho & Rheum Open Access | 2020; 16(2):6-14

## Summary of Real-Life-Experiences

The evaluation of qualitative focus group interviews with Spinomed users showed that patient expectations of the orthosis were met. Users confirmed that a spinal orthosis can be perceived as a close friend, which supports patients Kaijser Alin C et al. Arch Osteoporos 2020;15(1):171

Source

Two thirds of participants of a patient survey regarding the use of Spinomed or Spinomed active confirmed that

- → the orthosis supported them very much to much during their therapy
- → the orthosis led to an improved mobility
- → the orthosis contributed to an enhanced feeling of safety in everday life

More than half of the survey participants stated that

- → they experienced clear to very clear pain relief
- → wearing the orthosis led to improvements in quality of life

Good to very good ratings regarding the handling, fitting and comfort of the orthosis led to a high patient adherence rate. Recommendation rate is 94 %.

A survey of spinal soft support and orthoses users revealed that wearing the medical device shows a high to very high efficacy in 81 % of the participants and furthermore leads to

- → an improved quality of life (89 %) and increased mobility (72 %)
- → pain relief (84 %) and reduced consumption of analgesics (65 %) or complete renunciation from analgesics (14 %), respectively
- → the avoidance of surgery in 32 % of participants

medi GmbH & Co. KG, 2020

eurocom e V Published online at: https:// www.eurocom-info.de wp-content/uploads/2021/03/ eurocom\_Broschuere-Rue-cken\_Allensbach\_web.pdf (Last access 23/08/2021).

# Wearing the spinal orthosis Spinomed leads to numerous positive effects:

- ✓ Strengthened trunk muscles
- ✓ Significant pain reduction
- ✓ Increased mobility
- ✓ Improved quality of life
- Long-term vertebral straightening after kyphoplasty



Spinomed



Spinomed active Spinomed active men



Spinomed active

The application of the Spinomed met the patient's requirements and furthermore represents an alternative training method leading to a **high adherence** and **recommendation rate**.

## Intended purpose:

Spinomed® is a brace designed to actively relieve load and correct the lumbar spine / thoracic spine in the sagittal plane.

