IQSH

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Analysis of the Medical Value of the Anti-Decubitus seat cushion "VARILITE MERIDIAN TM" for the Prevention and Treatment of Decubitus Ulcers Manufactured by Cascade Designs USA

1. We assessed the medical value of the anti-decubitus seat cushion "MERIDIAN TM" for the prevention and treatment of decubitus ulcers manufactured by Cascade Designs USA. The product is used for the prevention of decubitus (for patients with a high risk of decubitus ulcers as per Braden) as well as the treatment of decubitus ulcers up to stage III (EPUAP).

2. Information on the Examiner-Facility/Institution

The team of experts consisted of a nurse scientist and an orthopaedic and rehabilitation technician. The nurse scientist has been a specialist for anti-decubitus systems and related topics for several years. She has provided consulting service during the development of related products, and has been involved in the practical testing of such systems, as well as the training of various groups participating in the healthcare system. The orthopaedic and rehabilitation technician has been working as a medical products consultant for more than ten years. Among other things, he has consulted and developed concepts for standard and special constructs, provides assistance during product development stages, and provides training courses on medical devices.

The assessment of the medical value was carried out in various healthcare settings such as hospitals, inpatient and outpatient geriatric facilities, as well as the home environment.
The anti-decubitus seat cushion "Varilite Meridian TM" was tested in a nursing home in Buxtehude. This large inpatient facility (number of residents < 80) provides care for persons (of all three care levels) requiring nursing assistance in several residential living areas and nursing care units.

3. Information on the Length of Time the Product was Used

We tested the device that was provided over a period of several months with the following results:
The test involved the medical value of the anti-decubitus seat cushion "Varilite MERIDIAN TM" manufactured by Cascade Designs. The product was used on five patients over a period of four months.
The anti-decubitus seat cushion "Varilite MERIDIAN TM" was used for the prevention and treatment of decubitus ulcers up to stage I (EPUAP).
The patients were between 61 and 85 years old and suffered from various underlying illnesses, such as the usual age-related diseases, for example contractures, hemiplegia, osteoporosis, an amputated lower leg, coronary heart disease, hemipareses, various forms of dementia, and diabetes.
The patients' mobility varied significantly.
The decubitus risk was determined with the Braden scale. The patients had varying decubitus ulcer risks. All patients were at risk for decubitus. One of the five patients had stage I decubitus in the sacral area.

4. Course of Treatment

Patient	01	02	03	04	05
Test Site	Buxtehude	Buxtehude	Buxtehude	Buxtehude	Buxtehude
Start Date	10.01.08	08.12.07	01.02.08	19.12.07	11.02.08
End Date	31.01.08	29.12.07	22.02.08	12.01.08	03.03.08
Age	61	72	79	85	75
Sex	male	female	female	male	female
Diagnoses	Amputated lower leg Occlusive arterial disease left Median insult Right hemiparesis Seizure disorder	ICP	Polyarthritis Polyneuropathy	Apoplexy Left hemiparesis Coronary heart disease Diabetes	Osteoporosis Mild dementia
Weight (kg)	54.3	46.5	79	68	52
Height (cm)	166	160	158	175	160
Braden Start	Moderate decubitus risk 14	High decubitus risk 12	General decubitus risk 18	Moderate decubitus risk 13	Moderate decubitus risk 14
Braden End	Moderate decubitus risk 14	High decubitus risk 12	General decubitus risk 18	Moderate decubitus risk 13	Moderate decubitus risk 14
EPUAP wound stage at test start				I	
Wound stage at test end				Healed	
Wound Development				positive	
Decubitus-Prophylactic Effect	positive	positive	positive	positive	positive
Skin Condition	positive	positive	positive	positive	positive
Special risk factors		Malnourished Spasms and Contractures	Contractures Permanently low blood pressure Circulatory instability	Advanced age Mild spasms Circulatory instability	Pain when sitting for longer periods of time
Additional information on the sitting aid	Limited sensation in the sitting area, sitting instability	Does not consciously relieve the sitting area, sitting instability Leg abduction is restricted	Limited sensation in the sitting area Leg abduction is restricted	Limited sensation in the sitting area, sitting instability	
# of hours used per day	3	5	6	7	6
Other					Patient sits without pain

The wound from the superficial decubitus ulcer (stage I, EPUAP) healed during the test phase. The skin of the risk patients remained intact during the entire test phase. The patients daily spent a few hours out of their beds.

5. Use

The seat cushion consists of the actual seat cushion and a protective cover. The cushion itself consists of three different types of foams of varying degrees of firmness and two inflatable chambers that are both equipped with a valve system. The seat cushion is protected with an incontinence cover.

Two different types seat covers are offered. One provides incontinence protection, is bi-elastic and breathable. The second type of cover consists of spacer fabric applied to coarse foam, which makes it breathable and therefore very good for the skin. Both covers were tested during the test phase.

According to the manufacturer, the seat cushion can be used for patients weighing up to 261 kg.

The seat cushion is easy to use. First, it must be placed on a sitting area, e.g. of a wheelchair. It is important to make sure that the cushion is placed in accordance with its labelling. The valves are opened, so the cushion can be fully inflated. After the cushion has been inflated, the valves are closed. The patient can then be placed on the seat cushion. First, the right valve of the air cushion - pelvic chamber - is opened. The valve is opened and air released, until the patient sits on approx. 13 mm air/foam in the area of the ischial tuberosity. Then, the valve is closed again.

As soon as the pelvis has been positioned in this manner, the air chamber for the thigh chamber is adjusted. The front left valve is opened and as much air released as necessary. After having properly positioned the thighs, also this valve is closed again. Due to the separated air chambers, the pelvis and the thighs can be positioned independently from each other. The ischial tuberosity can be supported to prevent the pelvis form dropping backwards. The cushion thus helps the patients sit straight.

6. Cleaning

The cushion can be wiped clean by using a damp cloth. The included covers can easily be removed from the cushion by opening the zipper and washed at a maximum heat of 60°C. The covers must be air-dried.

7. Risk Notice

The product information for the seat cushion lists indications and contraindications. According to the information provided by the manufacturer, the cushion can be used to prevent decubitus in patients with moderate decubitus risk and to support the treatment of up to stage III decubitus ulcers (EPUAP). The only contraindication provided by the manufacturer is the patient's maximum weight. The instructions for use include a table with information on the seating surface and maximum patient weight.

The manufacturer also indicates in the instructions for use under section on "seat cushion maintenance" that the cushion's valves should remain open for one night a week to allow the material to regenerate itself.

The manufacturer also points out that the air level should be checked once a day, especially if the patient uses the cushion at different heights.

8. Overall Assessment

The anti-decubitus seat cushion "Varilite MERIDIAN TM" was successfully used with five patients.

The patients were extremely satisfied with the product. Also the nursing staff had a very positive impression after having used the product for several weeks. The use of the product must be considered as easy. Due to the positive results and experiences made during the use of the tested cushion, the nursing staff considered the product to be suitable for the prevention of decubitus and the treatment of decubitus up to stage III.

Based on the positive test results for the tested product, the recommendation from the nursing facility, our own positive experience with the product and the good test results of the seat cushion "Varilite MERIDIAN TM" that is has a similar design, we can recommend the use of the anti-decubitus seat cushion "Varilite MERIDIAN TM" for the prevention of decubitus in patients at a high risk for decubitus and for the treatment of decubitus ulcers up to stage III (EPUAP) in accordance with the areas of application listed by the manufacturer, both within the home and the inpatient environment.

Stade, 07.03.08

Claudia Kiechle
(Certified Nurse Scientist)

Marco Möller
(Orthopaedic and Rehabilitation Technician)

BEO MedConsulting BERLIN GmbH

Test Plan for the Preparation of an Expert Report the Medical Benefits

of

Product description: **Anti-Decubitus seat-cushion**

Type/Model: **Varilite MERIDIAN TM** Prod. #:

(43 x 43 cm),

Tested accessory: **cover**, Prod. #:

Manufacturer: ***Cascade Designs; 4000 1st Ave South; Seattle, WA 98134 USA***

Customer: ***BEO Berlin, Helmholtzstr. 2, 10587 Berlin***

Tested by: ***IQSH; Alte Dorfstr. 38; 21684 Stade***

Please compile a written report that provides the following information:

1. Information on the product description, type/model including product #, if applicable, the tested accessories including their product #, manufacturer, and the customer, e.g. as shown above.
2. Brief description of your facility/institution demonstrating its autonomy and reputation and information about the inspector.
3. Information on the length of time the product was used/observed
   Note: We recommend a minimum observation period of at least 3 weeks for each patient.
4. Information on the users/test persons employed for the test and the number of test persons used.
   Please note: The test must be carried out in consideration of the intended users. The use of at least 5 patients is recommended.
5. Information on the test environment (e.g. hospital, home environment)
   Note: The studies/tests must be conducted in the overall living environment/home environment or must be transferrable to the same.
6. Statements on the entire scope of indications claimed by the manufacturer and on the effectiveness of the product in combination with all tested components (e.g. sheets, accessories, etc.) by providing the following:

   6.1. Describe the intended objective, such as
   - To guarantee effective treatment (decubitus ulcer therapy) and/or
   - To prevent a disability (decubitus ulcer prophylaxis) and/or
   - To counteract a disability (e.g. by counteracting the patient's inability to move by repositioning the patient)

   6.2. Clearly describe the achieved objective(s) described under 6.1 and the reasons for the inspector's opinion that the product is suitable for use **in the home environment** for the indications claimed by the manufacturer, e.g. also by listing clinical end points, the decubitus ulcer incidence rate (occurrence of a decubitus ulcer stage II or higher) to show the preventive effectiveness of the product, i.e. with products used for treatment of decubitus ulcers, the healing

rate of a manifested decubitus ulcer (including information on the assessment method). The claimed scope of indications should clearly be defined and shown by using standardized risk scales, the Braden scale for seniors, and other validated scales appropriate for other patient groups. If the product is to be used to treat decubitus, it must also be described in accordance with the decubitus ulcer stages as per EPUAP.

7. Weigh the benefits and risks against each other.
8. Assess the desired and undesired outcomes
9. Describe the product and answer the following questions:
   - 9.1. Can the user change the sheet?
   - 9.2. Can the product be adapted to the patient's weight and the respective pressure situation (manually or automatically)? Or can the product be selected according to the patient's weight?
   - 9.3. Can the user change all modifiable parameters himself?
   - 9.4. If applicable, other information on how to handle the product, e.g. how to clean/disinfect it, user-friendliness for the users/patients and nursing staff.

The report may be in German or in English, and may also include pictures or analysis tables.

Testing Facility/Expert Certification

I/we hereby certify that the expert opinion on the medical value of the above-referenced product was compiled in accordance with this test plan.

10.03.08

Date / Stamp / Signature