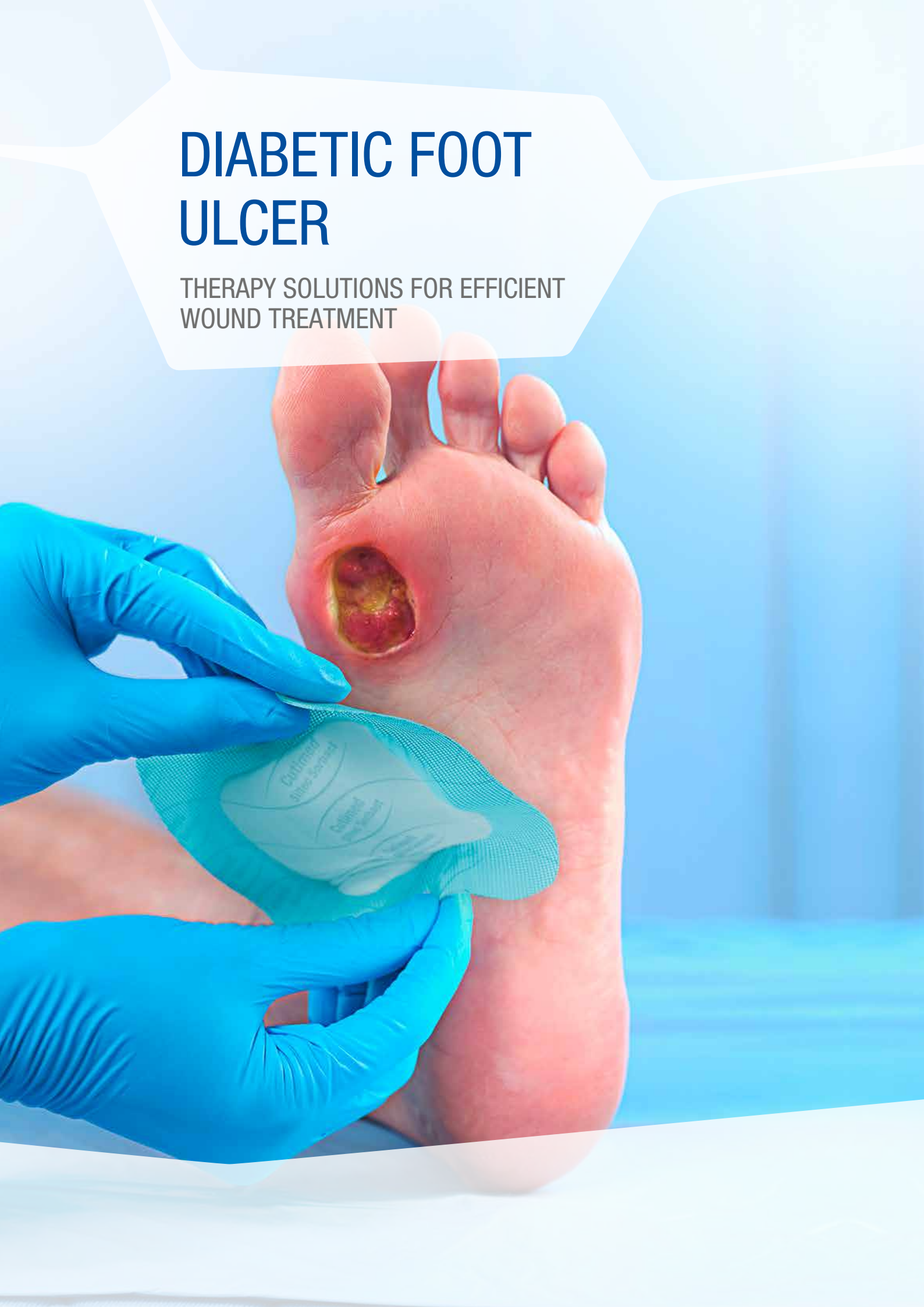
DIABETIC FOOT ULCER

THERAPY SOLUTIONS FOR EFFICIENT WOUND TREATMENT



A QUICKLY GROWING PROBLEM

According to the 2016 WHO Global Diabetes Report, the incidence of diabetes among the world's population has nearly quadrupled during the past 30 years.

8.5 %

of the world's population is suffering from diabetes[1]

Every 4th

diabetes patient develops a diabetic foot ulcer once in their lifetime[1]

DIABETIC FOOT ULCERS – A HUGE CHALLENGE

- Every year, more than a million people have to undergo an amputation as a result of diabetes[2]
- The incidence of diabetic foot disease will increase as the population ages and the obesity epidemic continues[2]
- In Europe, costs associated with the treatment of diabetic foot ulcers may be as high as ten billion euros per year[3]
- Diabetes affects developing countries disproportionately as more than 80 % of diabetes deaths occur in low- and middle-income countries

TURNING GUIDELINES INTO EFFICIENT TREATMENT SOLUTIONS

Cutimed`s therapy solutions for diabetic foot ulcers reflect the latest scientific findings and medical guidelines. We translate these into easily applicable treatment concepts, with advanced wound care products, effective offloading techniques and appropriate compression treatment where needed.

Adherence is key. But often patients do not follow their healthcare professionals' recommendations concerning prevention and treatment schemes. Up to 85% of amputations can be avoided when an effective care plan is adopted.[2]

Wound Management

- Prevent infections
- Accelerate healing
- Avoid amputations
- Reduce costs

Patient Adherence

- Involve patients
- Bring back confidence
- Increase cure rate
- Reduce recurrence

1 Anon, 2016 Global Report on Diabetes. World Health Organization. Available at http://apps.who.int/iris/bitstream/10665/204871/1/9789241565257_eng.pdf (accessed 20 April 2017).
2 Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg 2016; 63:3–21.
3 Prompers L, Huijberts M, Schaper N, et al. Resource utilisation and costs associated with the treatment of diabetic foot ulcers. Prospective data from the EURODIALE Study. Diabetologia 2008; 51: 1826–34.

CORNERSTONES OF ADVANCED DFU TREATMENT

Managing diabetic foot ulcers requires a multidisciplinary team approach. Basics of treatment include glycaemic control and ensuring adequate vascular supply, if necessary by surgery. Cutimed supports specialists in creating an optimal environment that encourages fast and effective wound healing. The assortment comprises advanced product solutions for proper wound bed preparation, removal of bacteria with unique bacterial binding technology, rebuilding tissue with for example innovative collagen dressings and reducing pressure with total contact casts.

DEBRIDEMENT

Regular sharp debridement of all devitalised tissue and surrounding callus material at one-week intervals is essential for DFU management.[1] According to relevant medical guidelines, surgical debridement is one of the key factors for healing and the reduction of the bacterial load, and autolytic debridement facilitated by appropriate wound dressings supports the process.[2] Exceptions are dry, necrotic, black areas such as ischaemic toes, where the aim of dressing is to keep the wound dry to prevent infection.

It is important to evaluate the patient for PAD before removing the necrosis.

Cutimed® Sorbact® Gel
Infection management and autolytic debridement in one dressing

- Binds bacteria and fungi in contaminated, colonised and infected wounds
- Promotes autolytic debridement
- Enables a moist wound environment

Cutimed® Gel
Effective and gentle debridement

- Highly moisturising effect supports effective and gentle debridement
- Pure formulation and preservative-free for less risk of allergic reactions
- Can be covered with many types of secondary dressings without risk of incompatibility

Cutimed® DebriClean
Fast and effective wound cleansing

- Looped monofilament fiber for gentle abrasion and biofilm/ microorganism removal
- Integrated foam layer for absorption function supports the cleaning efficiency
- With a hard blister pack, which can be used for moistening and disposal

1 Wilcox, James R.; Carter, Marissa J.; Covington, Scott: Frequency of Debridements and Time to Heal, A Retrospective Cohort Study of 312,744 Wounds; JAMA Dermatol. 2013;149(9):1050-1058.

2 National Disease Management Guidelines (NVL) Type 2 diabetes: prevention and treatment strategies for foot complications of the German Medical Association, AWMF and KBV (AWMF guidelines register NVL 001 / c).

INFECTION CONTROL

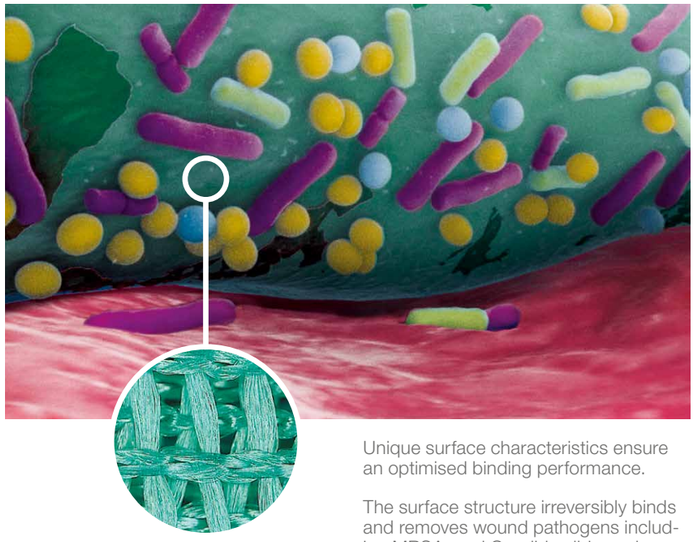
Infection is a major threat in DFU because of the amputation risk.

If not treated immediately, infection will escalate fast, leading to osteomyelitis and preceding about 60 % of amputations.[1] Since up to 50 % of patients show no classic symptoms of inflammation[2], it is important to recognise subtle signs such as:

- Increased exudate
- Friable or discoloured granulation tissue
- Undermining of wound edges
- Foul odour[3]

Although previous recommendations did not support the usage of antimicrobial dressings in order to avoid toxic effects and allergic reactions. Cutimed® Sorbact®, though, is the only solution without any known allergic reactions or side effects.[4*] Due to Cutimed® Sorbact®'s physical binding forces this dressing provides secure prevention features.

UNIQUE MODE OF ACTION



Unique surface characteristics ensure an optimised binding performance.

The surface structure irreversibly binds and removes wound pathogens including MRSA, and Candida albicans by hydrophobic interaction.[5, 6, 7]

Cutimed® Sorbact®

The first choice for safe and effective infection management and prevention

- Binds bacteria from the wound, which facilitates the healing process
- Does not kill bacteria and therefore does not trigger endotoxin release
- No bacterial/fungal resistance has been described since launch
- Low risk of allergic reaction

Application of Cutimed® Sorbact®

1 Lipsky BA. Medical treatment of diabetic foot infections. Clin Infect Dis 2004; 39(suppl 2):104–14.
2 Chadwick P, McCardle J. Assessing infected ulcers: a step-by-step guide. J Wound Care 2015; 24(5):15–19.
3 Lipsky B, Berendt A, Cornia PB. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. IDSA guidelines. Clin Infect Dis 2012; 54(12):132–73.
4 K. Bakker, J. Apelqvist, B. A. Lipsky, J. J. Van Netten, N. C. Schaper: Prevention and Management of Foot Problems in Diabetes Guidance Documents and Recommendations, www.iwgdf.org" www.iwgdf.org
5 Mosti et al., "Comparative study of two antimicrobial dressings in infected leg ulcers: a pilot study", Journal of Wound Care, 2015
6 Cutting, McGuire, "Safe bioburden management: a clinical review of DACC technology", 2015
7 Ronner et al., "Adhesion of meticillin-resistant Staphylococcus aureus to DACC coated dressings", Journal of Wound care, 2014

Cutimed® Sorbact® Hydroactive B
Infection and fluid management with soft debridement effect

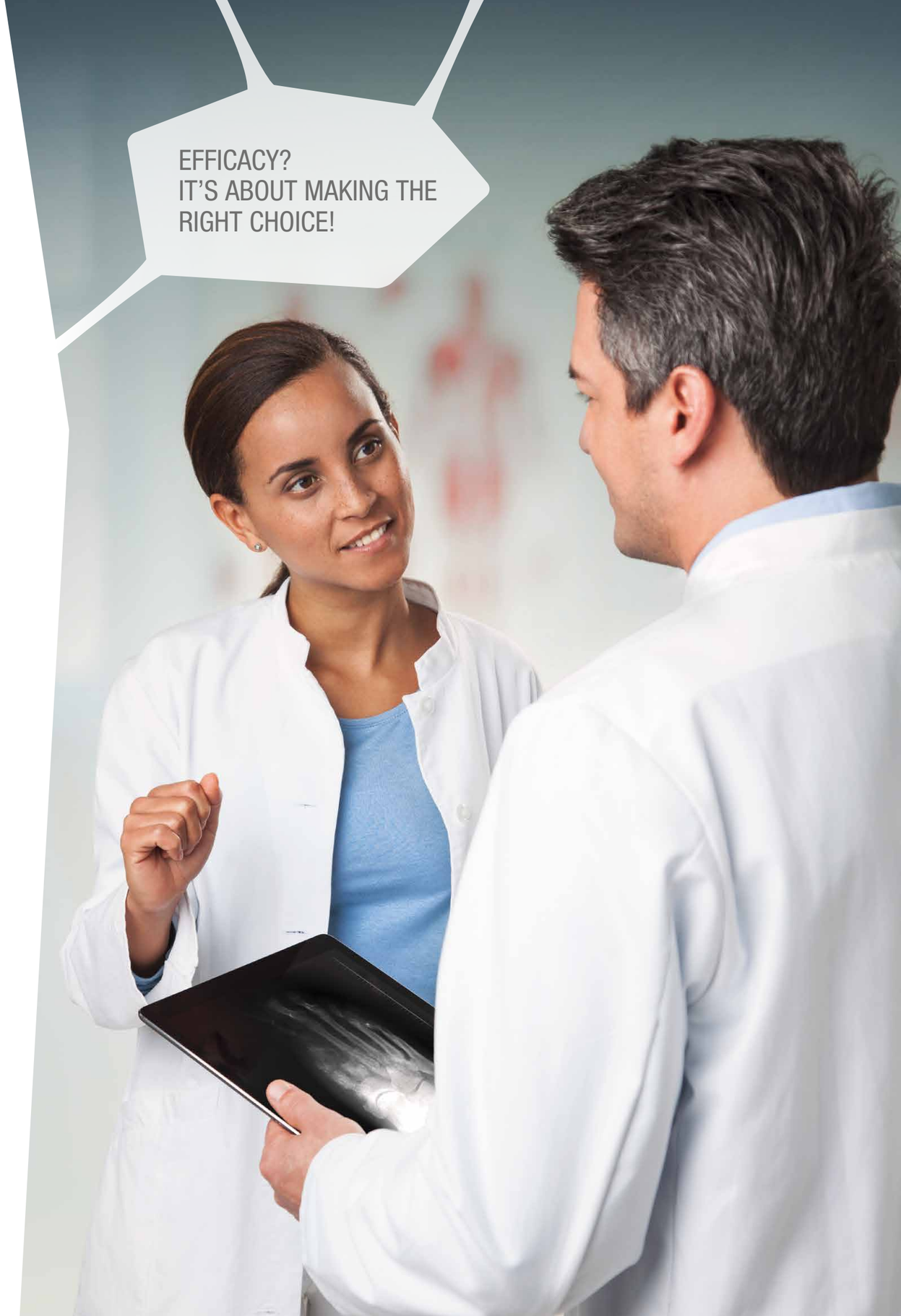
- Binds bacteria, which facilitates the healing process
- No bacterial/fungal resistance has been described since launch
- Stimulates autolytic debridement of fibrin and necrotic tissue
- Highly absorbent, also ideal for absorption of less viscous exudate

Cutimed® Siltec® Sorbact®
Proven quality - no compromises: Combines the benefit of infection and exudate management

- Ideal healing conditions due to moisture-balancing, highly breathable PU film
- Keeps the bacterial cell wall intact, avoiding release of endotoxins and leading to reduced bioburden
- No mechanism for the development of bacterial resistance

Cutimed® Sorbion® Sorbact®
The only dressing for infected and highly exuding wounds

- Binds irreversibly common wound pathogens
- Does not kill bacteria and therefore does not trigger endotoxin release
- Fast exudate absorption by superabsorber technology
- Fluid is retained within the dressings



PROMOTION OF TISSUE GROWTH

Moist wound healing is the gold standard: wound treatment should ensure a moist wound environment to aid cell migration and facilitate autolysis.

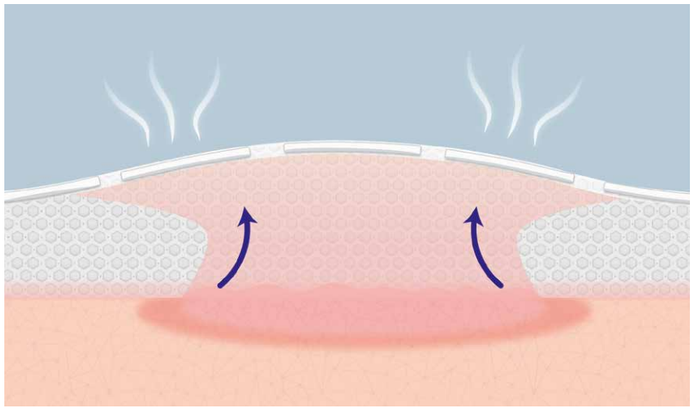
- Irrespectively of the level of exudation advanced, absorbent dressings should ensure the right level of moisture
- At the same time the risk of maceration of the surrounding skin needs to be reduced to a minimum

Cutimed® Siltec® Heel 3D

Cutimed® Siltec®

Excellent exudate management designed to protect fragile skin

- Silicone wound contact layer:
  - Ensures gentle adherence
  - Minimises pain on removal
  - Protects the new, fragile layer of epidermal cells
- Manages fluid even under compression
- Vertical absorption minimises risk of maceration



Cutimed® Siltec® fluid management

Cutimed® Siltec® B

Excellent exudate management and fixation in one dressing

- Silicone wound contact layer:
  - Ensures gentle adherence
  - Minimises pain on removal
  - Protects the new, fragile layer of epidermal cells
- Manages fluid even under compression
- Vertical absorption minimises risk of maceration
- Silicone border makes application easy and safe

Cutimed® Sorbion® Sachet *

Absorption performance without any compromise: for moderate to highly exuding wounds

- Creates a moist wound environment, absorbs large quantities of wound exudate
- Protects against maceration and skin irritation
- Removes wound debris, supports the wound cleansing phase
- The flexible shape supports application at difficult to cove areas e.g. on toes and at the heel

Cutimed® Sorbion® Sana *

Absorption performance for moderate to highly exuding wounds, with excellent atraumatic care

- Maintains a moist wound environment and absorbs wound exudate
- Suitable for use on pain-sensitive patients like DFU patients suffering from neuropathic pain

*This is one delivery form out of a comprehensive range.

CYTOKINES, FREE RADICALS AND EXCESS OF PROTEASES DELAY WOUND HEALING AND DEMAND ADVANCED PRODUCT SOLUTIONS

Cutimed® HydroControl
Exudate management with soft autolytic debridement to stimulate the wound healing process

- Promotes wound healing by creating the optimal moisture balance
- Due to an osmotic effect, it stimulates the perfusion of fresh fluid into the wound bed. This improves the supply of nutrients, enzymes and growth factors.
- Particularly suitable for supporting granulation on stagnant wounds
- Thin, flexible, cuttable and self-adhesive for easy application

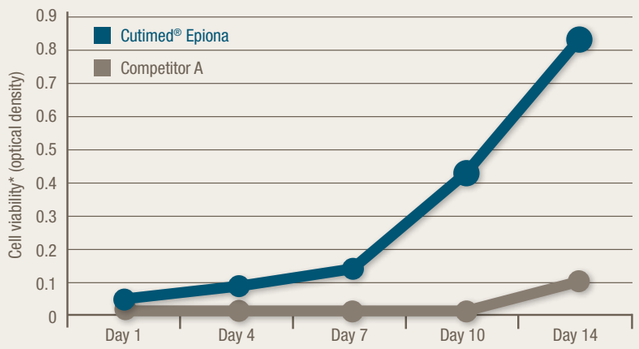
Cutimed® Epiona
3D native collagen structure for accelerated wound healing

Supports granulation and epithelialization by affecting multiple aspects in wound healing:

- Controls excessive MMPs[1]
- Protects growth factors[4]
- Provides a natural scaffold structure for cell growth [2,3] and fibroblast support

Cutimed® Epiona: Fibroblast cell multiplication

- Fibroblast cell growth was studied over 14 days of laboratory testing on samples of **Cutimed® Epiona** and Competitor A.
- **Cutimed® Epiona** showed faster, more pronounced cell growth than Competitor A.
- The increased viability of fibroblasts on **Cutimed® Epiona** can support the formation of granulation tissue.



*As measured by MTT Assay in optical density (Absorbance 570 nm to 630 nm). Assay done at BOKU Wien (Vienna). Data on file.

1 Ruszczak Z. Effect of collagen matrices on dermal wound healing. Adv Drug Deliv Rev. 2003.
2 Brett D. A Review of Collagen and Collagen-based Wound Dressings. Wounds. 2008.
3 Griffith LG. Emerging design principles in biomaterials and scaffolds for tissue engineering. Ann N Y Acad Sci. 2002.
4 Schultz GS, Ladwig G, Wysocki A. Extracellular matrix: review of its roles in acute and chronic wounds. World Wide Wounds. August 2005.

OFFLOADING

A fundamental principle of DFU management is to shield the foot from the pressure generated by weight bearing due to walking, sitting or lying. Effective offloading of the diabetic foot increases the healing rate by 90 %.[1]

DEVICES INCLUDE:

- Irremovable devices such as total contact casts (TCC) – the gold standard for plantar DFUs
- Removable devices such as:
  - Removable walkers
  - Cast boots
  - Healing sandals
  - Half shoes
  - Felted shoe inserts[2, 3]

Considering the lack of patient adherence, non-removable devices produce better results than removable ones. But any form of offloading is still preferable to none.[4]

Cutimed® Off-Loader/Cutimed® Off-Loader Select
Total Contact Cast System

- Highest reduction in impact, velocity and duration
  - Works to significantly reduce repetitive stress injury
  - Works to limit time under stress
- Highest reduction in shear forces
  - Protects fragile wound bed and wound edges from shear and friction damage
  - Reduces inflammation due to repetitive tissue damage
- Seals out contaminants and bacteria
  - Works to reduce opportunities for infection

1 Snyder RJ, et al. The Management of Diabetic Foot Ulcers through Optimal Off-loading. Building consensus guidelines and practical recommendations to improve outcomes. Journal of the American Podiatric Medical Association, Vol. 104, No. 6 Nov/Dec. 2014.
2 Cavanagh PR, Bus SA. Off-loading the diabetic foot for ulcer prevention and healing. J Vasc Surg 2010; 52:37–43.
3 Bus SA, van Deursen RW, Armstrong DG, et al. Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: a systematic review. Diabetes Metab Res Rev 2016; 32(suppl 1):99–118.
4 Lewis J, Lipp A. Pressure-relieving interventions for treating diabetic foot ulcers. Cochrane Database Syst Rev 2013; 1:CD002302.

PREVENT RECURRENCE EFFECTIVELY

Up to 60 % of patients with a healed diabetic foot ulcer suffer a relapse within three years.[1] But the reoccurrence of diabetic foot ulcers is not inevitable. With full patient involvement, new ulcers can be avoided or recognised and treated early on.

DIABETIC FOOTWEAR

Both pressure relief and maintaining mobility (and thus blood supply) are critical to healing and preventing diabetic foot ulcers. Healing sandals, orthopaedic walkers and shear-reducing insoles offer both comfort and protection during the day and can be removed for personal hygiene and rest at night.

DIABETIC SOCKS

Diabetic socks offer both comfort and protection. With extra padding for protection and acrylic multi-fibre yarns for improved moisture management, they are especially designed for the needs of diabetic feet.

JOBST® SensiFoot
Diabetic Sock

- Flat, soft, low-profile toe seam reduces pressure and irritation on the toes
- Antibacterial, antifungal finish inhibits growth of bacteria and fungi on the sock to help prevent odor

1 Dubsky M, Jirkovska A, Bem R, et al. Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup. Int Wound J 2012; 10:555–61.

MEDICAL SKIN CARE

Medical skincare products with a skin-friendly pH value but without colourants or fragrances can provide optimal care. Newly healed and dry skin needs to be stabilised by providing sufficient amounts of moisture and lipids to moisturise the barrier function of the skin.

Cutimed® ACUTE
Skin Care

- With 5 % or 10 % urea for very high moisture needs
- Provides regeneration and care to stressed and dry skin
- Helps prevent recurrence

Cutimed®,
an Essity brand

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