

Johannisheim e.V.

The home for care and support

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Providing care for life...

Johannisheim e.V. - Sandersweg 15 in 21680 Stade

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Director of Nursing

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02/02/2018

Proof of the medical benefit of the “POSIMED Heel Protect” free heel support shoe to support decubitus management (decubitus prevention and therapy by the manufacturer Funke Medical AG)

Dear Mr. Friedrich,

I am happy to send you my opinion on the proof of the medical benefit of the “POSIMED Heel Protect” free heel support shoe today. The test object received the CE marking and was provided with instructions for use. After several weeks of testing, the nursing council and I have come to the results presented below.

If you have any questions about these results, please contact me.

I hope the information I am providing here is helpful.

Best wishes,

Sandra Idem

(Nurse and Director of Nursing)

Institute no.: 510 331 818

Bank accounts:

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1. The “POSIMED Heel Protect” free heel support shoe with the article number PO-HEELPR was reviewed at our location. The product was equipped with a removable PU cover. According to the product documents from the manufacturer, the product is used to support decubitus prevention and decubitus therapy.

2. Information about the testing facility/institution

The “POSIMED Heel Protect” free heel support shoe has been tested in Johannisheim in Stade. Our location is a residential and inpatient nursing facility in which patients in need of care and people with disabilities are provided individual care and nursed in different living areas. The personal wishes and needs of our residents are the central focus of the nursing care provided.

Sandra Idem is the assessor. She is a registered nurse and the director of nursing at the home and has many years of experience in patient care.

3. Indications concerning dates of use

From 19th December 2017 to 9th January 2018 the “POSIMED Heel Protect” free heel support shoe was tested in our location by five male and female residents over a period of three weeks per resident.

4. Description of the subjects and course of use

The subjects were between 72 and 92 years of age, with different underlying diseases. These were the typical age-related neurological, medical or neurodegenerative diseases. The risk of decubitus was ascertained in accordance with the national expert standard for decubitus prevention on the basis of nursing expertise.

Resident	01	02	03
Town/city	Stade	Stade	Stade
Test period	19/12/2017 to 09/ 01/2018		
Sex	female	female	male
Age	81	83	92
Height in cm	144	178	178
Weight in kg	70	69	70
Diagnoses	<ul style="list-style-type: none"> • Degree of care V • Senile dementia • st.p. apoplexy • Contractures of the knees 	<ul style="list-style-type: none"> • Degree of care III • Cancer of the right breast • Tends to experience rashes on the heels 	<ul style="list-style-type: none"> • Degree of care III • st.p. apoplexy with right hemiparesis • Parkinson’s disease

	Functional bowel disorder Encephalomyelitis		• Diabetes mellitus
Risk of decubitus according to Braden	Very high risk	Medium risk	General risk
Specific risk factors	Advanced in years Bedridden There are moderately pronounced limitations of movement The ability to perceive sensations is limited	Advanced in years Danger of malnutrition Presence of pain symptoms	Advanced in years Diabetes mellitus Signs of paralysis Moderately pronounced limitations of movement are present Limited ability to perceive sensations
Existence of a pressure ulcer	Yes	Yes	Yes
Category per EPUAP	Buttocks III Heel IV	Buttocks II Heel I	Heel II
Healing progress	positive	positive	positive
Other Comments	Resident is positioned every 2 hours	none	none

Resident	04	05
Town/city	Stade	Stade
Test period	19/12/2017 to 09/ 01/2018	
Sex	male	female
Age	72	79
Height in cm	181	168
Weight in kg	72	72
Diagnoses	<ul style="list-style-type: none"> Degree of care III Diabetes mellitus Prostate cancer st.p. alcohol abuse Korsakoff syndrome 	<ul style="list-style-type: none"> Degree of care IV st.p. apoplexy Right hemiparesis
Risk of decubitus according to Braden	General risk	High risk
Specific risk factors	<ul style="list-style-type: none"> Bedridden Malnutrition Diabetes mellitus Presence of moderately pronounced limitations in movement	<ul style="list-style-type: none"> There are very severely pronounced limitations in movement Contractures and spasticity are present There are signs of paralysis Limited ability to perceive sensations
Existence of a pressure ulcer	Yes	Yes
Category per EPUAP	Heel I	Heels II
Healing progress	healed	positive

5. Information on test equipment

The “POSIMED Heel Protect” free heel support shoe has been tested in our facility in Stade.

Our home

Our nursing team in Johannisheim provides care and support to people with psychological and physical afflictions in all stages of care. Johannisheim can accommodate 86 residents. 90 single rooms and 17 double rooms of a wide range of different sizes are available. Our services range extend to short and long-term care and integrated support for patients with dementia. Johannisheim also provides care for residents with stroke, Parkinson’s, apallic syndrome, Alzheimer’s disease and MS, etc.

Our philosophy

As a social welfare institution, Johannisheim focuses on a Christian concept of humanity. This is reflected in the basic attitude toward social welfare and the social welfare actions in the all areas of life and work at the facility.

We view our profession as a calling

Everyone has an unlimited right to a dignified life – including in advanced age. This conviction guides us in our service to people in care and support. As a result of expert assistance and personal dedication – by helping and listening – we want to contribute to humaneness in our society.

Johannisheim considers itself a “humane company”.

- Our work is characterised by appreciation for people who are in need of care.
- We want to combine our professional expertise with personal dedication.
- We view our work together as an important chapter for our residents.
- The satisfaction of the people who have been entrusted to us, whom we work to support, is an important standard for us.
- Good personal relationships are an invaluable basis for our social welfare actions.

Feedback helps promote our development

The freely elected seniors' advisory board is also our internal governing body and monitors all services and activities in the home, such as nursing, meals, care, accommodation, care agreements, construction actions, investments, projects, etc., but also dealing with the residents entrusted to us in a socially responsible way. Our seniors' advisory board, as well as members, guests and visitors, improve the quality of our work with positive and negative critical feedback, and enrich our development.

The types of nursing care just described therefore make it clear that the results of the test can be transferred to the domestic setting both for people in danger of developing decubitus and those already affected by it.

6. Opinion on the effectiveness of the test object

The test object was used in our facilities to support wound management and to prevent the development of additional pressure ulcers in five residents.

The risk of decubitus was recorded in our facilities on the basis of professional nursing expertise and patient observation according to the national expert standard (DNQP). The five residents participating in the test showed a decubitus risk over the entire period of the test in different degrees of severity. Two residents exhibited a general decubitus risk, one a moderate risk, the fourth resident a high risk and the fifth a very high decubitus risk. At the end of the testing period of three weeks for each resident, none of them had developed new pressure sores.

All five subjects had pressure sores in the heel area, representing categories I, II and IV. All of the pressure sores showed a good healing tendency. One of the pressure sores healed.

The table below describes the wound development:

Subject	Decubitus location	Initial wound situation	Wound situation after the three-week testing period
1	Heel	Category IV EPUAP, fibrinous, wound infection, wound size (depth x length x width in cm) 0.5 x 7.0 x 4.6	Category IV EPUAP, fibrinous, wound infection, wound size (depth x length x width in cm) 0.5 x 6.8 x 4.4
2	Heel	Category I EPUAP, local swelling and rashes, wound size (length x width in cm) 1.5 x 1	Category I EPUAP, local swelling and rashes, wound size (length x width in cm) 1.3 x 1
3	Heel	Category II EPUAP, granulating, no rashes, wound size (depth x length x width in cm) 0.3 x 0.5 x 0.7	Category II EPUAP, granulating, no rashes, wound size (depth x length x width in cm) 0.2 x 0.5 x 0.3
4	Heel	Category I EPUAP, no signs of inflammation, wound size (length x width in cm) 0.3 x 0.5	healed
5	Heel	Category II EPUAP, fibrinous, local signs of inflammation, wound size (depth x length x width in cm) 0.5 x 1.2 x 1.5	Category II EPUAP, fibrinous, no signs of inflammation, wound size (depth x length x width in cm) 0.3 x 1.0 x 1.2

The description in the table of the individual wound progressions shows that there was improvement in every individual wound. New decubitus ulcers did not appear during the testing phase

The important components of wound management in our home include not only local wound treatment, but also nutrition, skin care, promoting exercise, distribution of pressure by means of individual positioning and the use of anti-decubitus products. Consequently, the use of a free heel support shoe represents an important part of our overall therapeutic concept.

In the end, the nursing team was very satisfied with the results of the test of the test object, not only because all the pressure sores showed a positive healing tendency, but also because the handling of the product is easy and self-explanatory.

7. Weighing the benefits against the risks

In our facility we did not observe any dangers arising from the product, either for users or for the handlers.

The manufacturer's instructions for use are brief, clearly laid out, easy to understand and contain the most important information about the product characteristics and the materials used, as well as instructions for cleaning, maintenance and care.

8. Review of desirable and undesirable consequences

Adverse effects did not result when using this product.

9. Product description

According to the manufacturer's specifications, the "POSIMED Heel Protect" free heel support shoe can be used to prevent and treat decubitus. It provides free heel support and can

only be worn by patients/residents when they are in a supine position.

The free heel support shoe consists of a foam core with GELTOUCH free support wedge. It is enclosed on the outside with a PU cover. The inside consists of a spacer fabric, which provides better climate control for the skin.

The shoe is closed with a variable Velcro fastener.

Technical data

Removable/changeable PU cover

Volume weight of the shoe: 33 kg/m³

Compression hardness of the shoe 6.0 kPa

Volume weight of the free support wedge: 35 kg/m³ Compression hardness of the free support wedge 1.5 kPa

Shoe size: 34 – 47

Weight:

Carbomer.....
..... .0.3 kg

Dimensions (H x W x D): 25 x 23 x 35 cm

Test for toxicological safety/biocompatibility: DIN EN ISO 10993-5, DIN EN ISO 10993-1

9.1 Changing the covers

The design of the cover allows users to change it.

9.2 Customization of the product

The heel shoe can be adjusted to the individual proportions of the leg to be cared for using the Velcro fastener.

9.3 Micro-climatic features

No increased occurrence of moisture was observed in the area of our residents' feet.

9.4 Cleaning and disinfection

The cover and inner shoe can be cleaned with common household products at up to 95°C. The product can be autoclaved when it is used in institutions. The cover can also be disinfected. The product is not approved for re-use.

9.5 Evaluation of pressure relief

Use of the "POSIMED Heel Protect" free heel support shoe resulted in excellent pressure relief on our patients' heels. The design of the product allows for free support of the heels. The support pressure is distributed over a large area in the lower leg region.

9.6 Evaluation of the reduction of shearing force

The "POSIMED Heel Protect" free heel support shoe is held in place of the user's feet by a Velcro fastener. The product does not shift during use. Thanks to the smooth cover, the product can be slide easily over the bed sheets while the foot rests stably in the free heel support shoe. As a result, the shearing forces that can act on the heels are not just minimised, but are practically eliminated.

9.7 Support option for patients

According to the manufacturer's instructions, the "POSIMED Heel Protect" free heel support shoe can only be used in a supine position. This is why our residents were not offered a 30° lateral position or a 130° lateral position while they were using the free heel support shoe. Other alternative position support types for pressure distribution, such as micro, LIN or nest supports, as well as an inclined plane, were avoided.

10. Overall assessment

The "POSIMED Heel Protect" free heel support shoe was used successfully in our facility. Our residents were very satisfied with the product.

The nursing staff also had a very positive opinion of the product after the three-week testing[§]

period. The product was assessed as very easy for handlers to use. The shoe only needs to be put on the foot and then closed with the available Velcro fastener.

The shoe remains stable on the foot and does not shift while it is being worn.

The product proved itself in decubitus management for our multi-morbid patients and those requiring a high degree of care. During the test period they had different degrees of decubitus risk. Despite the risk, they did not develop new pressure sores. Existing pressure sores of categories I, II and IV (EPUAP) on the heels showed a clear healing tendency.

Due to the positive results and experiences during use of the heel shoe being tested, we evaluated the product as very well-suited for the support of decubitus prevention and also for the treatment of heel pressure sores.

Based on the test results, we can recommend the use of the "POSIMED Heel Protect" free heel support shoe for the support of decubitus prevention and decubitus therapy management according to the indications stated by the manufacturer for both domestic and inpatient applications.

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Stade, den 02/02/2018



Sandra Idem
Nurse and Director of Nursing