

EINGEGANGEN
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Your reference / Your message dated	Queries to	Project	Date
	Guido Grimm	17-273 POSIMED Heel Protect	09/04/18

Addendum to the assessment

Dear Mr. Funke,

Attached is an addendum that was submitted to GKV-SV as proof of medical benefit, for your records.

Yours sincerely

Guido Grim

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BEO MedConsulting Berlin GmbH,
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Director of Nursing

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26/03/2018

Stade, 21 March 2018

**Addendum to the 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 our opinion on the proof of the medical benefit of the “POSIMED Heel Protect” free heel support shoe today.

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. Furthermore, the free heel support shoe is still being used successfully after the end of the test, without any incidents.

The product was used to prevent and to treat decubitus, with varying gradations of decubitus.

The documented wound progressions of the individual pressure sores show that the wound status improved for all pressure ulcerations. Particularly deserving of emphasis is the heel decubitus in female subject 1 described in the assessment. This category IV decubitus (EPUAP) was so extensive that an amputation of the foot had already been discussed as a therapeutic measure as an option by the treating physician.

As a result of the use of the free heel support shoe, this was successfully averted.

In principle, the skin of our male and female residents who are at risk of decubitus or who already have decubitus is carefully examined every day. Of course particular emphasis is given to typical areas of the skin that are at risk of decubitus, such as the back of the head, the shoulder blades, the sacral region and the feet. When examining the skin on the feet, not only the skin condition of the heels is checked; particular attention is also given to the tips of the toes, the outer edges of the feet and the balls of the feet. Within the testing period and beyond, no negative skin changes were found that were consistent with the development of a pressure ulcer.

As already described, the free heel support shoe is made of foam. It is lined with a soft spacer fabric. The inside of the shoe has no stitches that could create pressure spots. The part of the product that comes into contact with the soles of the feet is also made of foam, which adapts gently to the soles of the residents' feet.

In summary it can be concluded from the knowledge gained from the test on our male and female residents that the free heel support shoe for decubitus prevention and treatment can be used without side effects. The wound status of existing pressure sores improved, as already described in the assessment. An amputation of the foot of one female subject with category IV heel decubitus (EPUAP) was averted. Additionally, no negative skin changes were observed due to wearing the free heel support shoe.

Therefore, we can confirm the product's decubitus-prevention and therapeutic effect.

I hope the information I am providing here is helpful. If you have any additional questions, please do not hesitate to contact me at any time.

With kind regards from Hansesstadt Stade

Idem

Sandra Idem

(Director of Nursing)