Multi-center study
on the combined use of
Cutimed® Sorbact® & Cutimed® Siltec

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A multi-center study on the combined use of Cutimed® Sorbact® and Cutimed® Siltec (BSN medical GmbH) was carried out to test, through observing treatment practices throughout Germany, whether both of these products constitute a reasonable alternative to the current procedure for wound treatment (with silver dressings) for chronic, contaminated, colonized and infected wounds. In total, 50 patient questionnaires were assessed for this observational study.

In an advance extract of the observational study of Cutimed® Sorbact® and Cutimed® Siltec, 12 case histories that concern wound treatment for diabetic foot only, were published (by Hallern et al. 2011).

General aspects on chronic wounds

Appropriate treatment of acutely and chronically infected wounds is still today an increasingly important issue for doctors and healthcare staff. For a chronic wound to heal successfully, it must be recognized early on, and any underlying and concomitant illnesses that patient is suffering from must be treated promptly. In the professional literature, it is broadly agreed that wounds are to be described as chronic if they show no signs of healing after 12 weeks of professional treatment (Auböck 2007; Probst, Vasel-Biergans 2004).
Chronic wounds mostly develop following underlying illnesses such as diabetes mellitus, venous or arterial insufficiency or through immobilization (Probst, Vasel-Biergans 2004), and can also become chronic when the tissue is receiving insufficient nutrients (Blank 2007). Factors which influence wound healing may be related to the context (factors that produce systemic disturbances), such as stress, advanced age, malnutrition, or the consumption of alcohol and/or nicotine. Certain medications (e.g. corticosteroids, immune suppressants, cytotoxic drugs) and/or a depressed immune system may have a detrimental effect on wound healing.
Some of the most characteristic chronic wounds include venous/arterial leg ulcer, diabetic foot, pressure ulcer, and impairment to the wound healing process following surgery (Stremitzer, Wild 2007; Protz 2011).

Venous/ arterial leg ulcer

VLU is defined as a venous leg ulcer that forms mainly in the lower leg and is caused by chronic venous weakness (chronicvenous insufficiency, CVI). A tissue defect, worsened by bad metabolism, may form and could extend from the dermis to the subcutis. The lack of nourishment to the connective tissue produces a wound that heals slowly and requires time-consuming treatment. An arterial leg ulcer arises as the result of atherosclerotic plaques, which may lead to a narrowing or total occlusion of the arteries affected (Schröder G 2009; Blank 2007).

Diabetic foot syndrome

Diabetes mellitus is a chronic metabolic disorder with relative (type II diabetes) or absolute (type I) insulin deficiency. Twenty percent of all patients suffering from diabetes develop diabetic foot over time. It occurs as a complication in those diagnosed with diabetes mellitus, and is caused by impaired arterial blood flow and/or by a neuropathy. The clinical picture of the neuropathy is divided into several subtypes, and into peripheral vascular disease. The intima gradually thickens, plaques form, and ulcers appear on the vascular walls - there may be exogenous or endogenous causes for this (Schröder G 2010, Haslbeck 2006). The main factor responsible for damage caused by longterm diabetes is the blood sugar level being too high over a prolonged period of time (hyperglycaemia). This leads to the build-up of acid mucopolysaccharides in the basal membrane, which then leads to macro and microvascular changes, resulting in direct damage to the nerves (Nedder 2005; Schröder G 2010).

Pressure ulcers

Pressure ulcers are visible changes to the human skin, and often to the deeper-lying layers of tissue, which result from external pressure over a prolonged period. They mainly occur in immobile, ill and elderly individuals. The consequence is an impairment to the blood flow and the exchange of substances in the affected parts of the skin. This mostly results in cellular death (necrosis) and tissue destruction (Gesundheitsberichterstattung des Bundes, issue 12, 2007).
It has been observed with increasing frequency, that greater importance is being given to the patients' quality of life in studies and scientific observational studies. A failure to involve patients, a lack of communication with the care staff, and a lack of coordination between doctors, are increasingly seen as negative factors for wound healing, and affect the patient very adversely.
A chronic wound not only requires a great deal of time in terms of healing and care, but also severely affects the quality of life of the affected patient. The negative effects on quality of life range from physical impairment, such as reduced mobility, serious and lasting pain, the loss of personal self-determination, to a negative self image, and accompanying social isolation (Neil, Munjas 2000; Franks, Morgan 2003). These restrictions are serious for the patient, taking into consideration that chronic wounds can often last for years (Probst, Vasel-Biergans 2004). For this reason, during the observational study of the combined use of Cutimed® Sorbact® and Cutimed® Siltec, particular attention was focused on the affect of the products on the patients' quality of life. If the dressings are changed without causing pain, the patients' quality of life is improved. This is why questions about this aspect were included in the product acceptance test questionnaire.
For patients with a chronic wound, the immune response is massively reduced, and the susceptibility to infection is much more marked and in many studies, it has been proven that the healing took longer (Schröder G 2009; Protz 2011; Haslbeck 2006). There is a large range of wound dressings, local antiseptics, and systemic antimicrobial substances available to users for the treatment of infected wounds. However, the active substances used for this can adversely affect the body's own cells.

Special mode of action of Cutimed® Sorbact® and Cutimed® Siltec

In contrast, the wound dressing Cutimed® Sorbact® uses the Sorbact® method, based on the principle of hydrophobic interaction, to clean wounds on a purely physical basis, without producing any adverse effects. Thanks to hydrophobic interaction, pathogenic microorganisms are irreversibly bound to the dressing and rendered inert. This process is beneficial in that the patient is not subjected to chemical substances, and there is no release of intracellular microbial enzymes or toxins during treatment. With each Cutimed® Sorbact® dressing change, the bacterial count is reduced, which helps support natural wound healing. It can therefore be indicated for treating infections, as well as colonized and contaminated wounds.
Cutimed® Siltec, in turn, safely and comfortably absorbs exudate for moderately to heavily exudating wounds, due to a unique foam core with embedded super absorbers, and a skin-friendly silicone film which resists adhering to the wound or surrounding skin. Therefore, wound exudate is effectively absorbed and the patient's dressing can be changed without causing pain, offering two key advantages in wound care management, particularly related to patient quality of life.

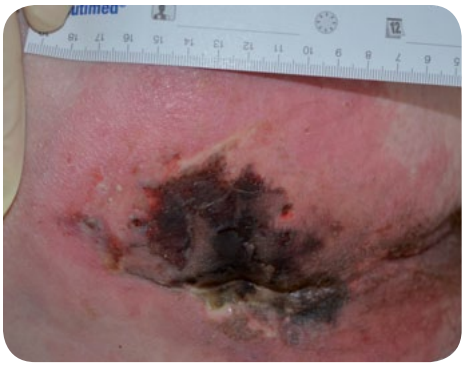

Fig. 1:
Admission status for a patient with a sacral pressure ulcer with solid black skin necrosis. The edges were soft in parts, and cloudy exudate seeped out when pressure was applied.

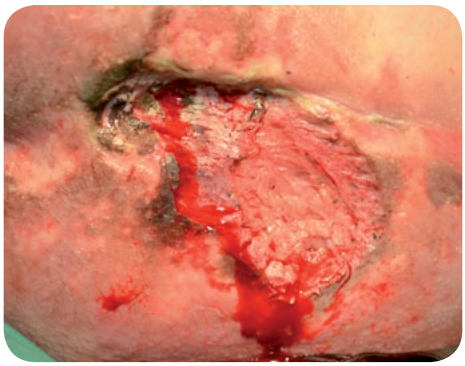

Fig. 2:
The skin necrosis was removed attempting to cause as little pain as possible.

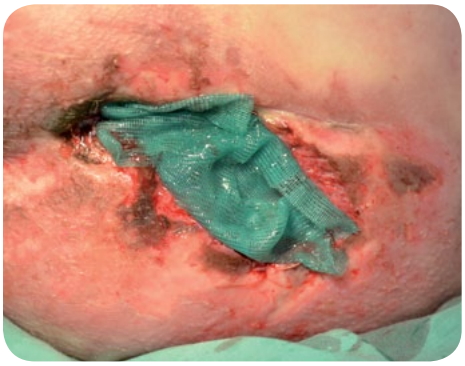

Fig. 3:
A Cutimed® Sorbact® Gel dressing is applied to provide antimicrobial treatment and autolysis...

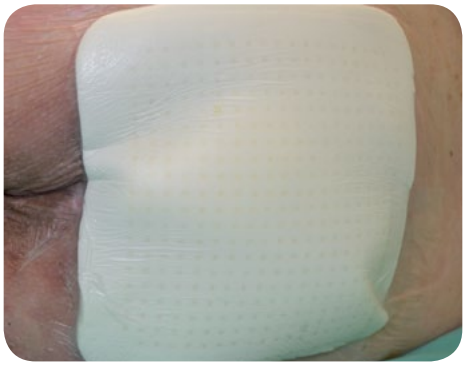

Fig. 4:
... and held in place for 24 hours with an absorbent dressing. Wound treatments were applied daily. From Day 2 forward, the dressing treatment also included Cutimed® Siltec.

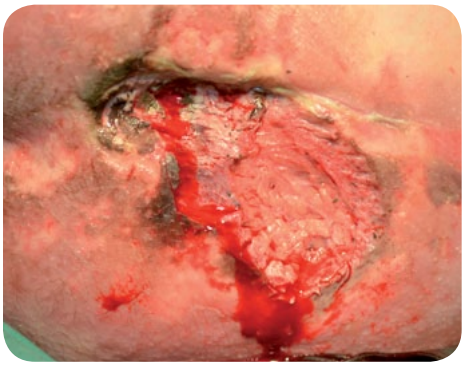

Fig. 5:
Wound pain prevented further debridement with only local anaesthetic. The decision was made to carry out debridement under full anaesthetic. After surgery, the condition of the wound showed signs of clear improvement, and after just a few days, it was possible to manage the wound exudate without antimicrobial dressings.

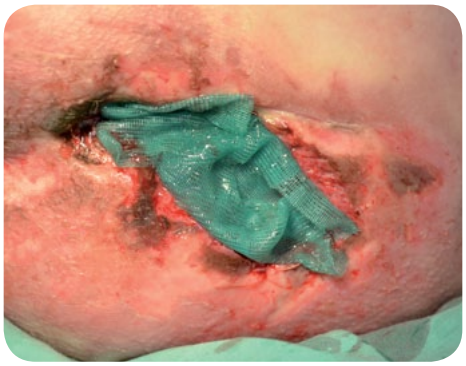

Fig. 6:
After surgery, on Day 10, one day before discharge, the wound had a fibrinous coating, granulation had started and there was no sign of infection.

Case 1: Large sacral pressure ulcer

Diagnosis

Peripheral vascular disease, stage IV, according to Fontaine, Arterial hypertension, COPD, Urinary incontinence, Grade III pressure ulcer (sacrum), Contracture of the left hip and knee joint

Findings and wound treatment of sacral pressure ulcer

When the patient was admitted, a large area of black skin necrosis of approximately 8 cm x 6 cm was found. When pressure was applied, pus seeped out of the edge. Initially, taking into account the overall situation, surgical and autolytic debridement was carried out carefully every day. The signs of inflammation regressed after a few days and it was no longer possible to carry out extensive surgical debridement using local anaesthesia and EMLA® Cream. So the wound was debrided extensively under full anaesthesia.
Local treatment was then carried out with Cutimed® Sorbact® Gel and Cutimed® Siltec until the patient was discharged.

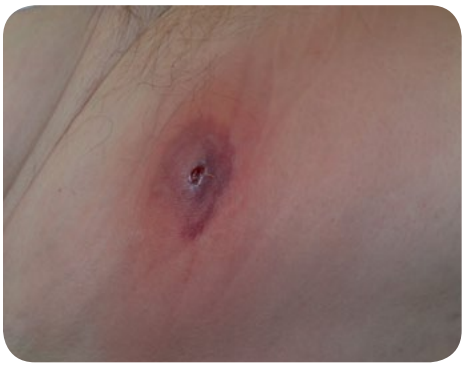

Fig. 1:
Local findings when the patient came to the out-patient department

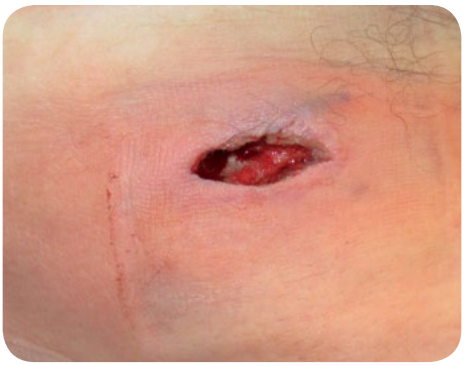

Fig. 2:
The abscess was excised and the capsule of the hair follicle was removed. A small Cutimed® Sorbact® ribbon gauze was inserted into the wound, and covered with an absorbent dressing until the following day.

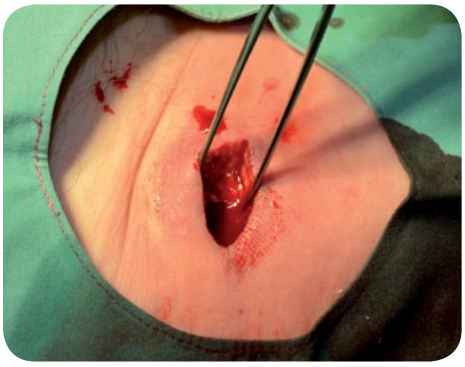

Fig. 3:
On Day 2 of treatment, the signs of infection had visibly regressed, and the superficial redness had become markedly lighter.

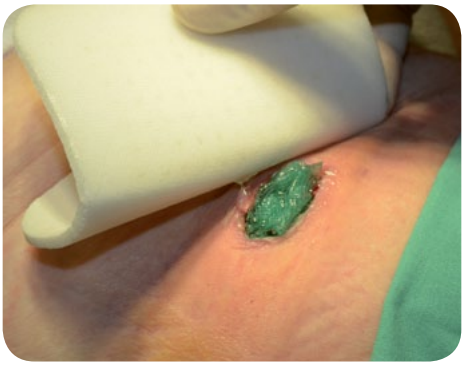

Fig. 4:
From Day 2 forward, the wound was treated with Cutimed® Sorbact® Gel and Cutimed® Siltec. The patient was transferred to his or her GP for any further treatment.

Case 2: Wound treatment for infected atheroma

Diagnosis

Infected atheroma on the proximal thigh

Findings and wound treatment

The patient had an infected atheroma on the proximal thigh with extensive redness of the skin. A few hours earlier, spontaneous perforation had occurred.
Under anaesthesia, the abscess was excised, and local antimicrobial treatment was introduced. Systemic antibiotics were not administered. After just 2 days – initially changing the dressing every 12 hours – the signs of infection had regressed visibly.

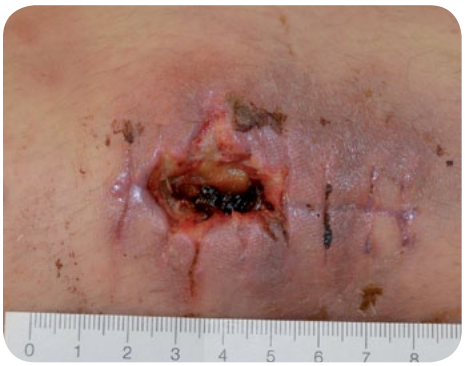

Fig. 1:
Opening of the wound 14 days after surgery

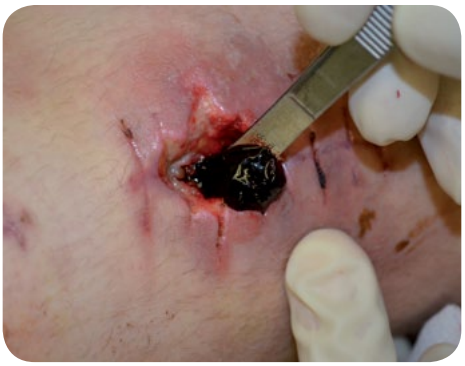

Fig. 2:
Old haematoma coagulum was removed from the wound. Then the wound was rinsed thoroughly with Octenisept® solution.

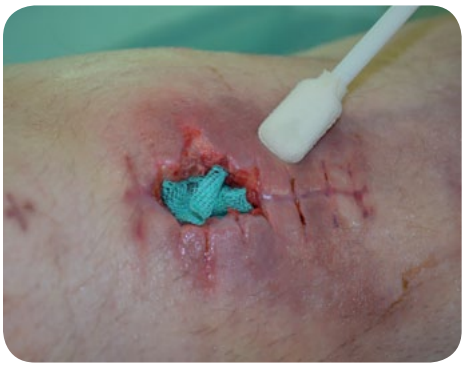

Fig. 3:
A Cutimed® Sorbact® ribbon gauze was inserted into the wound cavity and the edge of the wound was protected from excess moisture and the potential for maceration with Cutimed® Protect.

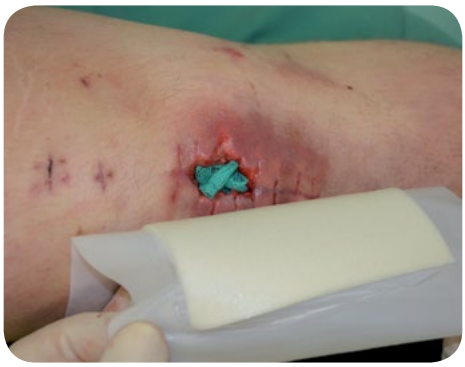

Fig. 4:
A Cutimed® Siltec B foam dressing was then applied to cover the wound.

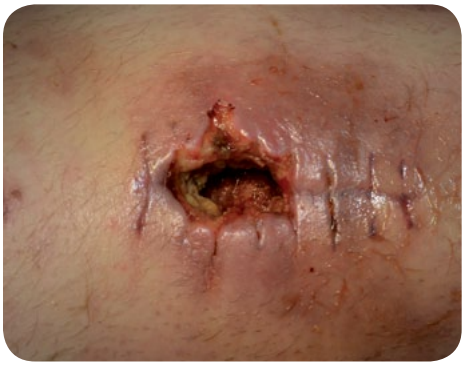

Fig. 5:
24 hours later there was no more coagulum. Treatment with Cutimed® Sorbact® and Cutimed® Siltec was continued. Going forward, the dressings were changed every 48 hours.

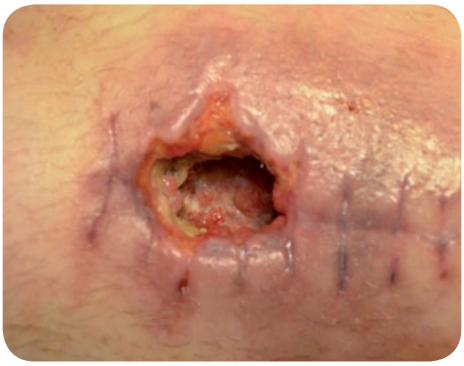

Fig. 6:
After 6 days, the wound was free of infection and necrosis. The wound was closed by a plastic surgeon.

Case 3: Post operative impairment to wound healing on the knee

Diagnosis

Traumatic injury above the patella and bursectomy.
A haematoma developed after surgery.

Findings and wound healing

14 Days after surgery, wound dehiscence occurred, and a dark, rich exudate oozed out. The wound was opened up proximally, and a haematoma became visible. This was cleaned out, and a deep wound cavity of approximately 3 cm in length resulted, medially and laterally. An antimicrobial treatment was administered with a Cutimed® Sorbact® ribbon gauze inserted into the wound, followed by wound dressing with Cutimed® Siltec B. The dressing was changed daily and the wound was rinsed with an antiseptic. On Day 2 of the combined product treatment, instead of a Cutimed® Sorbact® ribbon gauze, Cutimed® Sorbact® Gel was used to promote autolytic wound cleansing. The area around the wound was protected with Cutimed® Protect. After five days of treatment, the wound was infection-free, and the patient was prepared for flap plastic surgery, in order to stabilise and strengthen the skin above the knee and shin.

Statistical evaluation

Diagnosis

Before the treatment started, criteria were determined for excluding patients from the acceptance test. Exclusionary criteria included a maximum age of 80 years as well as a wound size smaller than 2 cm². The data on the points to be examined was obtained by way of a questionnaire. The following graphs on the product combination of Cutimed® Sorbact® and Cutimed® Siltec systematically show positive results.

The observation period extended from November, 2010 to September, 2011 and included 50 patients.

- 15 patients were diagnosed as having impairment to the wound healing process
- 9 patients were diagnosed as having a venous/arterial leg ulcer
- 12 patients were diagnosed as having diabetic foot
- 6 patients were diagnosed as having a pressure ulcer and
- 8 patients could not be clearly categorized.

Below, the first diagram shows whether the user stated that the efficacy of the product combination was “very good”, “very bad”, “good”, “average” or “bad”. In total, 39% of those questioned considered the level of efficacy of the product combination to be “good”, and 61% considered it to be “very good”. The categories “average”, “bad” and “very bad” were not selected by the users.

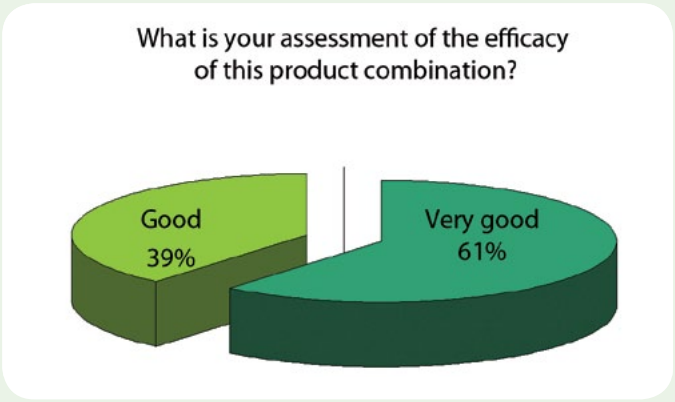

Diagram 1:
Assessment of the efficacy of the product combination as % of users

Users were asked to assess the effectiveness in fighting infection, from “very good” to “very bad”. Diagram 2 shows that 31% expressed that it was “good”, and 69% of the users stated it was “very good”. The “average”, “bad” and “very bad” options were not chosen.

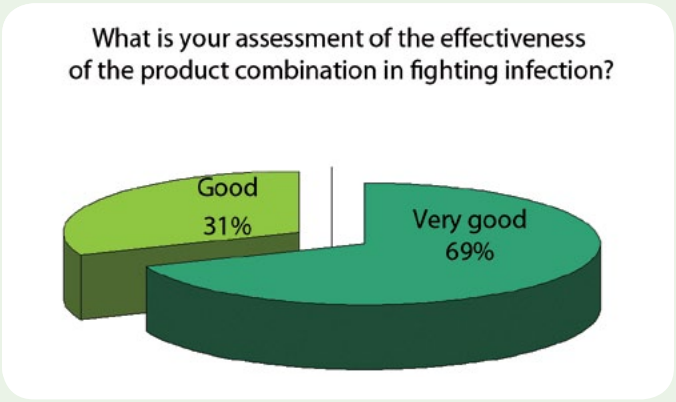

Diagram 2:
Assessment of the effectiveness in fighting infection as % of users

For Diagram 3, users were asked how safely they felt the exudate was bound and retained. Keeping in mind the quantity of exudate, 4% found the absorbency of the product combination to be sufficient, 49% considered it to be “good”, and 47% found it to be “very good”.

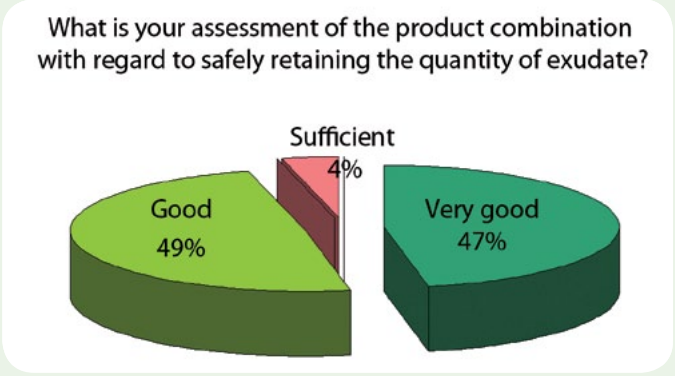

Diagram 3:
Assessment of the efficacy of the product combination as % of users

For the fourth diagram, users were asked to assess the product combination in terms of how effectively the dressing could be changed without causing pain to the patient. The categories were “very good”, “good”, “average”, “sufficient” and “unacceptable”. In total, 27% of the users said it was good, while 73% deemed the combination very good. The “average”, “sufficient” and “unacceptable” were not selected by the users.

Diagram 4:
Assessment of whether the combination of dressings could be changed without causing pain as % of users

In the fifth diagram, users were asked whether they would recommend the product combination used to others for specific types of wounds. The users could answer “yes”, “with reservations”, or “no”. In this case, 86% said they would recommend the product combination used to others and 14% of users replied “with reservations”. None of the users indicated they would not recommend the product combination to others.

Diagram 5:
Recommendation of the product combination to others for specific types of wound as % of users

For Diagram 6, users were asked whether they would consider the product combination a therapeutic standard for certain types of wound. They could answer “yes”, “with reservations”, or “no”. In total, 64% of the users would establish the product combination of Cutimed® Sorbact® and Cutimed® Siltec as the therapeutic standard, while just 16% of users replied “no”, and 20% replied “with reservations”.

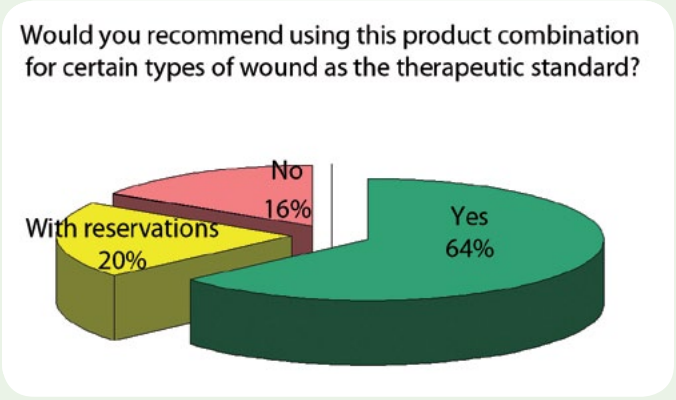

Diagram 6:
Establishment of a therapeutic standard, using the product combination for certain types of wounds as % of users

The seventh diagram shows the results of the question about the effect of the product combination on the patients’ quality of life. There were five possible categories to choose from: “very good”, “good”, “average”, “bad” and “very bad”. Only 2% of users chose “average”, 43% chose “good”, and 55% gave “very good” as their answer. The “bad” and “very bad” options were not chosen.

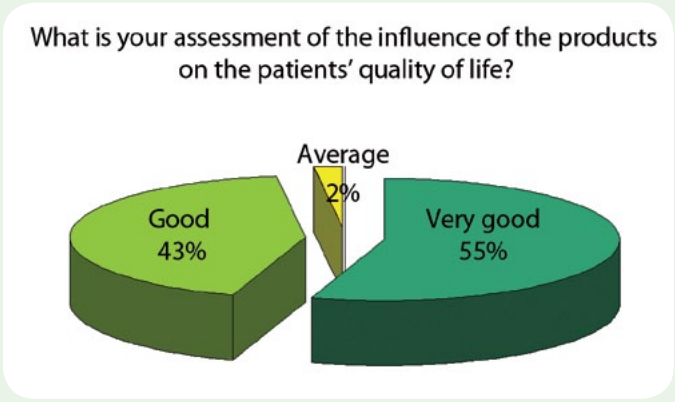

Diagram 7:
Assessment of the effects of the product combination on the patients’ quality of life as % of users

Results

The combination of Cutimed® Sorbact® and Cutimed® Siltec was shown to be quite effective for complex wound management. The results of the product acceptance test clearly demonstrate the benefits of the product combination with regard to efficacy, its effectiveness in fighting infection, its exudate absorbing capacity and the improvement in quality of life, expressed in terms of less pain when the dressing was changed. It was also demonstrated that a therapeutic standard could be derived from the product combination used, for certain types of wounds.

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Participating clinics:

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- Universitätsklinikum Heidelberg
  Department of Paraplegiology
- Universitätsklinikum Heidelberg, angiology outpatiens'
  department, medical clinic
- Kreisklinikum Oberberg, Gummersbach
- St. Nikolaus-Stifthospital GmbH, Andernach
- Wundtherapiezentrum am Bergmannsheil
  Gelsenkirchen-Buer
- Universitätsklinikum Düsseldorf,
  wound management department
- Kliniken Maria Hilf GmbH, Mönchengladbach
- Krankenhaus der Barmherzigen Brüder Trier
- Städtisches Klinikum Leverkusen
- Klinik Prof. Schedel GmbH, Thyrnau-Kellberg
- Die Filderklinik, Filderstadt-Bonlanden
- Mühlenkreis Kliniken AÖR, Krhs. Bad Oeynhausen,
  wound management department
- Niels-Stensen Kliniken, Christliches Klinikum Melle,
  wound management department
- Klinikum Friedrichshafen GmbH
- Kreiskliniken Reutlingen GmbH

Note:
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