Zentrum für Beatmung und Intensivpflege im "Storkower Bogen" GmbH
Franz-Jacob-Straße 4D, 10369 Berlin

BEO MedConsulting Berlin GmbH
Att.: Hr. Friedrich
Helmholzstr. 2
10587 Berlin – Charlottenburg

Date
09.08.2017

Documentation for the medical benefit of the LEJRELET cushion series consisting of the "Oval", "Tube 250", "Tube 125", "Pad High", "Pad Low" and "Wedge" for positioning and decubitus management (support for decubitus prevention and therapy) from the company Vendlet ApS, Denmark.

Dear Mr. Friedrich

Hereby I would like to send my opinion on the medical benefit of the above-mentioned positioning cushions. After the test, which lasted several weeks, the caregivers and I have come up with the results described in this document.

At the start of the test, the manufacturer's declaration of conformity was available. The cushions are marked with a CE marking and the instructions are provided in German.

If there are any clarifying questions about the results, please contact me.

I hope my presentation is helpful to you.

The best greetings

Sebastian Kruschwitz
- Fachbereichsleitung Wundmanagement

BEO MedConsulting Berlin GmbH
z. Hd. Herrn Friedrich
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10587 Berlin - Charlottenburg

1. The specialist report relates to Vendlet ApS's cushion series LEJRELET. The series consists of the cushions Tube 250, Tube 125, Pad High, Pad low, Oval, and Wedge cushions for positioning as part of the decubitus management (support for decubitus prevention and therapy). According to the product information, the cushions act as positioning support for persons at risk of developing pressure ulcers and / or who are affected by decubitus.

The following parts of the LEJRELET series were tested:

• Pad Low	H4 x B30 x L50 cm	Article no. 5000004
• Tube 250	Ø 25 x L250 cm	Article no. 5000001
• Tube 125	Ø 25 x L125 cm	Article no. 5000000
• Pad High	H15 x B30 x L50 cm	Article no. 5000003
• Oval	H10 x B25 x L40 cm	Article no. 5000009
• Wedge	H15 x B30 x L50 cm	Article no. 5000002

2. Information about the investigator's institution

The mentioned positioning cushions in the LEJRELET series were tested by the Zentrum für Beatmung und Intensivpflege (ZBI), Storkower Bogen, Berlin.

Since its founding in 2006, the center has established itself as a fully institutional and outpatient specialized care center in Berlin. The center is specialized in an innovative, rehabilitative and professional care concept for people who receive oxygen treatment at home and in need of intensive care, for people in the so-called vegetative state and for people in minimal consciousness state (MCS).

Sebastian Kruschwitz, head of the field of wound care, works as a specialist. He is trained in the field of care and is a specialist in wound care [1] ICW[2].

3. Information about the period of application

From 10th June 2017 to 28th July 2017, the abovementioned positioning aid was tested by eleven patients / residents in our institution over a period of seven weeks.

[1] Wundexperte/Pflegeterapeut Wunde ICW: Two seminars, offered at ICW in Germany.

[2] Initiative Chronische Wunden e.V.: The name of an association that works to improve prevention, diagnosis and treatment of people with chronic wounds.

4. Description of test subjects and course of usage

The test subjects were between the ages of 22 and 83 with various underlying diseases. These were neurological and / or somatic illnesses. Patients / residents were to a varying extent limited in their mobility.

The risk of decubitus was determined on the basis of specialist knowledge for care according to the national expert standard. There were different assessments as to the test subjects' risk of decubitus. All showed a risk of developing decubitus. A test person also had an existing decubitus on the head, which healed during the test period.

Residents	**01**	**02**	**03**
Location	**Berlin**		
Test period	10.06.2017 - 28.07.2017		
Gender	Man	Woman	Man
Age	58	80	50
Hight in cm	182	163	165
Weight in kg	68,6	98,6	73,6
Diagnoses	• Brain Injury • Condition after resuscitation • Subendocardial myocardial infarction • Spastic Tetraparese • Global aphasia • Dysphagia • tracheostoma • Incontinence	• Acute renal failure • Acute respiratory insufficiency • Pneumonia caused by pseudomonas sepsis • Acute infectious endocarditis	• leeding in the cerebellum • Posttraumatic hydrocephalus • tracheostoma • Ataxia • Urinary incontinence
Decubitus risk	**Very high risk**	**High Risk**	**High risk**
Special risk factors	• Prevalence of malnutrition • Spastic movements and contractures • Permanent unstable blood pressure • Limited balance • No active change of seat position	• Permanent low blood pressure • Unstable circuitry • Diabetes	• Contractures • Permanent unstable circuit • Limited balance • No active change of sitting or sleeping position
Were there pressure ulcers?	No	No	No
Category according to EPUAP[3]	Not applicable	Not applicable	Not applicable
Healing Process	Not applicable	Not applicable	Not applicable
were there any previous decubitus?	No	No	No
Used methods of positioning	• 30˚ sideways • Full body positioning • Micro positioning • Bobath positioning • Positioning of extremities	• 30˚ sideways • Micro positioning • Seated position	• 30˚ sideways • Full body positioning • Seated position • Micro positioning • Bobath positioning • Positioning of extremities • LIN positioning method

[3] European Pressure Ulcer Advisory Panel

Used cushions	• Tube 250 • Pad high • Wedge • Pad low • Oval	• Pad low • Oval	• Tube 250 • Tube 125

Resident	**04**	**05**	**06**
Location	**Berlin**		
Testperiode	10.06.2017 - 28.07.2017		
Gender	Man	Woman	Man
Age	76	58	51
Hight in cm	176	162	176
Weight in kg	80,0	78	68
Diagnoses	• Hypoxic brain injury • Acute respiratory insufficiency Type 1 • Condition after CPR after ventricular flicker	• Severe cerebral hypoxia • Acute respiratory insufficiency • SIRS • Pneumonia	• Hypoxic brain injury • Acute respiratory insufficiency
Decubitus risk	General risk	High risk	Very high risk
Special risk factors	• Diabetes • Limited balance • No active change of sitting and sleeping position	• Contractures • Permanent low blood pressure • Permanent unstable circuitry • Limited balance • Limited active change of sitting and sleeping position	• Spastic movements and contractures • Permanent unstable circuitry • Limited balance • No active change of sitting or sleeping position • Occurrence of pain symptoms
Are there pressure ulcers?	No	No	No
Category according to EPUAP	Not applicable	Not applicable	Not applicable
Healingsprocess	Not applicable	Not applicable	Not applicable
Were there any existing pressure ulcers?	No	No	No
Used methods of positioning	• 30˚-sideways • Full body positioning • Bobath positioning • Positioning of extremities	• 30˚- sideways • 135˚-sideways • Full body positioning • Seated position • Micro positioning • Positioning of extremities	• 30˚-sideways • Full body positioning • Micro positioning • Positioning of extremities
Used cushions	• Tube 125 • Wedge • Pad low	• Tube 125 • Pad High • Pad Low	• Tube 250 • Wedge

Resident	07	08	09
Location	**Berlin**		
Testperiode	10.06.2017 - 28.07.2017		
Gender	Woman	Woman	Woman
Age	66	83	56
Hight in cm	175	160	160
Weight in kg	70	62	65
Diagnoses	• Condition after cardiopulmonary resuscitation • Art. hypertonia • Chronic renal failure • Decubitus Category III at the head	• Pneumonia due to food or vomiting • Sepsis • Acute respiratory insufficiency • Acute renal failure • Diabetes mellitus type II • Permanent chamber chamber flare	• Severe cerebral hypoxia • Heart rate mode with subsequent resuscitation • Unconsciousness unclear genesis • Acute respiratory insufficiency • Pneumonia both sides
Decubitus risk	Medium risk	Very high risk	Medium risk
Special risk factors	• Malnutrition • Contractures • Permanent unstable circuitry	• Malnutrition • Contractures • Diabetes • Very old • Permanent unstable circuitry • Limited balance	• Contractures • Permanent low blood pressure • Diabetes • Permanent unstable circuitry • Limited balance • No active change of sitting and sleeping position
Are there pressure ulcers?	Yes	No	No
Category according to EPUAP	III Back of head	Not applicable	Not applicable
Description of ulcer at test initiation	Fibrinous wound, red, size 1.5 x 1.5 cm		
Description of ulcer at end of test	From 21.07.2017 it was healed		
Healing process	Positive	Not applicable	Not applicable
Were there previously pressure ulcers?	No	Yes	Yes
Used methods of positioning	• 30˚-sideways • 135˚-sideways • Full body positioning • Seated position • Micro positioning	• 30˚- sideways • Full body positioning • Seated position • Micro positioning	• 30˚-sideways • Full body positioning • Micro positioning • Bobath positioning

	• Positioning of extremities • LIN positioning method	• Positioning of extremities • Bobath positioning	• Positioning of extremities • LIN positioning method
Used cushions	• Wedge • Oval	• Wedge • Pad Low • Oval	• Tube 125 • Oval

Resident	10	11
Location	**Berlin**	
Testperiode	10.06.2017 til 28.07.2017	
Gender	Woman	Man
Age	43	22
Hight in cm	175	173
Weight in kg	80,0	97
Diagnoses	• Brain injury and reanimation of the ventricle limb • Appeal syndrome • Spastic tetraparesis • Chronic respiratory insufficiency • tracheostoma • Dysphagia • PEG • Incontinence	• Duchenne Muscular Dystrophy • Sinus tachycardia • Respiratory acidosis • Long time oxygen treatment • Exsikkose • Decubitus Category II Crossbones, on both sides
Dekubitusrisiko	Very High risk	High risk
Special risk factors	• Spastic movements • Permanent unstable circuitry • No seat stability • Limited balance • No active change of sitting and sleeping position • Chronic pain symptom	• Spastic movements • Limited balance • Limited active change of sitting and sleeping position • Decubitus at an earlier time
Are there pressure ulcers?	No	No
Category according to EPUAP[4]	Not applicable	Not applicable
Healing process	Not applicable	Not applicable
Were there previously pressure ulcers?	No	No
Used positioning methods	• 30˚-sideways • Full body positioning • Micro positioning • Bobath positioning • Positioning of extremities	• 30˚- sideways • Full body positioning • Seated position • Micro positioning • Bobath positioning • Positioning of extremities
Used cushions	• Tube 250 • Wedge • Oval	• Tube 250 • Pad Low • Oval

[4] European Pressure Ulcer Advisory Panel

5. Information about the test institution

The mentioned positioning cushions in the LEJRELET series were tested by ZBI in Berlin.

At the Storkower Department, a total of 70 beds are available for the specialized care of people receiving oxygen treatment at home, as well as people in the so-called vegetative state (UWS) and in minimal state of consciousness (MCS) in long-term rehabilitation phase F.

- Professional care in the institution
- Ambulant professional care in care homes

Our concept of healthcare and care is based on our clients' individual wishes and their personal medical needs.

This is facilitated by a strong rehabilitation effort in our healthcare. This approach is based on the recommendations regarding long-term rehabilitation, Phase F, from the Bundesarbeitsgemeinschaft für Rehabilitation (BAR). In addition, we strive for the care of our clients, in their last part of life, is performed in a dignified manner using recognized methods of palliative treatment.

This can only be realized with highly qualified employees and in a comfortable working environment that is fully equipped from a technical point of view.

Care facilities at ZBI, in the institution and in the sheltered homes are comfortably furnished. The apartments have an area of 20 m2 and are bright and friendly. All apartments and rooms are equipped with modern media and emergency call systems. Clients' security and privacy are the top priority.

The specialization and comprehensive services offered makes the ZBI a unique institution in Berlin.

Details of equipment and decor

- Apartments of more than 20 m2 living space for individuals
- Wet room in the apartment
- Cot, closet, bedside table
- Therapy rooms for functional therapies
- Snoezelen room
- Living room on all floors - centrally located
- Bathtub and shower on all home floors
- Central monitoring on screen - mobile
- Monitor monitoring on emergency situations
- Mobile analysis of CO2 in the blood - centrally
- Compressed air and oxygen systems - mobile
- Units for exhaust and oxygen units - centrally located
- Call centers for nurses / patients in the care homes
- Heart start and emergency equipment for emergency situations
- Central emergency power supply
- Lounge for guests and events

Professional care staff

ZBI is specialized in the care of people who need a high degree of care and with a particular focus on those who receive oxygen treatment, on the so-called vegetative state (UWS) and at minimal state of consciousness (MCS).

A key guarantee for the successful implementation of our treatment concept is our employees. Our team consists solely of professionals with a three-year education in nursing care as well as elderly care. In addition to weekly training in subject-specific themes, our employee are qualified in the following areas:

- Specialists in the field of oxygen treatment at home
- Careers in the field of oxygen treatment at home
- Care experts for people in the vegetative state / MCS
- Respiratory Therapist (DGP / Respiratory Therapist)

In addition, we employ occupational therapists as well as a respiratory and physical therapist in our institution. These are supported by our external therapists. Together, caregivers and therapists form a multi-professional team. All individualized care and therapy goals are prepared and evaluated with the client and their relatives. Weekly therapy meetings also result in a holistic course of the rehabilitation process. Care staff can recommend the use of the positioning cushions both in the institution and at home with people in need of care. The reason for this recommendation is observations of the use of the positioning cushions of eleven Resident / Patients over a period of 7 weeks. The good results achieved with the products with regard to the pressure-reducing positioning as well as the easy handling of the cushions lead to a recommendation of the products.

6. Opinion on the test subjects' effectiveness

For positioning for people in need of care, decubitus prevention and therapy aim to spread the pressure on different parts of the body in time intervals, which must be determined individually. In this connection, blood flow in the tissue must be secured in the relieved parts of the body, thereby relieving pressure in the stressed areas.

For more than 100 years, patients have been positioned on the basis of these considerations. Various positioning techniques have been developed today. These methods include approaches from different therapeutic concepts, such as Bobath concept or tactile stimulation. Thus 135 degree positionings, micro positioning, stomach retention, LIN positioning method or Full Body positioning were also carried out.

These positioning methods do not focus exclusively on the pressure-reducing aspect, but also pursue additional therapeutic goals, such as sensory integration, mobility, mobilization of secretion or support of the body sensation. In order to complete these positioning s, you need positioning cushions. For everyday use, ordinary pillows, blankets and towels are also used in addition to special cushions.

The positioning cushions were used in our institution with different objectives, such as pressure distribution, regulation of muscle tone, for relief of respiration or for sensory integration. The care staff worked with all the test subjects and positioned patients / Residents with the necessary techniques.

The following types of positioning were completed using the cushions:

- 30˚-sideways
- 135˚-sideways
- Bobath positioning
- Seated position
- Micro positioning
- Full body positioning
- LIN positioning method
- Positioning of extremities

The care staff selected the positioning methods that were necessary for the individual positioning. The care staff could complete all the desired positioning techniques with the cushions available in the LEJRELET series.

In our institution, the risk of decubitus is determined on the basis of specialist knowledge and according to the national expert standard. Over the entire test period, eleven patients / Resident had different degrees of decubitus risk. At the end of the 7-week test periods, no pressure ulcers could be detected in any of the patients / Residents.

7. Benefits and risks

In our institution we could not observe any direct or immediate hazards of the product, either for the patients / Residents or carers.

8. Evaluation of the outcome

The testing of the positioning cushions took place over a period of 7 weeks with a total of 11 patients / Residents in our institution. It can be concluded that the use of the products did not cause any damage to the skin of the patients / residents during the test period.

The cushions are also easy to handle and adapt easily to the patient's / resident's body. When the cushions are placed in a certain way they remain there and do not slip away.

No changes in the microclimate could be observed in the bed, despite the summery temperatures.

The cleaning / disinfection of the cushions is also easy.

9. Product Description

The manufacturer handed over the mentioned LEJRELET positioning cushions to us for testing. The individual cushions are described in the following text:

9.1. Tube 250

LEJRELET Tube 250 is a long, soft cylinder that is filled with pressure-reducing foam granules. This makes the Tube (250) stable and easy to shape and the filling stays where you need it. The filling also gives Tube (250) a good weight, which results in good tactile stimuli. Therefore, the cushion has a calming effect on many people.

The Tube 250 is longer than other cylinder cushion, so it is possible to make a full body positioning.

LEJRELET Tube 250

The weight is 6000 g. Length is 250 cm, diameter is 25 cm. The pad is filled with viscoelastic foam granules.

9.2 Tube 125

LEJRELET Tube 125 has the same structure and good features as the LEJRELET Tube 250. The high flexibility of the material offers many applications.

However, the Tube 125 is only half as long, 125 cm, and therefore weighs only 3 kg.

LEJRELET Tube 125

The weight is 3000 g. Length is 125 cm, diameter is 25 cm. The pad is also filled with viscoelastic foam granules.

9.3 Wedge

LEJRELET Wedge is a triangular cushion, which is used in different situations, both for stabilization and relieving pressure.

Wedge is formed based on the anathomy of the thorax and pelvis.

Suspension in the side with Wedge, either in front of the body or behind the back, gives the bedridden client good stability, which facilitates the work health and safety of the caregivers.

LEJRELET Wedge

The weight is 550 g. Length is 50 cm, width is 30 cm and height 15 cm.
The pad consists of polyurethane and viscoelastic foam.

9.4 Pad High

LEJRELET Pad High is a rectangular cushion, which is used in various stabilization and pressure relieving situations. Pad High is designed based on the anothomy of the thorax and pelvis. When Pad High e.g. is used to support the leg in a sideway position, it ensures that the bedridden client's hip is bent in a neutral position. This means avoiding rotation and compression of the hip joint and tension of the joint.
Supporting the leg with Pad High ensures a better working position for the care staff, for example in situations of lower hygiene processes or when applying support stockings in bed.

LEJRELET Pad High

The weight is 800 g. Length is 50 cm, width 30 cm and height 15 cm.

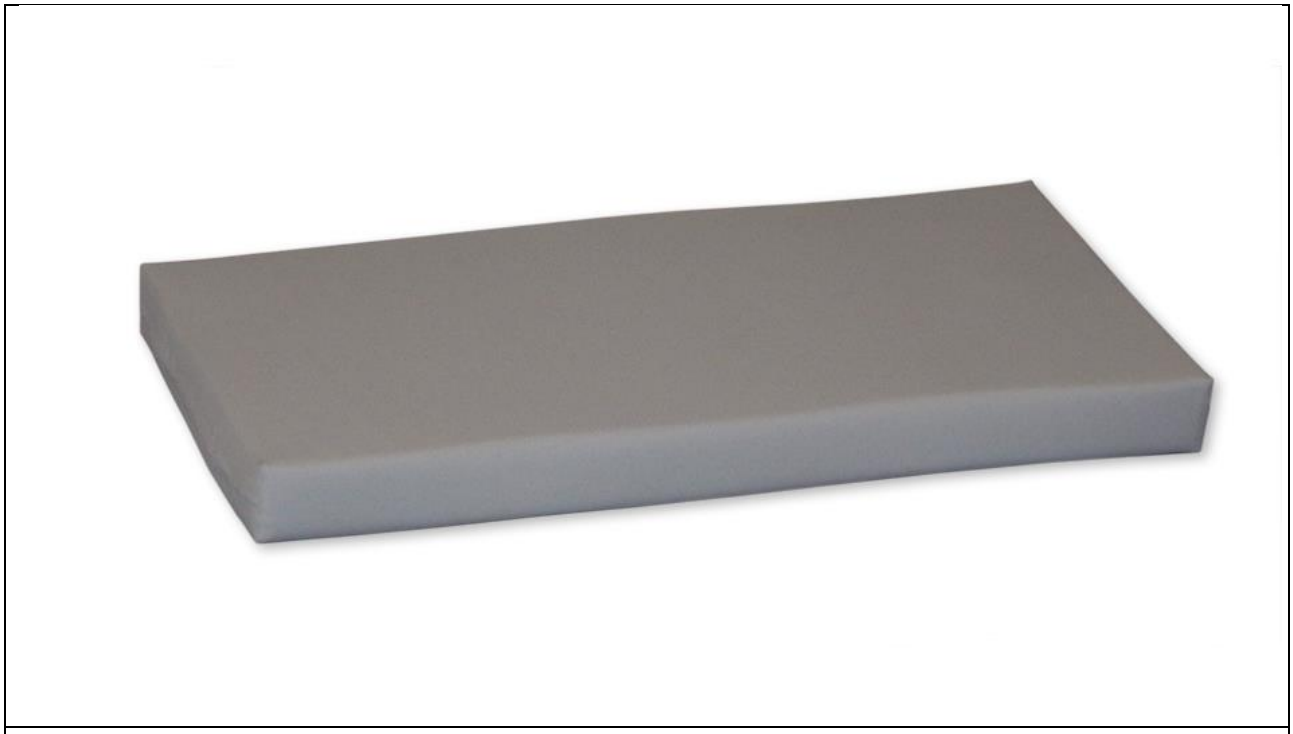
The pad consists of polyurethane and viscoelastic foam.

9.5 *Pad Low*

LEJRELET Pad consists of pressure-reducing foam, which is easy to shape and adapt to the individual bedridden person. This ensures optimum relief and possibility of adaptation in situations where greater stability and support is required.

Pad Low can be used in many positioning and pressure reliefing situations. Pad Low protects the bedridden client from hard or sharp edges, which can cause damage.

Pad Low can be used flat, rolled and folded.



LEJRELET Pad Low

The weight is 350 g. Length is 40[5] cm, width is 30 cm and hight is 14[6] cm.

The pad consists of viscoelastic foam granules.

9.6 Oval

LEJRELET Oval is a cushion especially developed for micro re-positioning.

This principle is designed to achieve the best possible pressure relief effect for the bedridden client using minimal and soft shift re-positioning.

LEJRELET Oval is made of a very smooth foam granulate that adapts to the body. Thus, the LEJRELET Oval is easy to use and gives the bedridden client the best possible support and comfort.

[5] Pad Low is really 50 cm long

[6] Pad Low is really 4 cm high

LEJRELET Oval

The weight is 350 g. Length is 40 cm, width 25 cm and height 10 cm.
The pad consists of viscoelastic foam granules.

9.7 Product adaptability
The cushions cannot be adapted but adapt to the bedridden client's body.

9.8 Microclimatic properties
The professional care staff in ZBI could not detect increased incidence of skin moisture in the patients / residents while using the cushions.

9.9 Cleaning
LEJRELET products can be wiped with soap and detergents.

10. Overall Rating
The LEJRELET series positioning cushions were used in our institution over a 7 week period in 11 patients / Residents for positioning.
It can be concluded that none of our patients / Resident developed negative changes in the skin during the said period. The cushions are easy to clean and do not slip away when used by the patients / Residents.
Based on our experiences and targeted observations, we come to the overall conclusion that the LEJRELET cushions are suitable for positioning in institutions and for outpatient as well as decubitus treatment and prevention.

Berlin, den 9.08.2017

Sebastian Kruschwitz
-Fachbereichsleitung Wundmanagement-

Fra: Thomas Friedrich <t.friedrich@beoberlin.de>
Sendt: 1. august 2018 09:55
Til: Jane Maindal <jane.maindal@vendlet.dk>
Cc: Peter Maindal <peter.maindal@vendlet.dk>
Emne: Re: Gutachten med. Nutzen und Prüfplan Lagerungskissenserie LEJRELET

Hello Jane,

Mr. Kruschwitz released the expert opinion to publish it. See the attached report.
The original was sent 2017-08-11 to Peter Maindal.

Mit freundlichen Grüßen / Best regards

Thomas Friedrich
Division Manager
German Reimbursement

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Test plan for the preparation of a specialist report on the medical gain

relating to.

Product description: Positioning cushions

Type/Art: Positioning cushion series

LEJRELET consistent of:

Tube 250	Artikel no.: 5000001
Tube 125	Artikel no.: 5000000
Wedge	Artikel no.: 5000002
Pad High	Artikel no.: 5000003
Pad Low	Artikel no.: 5000004
Oval	Artikel no.: 5000009

Testet accessories: Nothing Artikel no.:

Manufacturer: Vendlet ApS, Egelund 33, 6200 Aabenraa, Denmark

Contracting Authority: BEO MedConsulting Berlin GmbH, Helmholzstr. 2, 10587 Berlin

Testet by: Zentrum für Beatmung und Intensivpflege, Franz-Jacob-Straße 4c, 10369 Berlin

Would you please prepare a written report with the following content:

1. Information about product designation, type / species with item no., If applicable, the tested accessory with item no., Manufacturer and contractor, eg. as stated above.

2. Brief description of your institution, in which your institution's independence and reputation are presented, as well as information about investigating.

3. Information on the period of application / observation

Note: It is recommended to observe a minimum of 3 weeks observation period. patient.

4. Information on the care staff / test subjects participating in the test and the number of test subjects.

Note: The test must be carried out taking into account the circle of users for which the positioning cushions is intended. It is recommended to observe at least 5 patients.

5. Information about the test environment (eg clinic, living environment)

Note: The studies / studies must be carried out in the general area / living environment or be able to be transferred to this.

1. The position of the total indication range as claimed by the manufacturer and the effect of the product in combination with all tested components (eg covers, accessories, etc.) at
   6.1. Description of the intended objective, such as
   - Securing the surgical procedure (Decubitus therapy) and / or
   - Prevention of constraints (Decubitus prophylaxis) and / or
   - Compensation for limitations (eg compensation for inability to move by means of change of lease)

   6.2. Clear description of the obtained and under item 6.1. described objective (s) including the examiner's reasoning why the product according to him is suitable for use in the bombardment of the indications that the producer has claimed. For example, Also mentioned are clinical endpoints, decubitus occurrence (occurrence of decubitus stage II or higher) for evidence of the preventive effect against decubitus, respectively. the recovery rate (with information about the measurement method) of a detected decubitus. In this context, the affected area of indication must be formulated clearly and depicted using standardized risk scales - in the case of older people patients Braden scale, in case of other patient groups using validated scales to these groups. If the product is to be used for decubitus therapy, there is furthermore, need a description according to the decubitus stages of EPUAP.En afvejelse af gevinsten i forhold til risiciene.
2. A weighing of the winnings in relation to the risks.
3. An evaluation of the desired and undesirable consequences ("outcome")
4. Description of the product with regard to the following items:
   9.1. Can the cover be changed by the care staff?
   9.2. Can the product be adjusted individually to the patient's weight and to the person concerned load situation (manually or automatically)? Or can the product be selected in according to the patient's weight?
   9.3. Can all values that can be changed individually be served by the care staff?
   9.4. Microclimatic properties that can be observed.
   9.5. If necessary, further statements regarding handling the product, eg. cleaning / disinfection, comfort for the user / patient and caregivers.
5. Overall Rating

The report may be drawn up in German or English and, if necessary, supplemented with images and data in tabular form.

Confirmation of the test institution / specialist

This confirms that the specialist report concerns The medical gain of the above product was made according to the current test plan.

9.08.2017 S. Schmidt

Datum / Stempel / Unterschrift