schülke

Wound compendium

Octenidine. More than antisepsis. For successful wound treatment.

we protect lives worldwide

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Octenidine:
The success story of an active substance

During the search for a new antiseptic active substance, we synthesised octenidine for the first time from our own research over 30 years ago. After comprehensive clinical studies, octenisept®, the first mucosal antiseptic with octenidine, was approved in 1990. Only a few years later (1995) the marketing authorisation was extended to include antiseptic wound care.

Since then, octenisept® has become well established as a reliable medicinal product with broad efficacy and a high safety profile in a wide variety of interdisciplinary areas of application: today you will find octenisept® not only in professional wound management, but also in gynaecology, in intensive care units, in operating rooms, in pharmacies, and thus also in many households to treat minor injuries.

A brief look back: With the approval of octenisept® as wound and mucous membrane antiseptic in 1995, an innovative alternative to the PVP-iodine based products was available. Apart from the good efficacy and tolerability, octenisept® quickly impressed users by its special, unique characteristic of colourlessness which makes it possible to easily detect any change in the wound situation. Initially still unfamiliar and new, octenisept® offered extensive benefits not only to users but also to patients. More than 3 decades later, octenisept® has become a standard part of modern wound treatment and is well established as a market leader in the area of wound and mucosal antisepsis.[1]

The requirements with regard to the local treatment of acute and chronic wounds are sometimes extremely diverse. In collaboration with our national and international experts from various specialist disciplines, we have continuously developed the entire octenidine family around octenisept® further in recent years. This allows us today to offer optimised products for each phase of wound healing and the respective wound situation in terms of a holistic strategy.

Our key objective is to provide optimal support in daily life to patients with a wide variety of wounds and to medical staff in the form of innovative therapy solutions. Along with the good tolerability and easy handling, we also simultaneously apply high standards to the proof of clinical effectiveness of our octenidine-based products in modern wound care – with a practical orientation and according to the current state of scientific evidence. To increase the quality of life of affected patients.

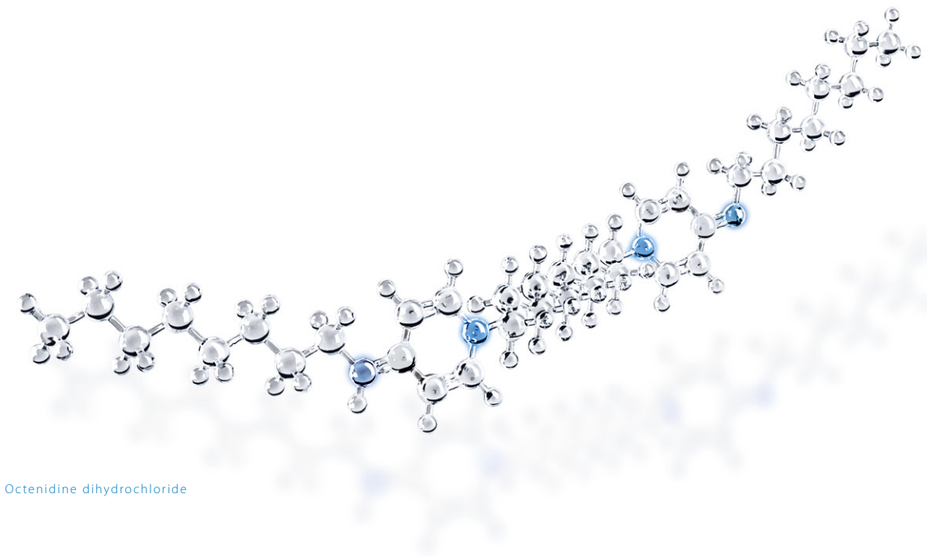


Fig.: Octenidine dihydrochloride

01 Modern wound management: Patient-centered care

"Time heals all wounds" – said the philosopher Voltaire, one of the most influential writers of the Enlightenment in the 18th century. In reality, this unfortunately does not always apply.

Various conditions can cause chronic wounds to develop from allegedly small injuries. The issue here is competent treatment which addresses the causes of wound healing disorders and ensures personalised measures to improve the wound situation.

Professional wound treatment begins by acquiring an overall picture of the patient: broad knowledge of the individual state of health, the general skin integrity, as well as the nature and condition of the wound are essential in order to have a positive effect on the success of the treatment and to avoid complications or protracted healing processes for patients whenever possible.

An **important objective in modern wound treatment** is to support the body's self-healing powers as best possible. A thorough understanding of the physiology of wound healing is important for this in order to be able to apply individual therapeutic strategies according to the latest scientific knowledge. The benefit of interdisciplinary collaboration between various disciplines is increasingly recognised here.

! Careful documentation of the medical history which focuses on the patient and includes his/her life circumstances is critical for the nature and scope of the further therapeutic measures. Because only then can the wound be optimally treated.

02 The wound: Definition and classification

A wound is defined as a damage, destruction or break of the skin or mucous membrane and the underlying tissue.

According to its root cause, depth and extent, but also the time until complete closure, a differentiation is made between a variety of types of wounds which may fundamentally differ from one another with regard to treatment and healing process. A common and useful classification is between acute and chronic wounds.

Acute wounds: They are based on external injuries, such as the effect of mechanical force, heat, cold, chemical substances, or radioactive radiation and generally heal within a short time without major complications. Since the injury causes the natural protective function of the skin to be lost, infections can easily occur.

DIFFERENCES AND CHARACTERISTICS OF ACUTE WOUNDS

TRAUMATIC (OR ALSO MECHANICAL) WOUNDS

Traumatic wounds generally occur mechanically due to external influences of sharp or blunt force and impact on the tissue (compressive, tensile or shear forces). They include wounds due to accidents (abrasions, cuts, punctures, bites, contusions, lacerations and gunshot wounds) as well as planned surgical wounds and amputations.

THERMAL WOUNDS

Thermal wounds are caused by the effects of heat or cold on tissue (burns, scalding, frostbite, electrical burns).

CHEMICAL WOUNDS

Chemical wounds occur due to chemical burns of the skin or mucosa due to acids or bases.

RADIATION-INDUCED WOUNDS

Radiation-induced wounds can be caused by radioactive isotopes or ionising radiation, as it is used in radiography or radiotherapy. Sunburn caused by ultraviolet radiation also falls within this category.

The quality of the first aid for acute wounds is crucial for the functional and aesthetic result. The wound healing process should be supported in the best possible way in its physiological process.

Chronic wounds: The definitions are diverse, however there are a few similarities. Wounds are described as chronic when they do not heal within several weeks. Chronic wounds can also arise from acute wounds, for example, through an undetected persistent infection or inadequate first aid. However, chronic wounds generally represent the last stage of progressive tissue destruction, triggered by existing underlying diseases (venous, arterial or metabolic vascular problems), compression damage, or tumours.

VARIOUS DEFINITIONS OF A CHRONIC WOUND

"A wound which has not healed after eight weeks is referred to as chronic. There are wounds which should be considered chronic from the very start, since their treatment requires therapy of the ongoing cause. These include, for example, diabetic foot ulcers, wounds in the case of PAOD, venous leg ulcers or decubitus ulcers."

Dissemond et al., Initiative Chronische Wunde 2020

"A chronic wound is defined as a break in the skin of long duration (> 6 weeks) or frequent recurrence."

Fonder et al., Journal of the American Academy of Dermatology 2008

"Chronic wounds are commonly defined as wounds that have not proceeded through an orderly and timely reparation to produce anatomic and functional integrity after 3 months."

Dubhashi and Sindwani, Indian Journal of Surgery 2015

"Chronic wounds: a wound that lacks a 20–40% reduction in size after 2–4 weeks of optimal treatment or when there is not complete healing after 6 weeks."

Leaper and Durani, International Wound Journal 2008

"Chronic wound: ongoing inflammation and proliferation after 6 weeks."

Teot, European Wound Institute 2006

"A chronic wound is a wound that does not heal in a timely fashion and has not responded to conventional therapy."

Eaglstein and Falanga, Surgical Clinics of North America 1997

"Chronic wounds are, by definition, wounds, that have failed to progress through the normal stages of wound healing and therefore enter a state of pathologic inflammation. As a result, the healing process is delayed, incomplete, and does not proceed in a coordinated manner, subsequently resulting in poor anatomical and functional outcome."

Menke et al., Clinics in Dermatology 2007

"Chronic wounds are defined as wounds expected to take time to heal because of 1 or more factors delaying healing. Depending on the cause of the wound, wounds taking more than 4 to 6 weeks to heal are considered to be chronic."

Vaneau *et al.*, Archives of Dermatology 2007

"A chronic wound is defined as a loss of integrity of the skin and one or more underlying structures with a lack of healing within 8 weeks."

Deutsche Gesellschaft für Wundheilung und Wundbehandlung e.V. Lokaltherapie chronischer Wunden bei Patienten mit den Risiken periphere arterielle Verschlusskrankheit, Diabetes mellitus, chronische venöse Insuffizienz | Last updated: 12/06/2012 Version 1

"Common features shared by chronic wounds include prolonged or excessive inflammation, persistent infections, formation of drug-resistant microbial biofilms, and the inability of dermal and/or epidermal cells to respond to reparative stimuli."

Frykberg and Banks, Advances in Wound Care 2015

"A chronic wound is one that fails to progress through a normal, orderly, and timely sequence of repair, or in which the repair process fails to restore anatomic and functional integrity."

Bowers and Franco, American Family Physician 2020

The normal healing process is impaired in chronic wounds: It lasts longer than expected and may be hampered by additional complications (e.g. infections).

THE MOST COMMON TYPES OF CHRONIC WOUNDS

ULCUS CRURIS

The leg ulcer or *ulcus cruris* often occurs on the lower leg in the vicinity of the ankle, usually on the inside. It primarily affects older people who have multiple underlying diseases. Other possible causes for a *leg ulcer* are allergic reactions (vasculitis), various skin tumours, or inflammation.

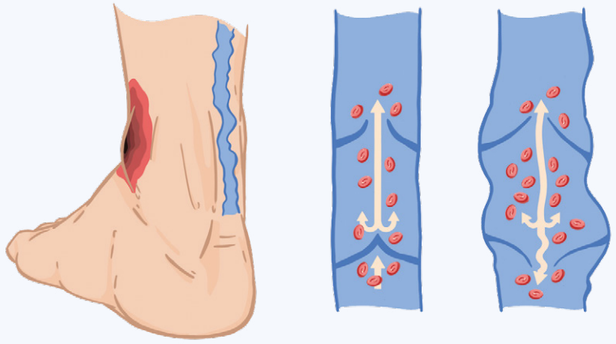


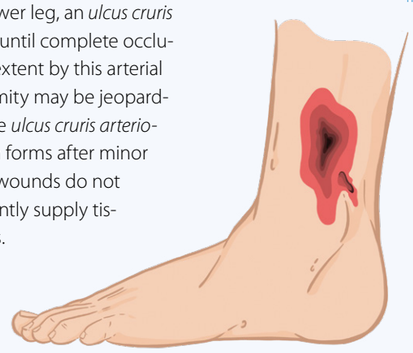
Fig.: *Ulcus cruris venosum.* Intact venous valve (undisturbed blood flow) and chronic venous insufficiency (CVI).

ULCUS CRURIS VENOSUM

The *ulcus cruris venosum* is the most common occurrence, accounting for about 60 – 90% of cases. This ulcer is caused by chronic venous insufficiency (CVI). Here the efferent vessels (i.e. veins) are damaged to the degree that they can no longer transport the blood back to the heart. The accumulation of the blood disturbs the proper metabolism and nutrition of the tissue. Thus, the tissue is damaged. The ulcer then forms in the damaged tissue.

ULCUS CRURIS ARTERIOSUM

If, as a result of atherosclerosis, calcifications are deposited in the afferent vessels (i.e. arteries) of the lower leg, an *ulcus cruris arteriosum* can form. The arteries narrow until complete occlusion. If the tissue is affected to a greater extent by this arterial occlusive disease (AOD), the entire extremity may be jeopardised. Occurring in about 10% of cases, the *ulcus cruris arteriosum* is rather rare. This type of ulcer often forms after minor injury. Even if otherwise harmless, these wounds do not heal, because the arteries cannot sufficiently supply tissue in order to begin the healing process.



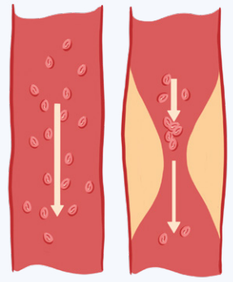


Fig.: *Ulcus cruris arteriosum.* Intact artery and arteriosclerosis (AOD).

ULCUS CRURIS MIXTUM

The *Ulcus cruris mixtum* is a hybrid form of *ulcus cruris venosum* and *ulcus cruris arteriosum.* This type of ulcer is caused by a combination of the above two types of wounds.

DIABETIC ULCER

The diabetic ulcer, also known as diabetic foot syndrome (DFS), comprises various pathological tissue changes in the foot area. These are due to the underlying disease, *diabetes mellitus*. Apart from the ulcer, feet and nail beds are often deformed or damaged. In diabetic ulceration, the conductivity of sensory, motor and autonomic nerves is usually disturbed due to the underlying disease. In addition, vascular function is often limited as well.

In the case of diabetic foot syndrome, the patient's underlying disease must be primarily treated. However, local treatment of the wound is also important to ensure that the condition of the wound does not deteriorate, which might even lead to amputation.

Many patients with *diabetes mellitus* suffer from diabetic ulceration. This is often due to unsuitable footwear, which damages the tissue by pressure. However, lacking or improper foot care can also be a cause of ulceration.

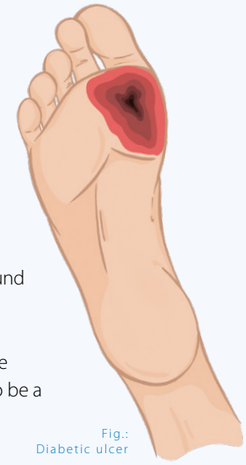
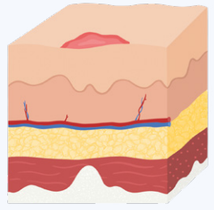


Fig.: Diabetic ulcer

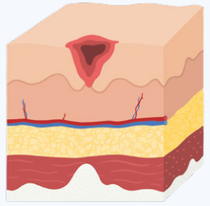
DECUBITUS ULCER

Pressure ulcers (decubitus ulcers) are hard-to-heal or slowly healing wounds. A pressure ulcer can be formed if high pressure is applied to layers of tissue and blood vessels from the outside. Friction and shear forces increase the risk. As a result, the skin and tissue are no longer sufficiently perfused, and a pressure ulcer can develop. Various underlying diseases (e.g. *diabetes mellitus*) encourage the formation of pressure ulcers. The risk is highest for patients who are immobile, e.g. bedridden.

The European Pressure Ulcer Advisory Panel (EPUAP) and the American National Pressure Ulcer Advisory Panel (NPUAP) have published a common international definition and classification of pressure ulcers.[2]



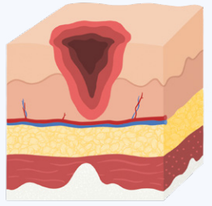
Category 1: Nonblanchable erythema



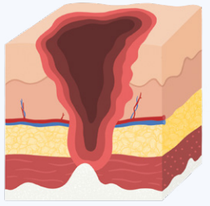
Category 2: Partial thickness skin loss

Special cases:

- Unstageable: Depth unknown
- Suspected deep tissue injury: Depth unknown



Category 3: Full thickness skin loss



Category 4: Full thickness tissue loss

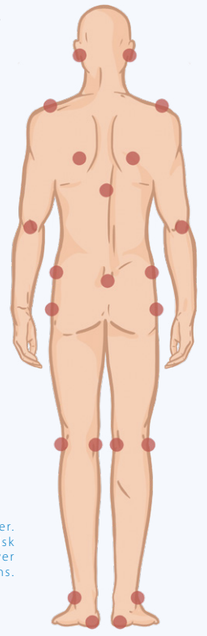


Fig.: Decubitus ulcer. Zones at risk are generally over bony protrusions.

03 The miracle of wound healing: Definitions and processes

Wound healing refers to the body's own process for wound closure through restoration of the damaged tissue.

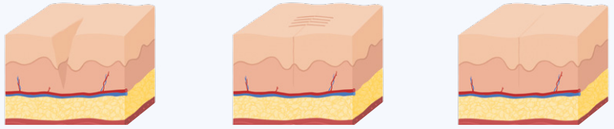
The natural wound healing process generally proceeds automatically, however it can be optimised or therapeutically supported by careful wound treatment.

A differentiation is made clinically between primary wound healing (*sanatio per primam intentionem)* and secondary wound healing (*sanatio per secundam intentionem*).

CLASSIFICATION OF WOUND HEALING

PRIMARY WOUND HEALING

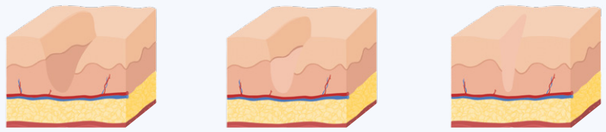
A precondition for primary wound healing are smooth, close-fitting wound edges, a minimal tissue defect, a well perfused wound area, and the absence of foreign bodies and infections. By drawing the edges of the wound together closely, the healing process can proceed quickly (generally within a week) and often only a minimal scar remains. Therefore wounds, particularly following surgical procedures, in the case of trauma by sharp objects (such as cuts) but also large, superficial defects (such as abrasions) undergo primary healing, through regeneration of the epidermis.



Smooth cut wound | Wound closure using suture | Hair-thin scar

SECONDARY WOUND HEALING

In secondary wound healing, no primary closure is possible. The edges of the wound gape widely and the risk of infection is greatly increased due to massive tissue defects in some instances or an infection is already present. Increased granulation tissue must be built up to close the wound, and larger scars frequently remain. Secondary wound healing is often found in the case of acute wounds with major tissue loss (such as dog bites), in chronic wounds or even major burns. It could take months until a wound undergoes secondary healing.



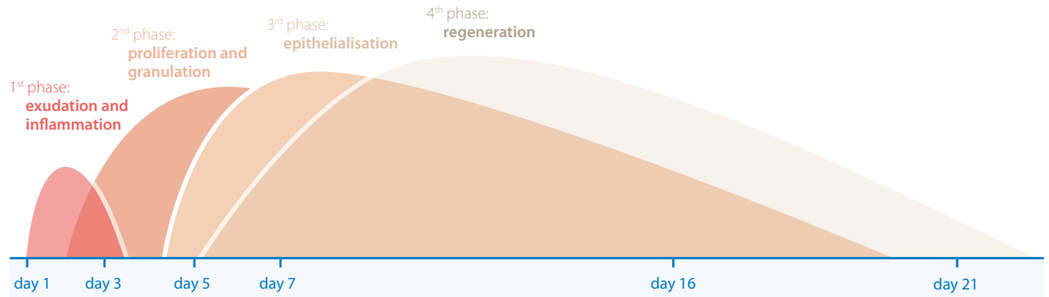
Gaping laceration | Build-up of granulation tissue | Wound closure and scar formation

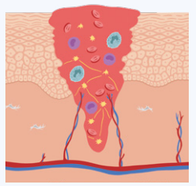
EPITHELIAL WOUND HEALING

Epithelial wound healing occupies a special position. It occurs in the case of superficial wounds, such as sunburns or abrasions and it is completed after a few days. Only the uppermost layer of skin is affected by the injury, healing takes place with restoration of the destroyed tissue and is typically scar-free. In the case of epithelial wound healing, there is neither formation of granulation tissue nor a contraction of the wound.

PHASES OF WOUND HEALING

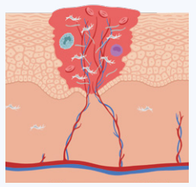
Independent of the type of wound and the extent of the tissue loss, every wound heals in four phases which chronologically merge with one another, partially overlap, and thus cannot be strictly separated from one other.





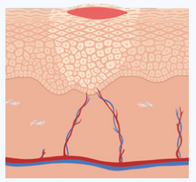
1st phase: **exudation and inflammation**

The exudation and inflammation phase starts at the moment of the injury and lasts about 3 days under physiological conditions. Cellular debris, germs and metabolic waste products are mechanically flushed out and the clotting system is activated (fibrin fibres surround erythrocytes and platelets) to stop the bleeding. Leukocytes (especially neutrophilic granulocytes and macrophages) migrate into the wound area and absorb and degrade pathogens and small dirt particles by phagocytosis, secrete various proinflammatory cytokines and growth factors, and release proteases.



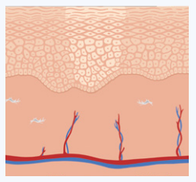
2nd phase: **proliferation and granulation**

In the proliferation phase, connective tissue rich in cells and vessels is formed to fill the defect, known as granulation tissue. In normal wound healing, about 4 days after the injury, small blood vessels grow and supply the granulation tissue. Fibroblasts form collagen as connective tissue cells. In the granulation phase, the wound is usually well-perfused, light red, glassy to transparent and moist. The newly formed tissue fills the wound. This forms the necessary basis for subsequent epithelialisation.



3rd phase: **epithelialisation**

From approximately day 6 to day 10, the epithelialisation begins. In this phase, the wound contracts. The collagen fibres mature, the granulation tissue becomes increasingly drier and contains fewer vessels, and transforms into scar tissue. The increasing epithelialisation then enables wound closure. The characteristic of this phase is a delicate, pale pink skin. The exudation decreases in this wound stage.



4th phase: **regeneration**

After completion of the epithelialisation, remodelling processes take place with the goal of strengthening the newly formed tissue and largely restoring the original tissue formation. However, the result does not represent a complete skin replacement, rather a thin, poorly vascularised replacement tissue, which is lacking important epidermal components (such as sebum and sweat glands, pigment cells) and important properties of the skin (such as neurotisation).

FACTORS AFFECTING WOUND HEALING

Wound healing is much more than just a "simple" closure of the defect. It is a complex process on the cellular and molecular level that is possible only if the body meticulously coordinates all components with each other.

Not all wounds heal quickly and according to plan. Impaired wound healing refers to a delayed or atypical wound healing course. A variety of local and systemic factors can affect the individual physiological healing process. How fast and how well a wound heals is influenced not only by the site, depth and area of the wound but also depends on the patient's **general physical condition**. This includes, for example, age, nutritional status, immune status, (chronic) underlying diseases (such as *diabetes mellitus*, circulatory problems, anaemia, tumours), postoperative complications, acute trauma or medication.

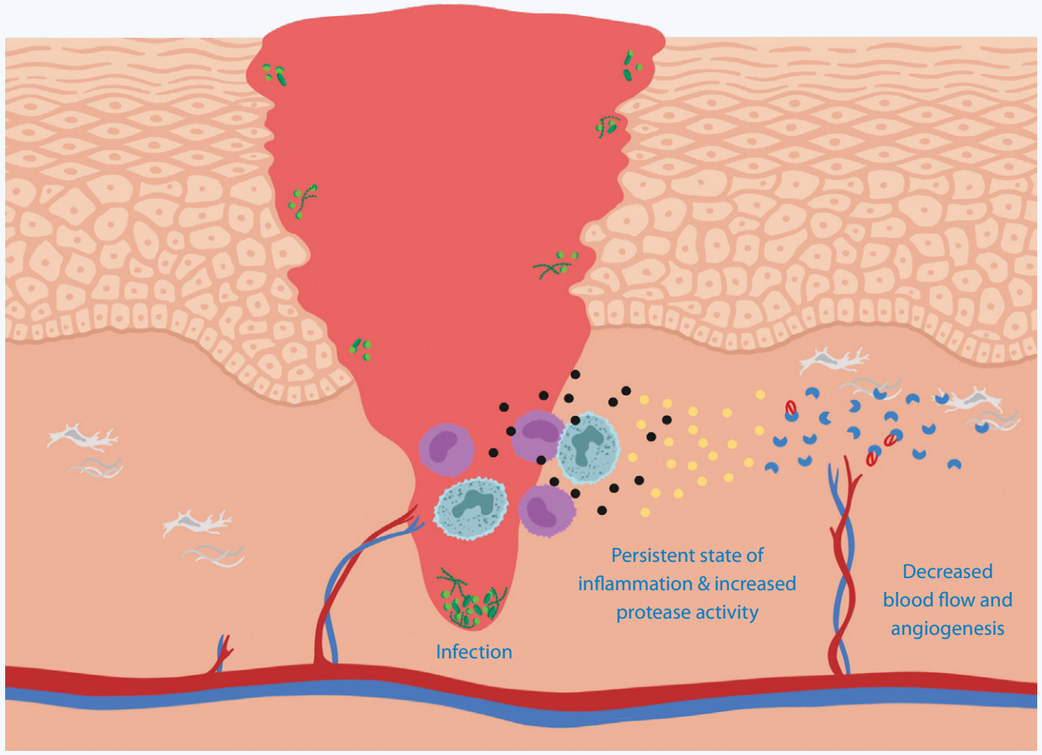


Fig.: Factors which impair epithelialisation and delay wound closure.

Wound infection is considered to be the most common and serious problem in the healing process. It is caused by a wide variety of microorganisms (generally bacteria and fungi, more rarely viruses) which penetrate the wound, multiply there unhindered and create harmful toxins, subsequently damage surrounding tissue, and contribute to the formation of necrosis. Through the activation of local defence mechanisms, there is a chronological prolongation of the inflammatory phase and thus a delay in the wound healing process. The longer a wound exists, the higher the risk that the infection will spread systemically and in the worst case lead to life-threatening sepsis.

Numerous scientific studies from recent years have also shown that various cell types and different regulatory mediators, such as growth factors, cytokines and chemokines but also components of the extracellular matrix are involved in the multistage process of wound healing. Fundamental differences in the local microenvironment of acute and chronic wounds were able to be determined and promising biomarkers for assessing the wound healing were able to be identified on a molecular level.

Matrix metalloproteases (MMPs), as proteolytic enzymes, play a key role in each individual phase of the wound healing process. They control processes, such as removing damaged fragments of the extracellular matrix (ECM), cleaning the wound from microorganisms, and coordinating complex cell-cell interactions for the formation of granulation tissue, as well as cell-matrix interactions which lead to the initiation of epithelialisation and finally to wound closure. In the normal course of wound healing, the MMP level quickly increases in the first few days and decreases within a week back to a very low level. The MMP activity is primarily regulated via tissue inhibitors of metalloproteases (TIMPs). In many chronic wounds or acute wounds which show delayed wound healing, a significant imbalance between MMPs and TIMPs has been described. MMPs reach not only a higher level but also persist for longer periods of time. The result is an unfavourable wound healing environment. An excess of MMPs leads to the breakdown of the ECM, damage to the newly formed tissue, and has a negative impact on the wound bed. As a consequence, the healing process is impaired.

In addition, due to the ongoing tissue damage, the migration of inflammatory cells, such as **neutrophil granulocytes and macrophages**, into the wound area persists. These in turn continuously secrete **proinflammatory cytokines**, which synergistically promote, among other things, the production of MMPs, while the synthesis of TIMPs is reduced. In addition, **growth factors**, including their receptors, are degraded at the target cells such that the wound healing process cannot proceed normally, because mediators for the corresponding stimulation are missing. As a result, the inflammatory reaction is maintained.

If the physiological process is chronologically disrupted and the body is consequently no longer able to complete the healing process alone, this gives rise to a **chronic wound** which is often characterised by a prolonged inflammatory phase. In addition to patient-specific and local causal factors (such as underlying illnesses, compression damage, infections), elevated concentrations of certain cytokines and chemokines as well as proteases have already been identified as relevant disruptive factors in chronic wounds.

In addition, **keloids or hypertrophic scars** can often be attributed to a lack of or excessive effects of regulatory mediators. It is known from the literature that a shorter inflammatory phase has a positive influence on the resulting scar tissue.

The physiological wound healing cascade can only function if the vicious circle of the excessive inflammatory reaction with the elevated protease activity is broken. Knowledge of the condition of the wound environment as well as of the options for influencing it in a specific way are crucial for successful wound management.

04 Octenidine: Between tradition and innovation

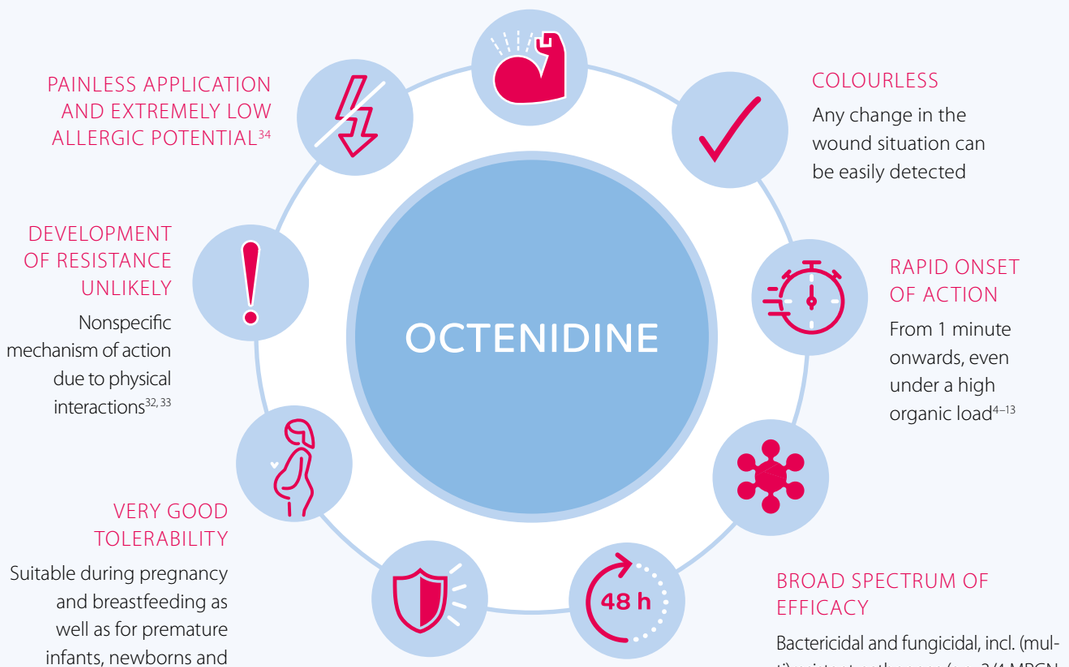
Octenidine has been already successfully used as an antimicrobial agent for more than 3 decades and is indispensable in a wide variety of areas of application.

Because of the presently increasing problem of persistent (multi)resistant pathogens and the associated limited therapeutic options, octenidine is more relevant now than ever because of its broad spectrum of antimicrobial activity and high safety profile even more than 30 years after its first clinical use.

THE ADVANTAGES OF THE ACTIVE SUBSTANCE OCTENIDINE

STABILITY AND ANTIMICROBIAL ACTIVITY WITHIN A BROAD pH RANGE (pH 1.6–12.2)[3]

Suitable for all wounds with different pH values during the healing phase



PAINLESS APPLICATION AND EXTREMELY LOW ALLERGIC POTENTIAL[34]

COLOURLESS

Any change in the wound situation can be easily detected

DEVELOPMENT OF RESISTANCE UNLIKELY

Nonspecific mechanism of action due to physical interactions[32, 33]

RAPID ONSET OF ACTION

From 1 minute onwards, even under a high organic load[4–13]

VERY GOOD TOLERABILITY

Suitable during pregnancy and breastfeeding as well as for premature infants, newborns and children*[29–31]

EFFECTIVE AGAINST (POLY)MICROBIAL BIOFILMS[16–28]

LONG TERM RESIDUAL EFFECT

48-hour remanence[15]

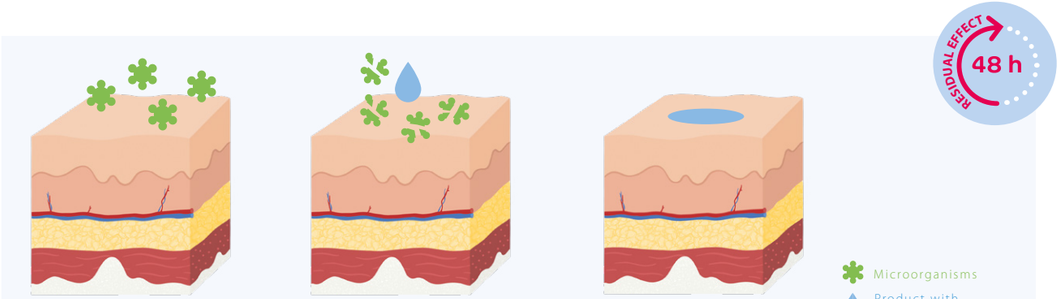
BROAD SPECTRUM OF EFFICACY

Bactericidal and fungicidal, incl. (multi)resistant pathogens (e.g. 3/4 MRGN, mupirocin-resistant MRSA, *Candida spp.*); virucidal against enveloped viruses (e.g. corona viruses, HBV, HIV, HCV)[4–14, 48]

*Follow the instructions for use of the preparations

UP TO 48-HOUR REMANENCE

The long-term residual effect (remanence) describes the antimicrobial effect of an active substance which still remains detectable after application and continues to inhibit pathogen growth, to effectively avoid infections. Especially in wound care, a residual effect which is as long as possible is a major advantage. Not only are the microbes already in the wound killed, but newly penetrating microorganisms (from the outside), including those from skin flora, are also killed. Octenidine is not absorbed but instead remains on the cells of the surface of the body[35, 36] where it can demonstrably be effective against a broad spectrum of microbes for at least 48 hours.[15] It should be ensured in practice that products containing octenidine are not rinsed off after use, since the long-term residual effect will otherwise be lost.



Octenidine is used not only for the treatment of infected wounds, but it also protects the clean wound from possible contamination and thus minimises the risk of a subsequent infection.

HIGH BIOCOMPATIBILITY INDEX

To be able to compare various antiseptics with each other, Müller and Kramer established the "biocompatibility index" (BI) in 2008 as a ratio between microbicidal effect and cytotoxicity.[37] A BI greater than 1 represents an antiseptic substance with an effective microbicidal activity combined with a relatively low cytotoxicity, whereas a BI less than 1 indicates an antimicrobial agent with a relatively high cytotoxicity in a defined medium.

For antiseptics with a BI < 1 incompatiblity is higher than efficacy. Therefore, their use is no longer recommended. Compared to other antiseptic actives octenidine's BI value is highest and thus most favourable.

Despite its rapid and high level of antimicrobial efficacy, octenidine is proven in clinical use to have no cytotoxic effects on human tissue and is even recommended as the active substance of choice in neonatology.[38]

COST EFFECTIVENESS

In the treatment of chronic wounds, a case control study demonstrated the superiority of octenilin® wound gel in direct comparison to other modern wound dressings (e.g. foam or alginate dressing, in each case with and without silver). Here the duration of treatment could not only be significantly shortened but the octenidine-containing hydrogel was also the most cost-effective treatment method for venous leg ulcers.[39]

Not least because of the increasingly ageing population and the rapidly growing number of patients with chronic wounds, economic analyses on the optimisation of wound care play an important role.

IMPROVED SCAR QUALITY

Results from animal experiments and clinical observations have shown that octenidine, apart from its significant antimicrobial effect, also has a positive effect on wound healing.[39–43] Hypertrophic scars and keloids in particular represent not only a cosmetic problem for patients but also may mean functional limitations and pain. Therefore it is expedient to avoid this undesirable scar tissue as much as possible and to ensure an appropriate choice of therapy as early as during wound care. The clinical use of various hydrogels, known as moist wound treatment, is considered to be state-of-the-art today for favouring epithelialisation and thus wound healing.
In a clinical study, it was demonstrated in an intra-individual study design that patients post abdominoplasty significantly benefitted from octenilin® wound gel when it was applied immediately postoperatively: In addition to significantly reduced personal sensations of pain during dressing changes, the treatment with the octenidine-containing hydrogel resulted in significantly fewer wound healing disorders, a decreased frequency of hypertrophic scars and keloids, less transepidermal water loss, as well as greater skin elasticity in comparison to conventional wound care.[44]

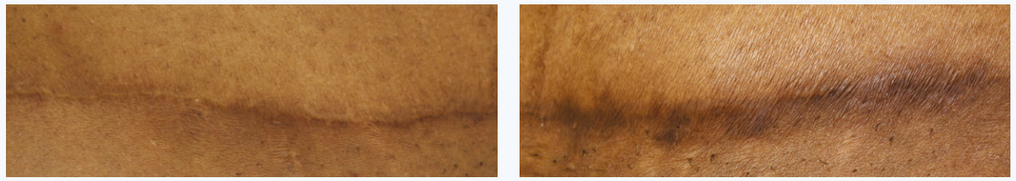


Fig.: Scars of a 47-year-old female patient twelve months after abdominoplasty. Wound care was performed immediately postoperatively using octenilin® wound gel in combination with a transparent film dressing (image on the left) and using Omnistrip® with significant hypertrophy of the scar (image on the right).

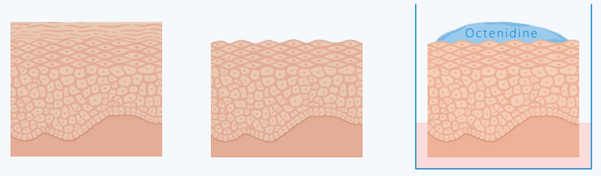
Wound care started immediately postoperatively with octenilin® wound gel and a film dressing creates a moist wound environment, guards the wound against infections, promotes the natural healing process, and optimises the functional and aesthetic outcome of the scar formation.

ANTI-INFLAMMATORY AND PROTEASE-INHIBITING PROPERTIES

Numerous recent investigations on the molecular level indicate that the wound healing outcome is closely linked among other things with various types of cells and inflammatory mediators (e.g. cytokines, chemokines, components of the extracellular matrix) as well as the activity of proteolytic enzymes (e.g. matrix metalloproteases). A shorter inflammatory phase appears to have a positive effect on the duration of the healing process and on the resultant scar tissue.

This very effect was recently investigated for octenidine in standardised wounds on human skin explants: here, a hydrogel containing octenidine demonstrated significantly anti-inflammatory and protease-inhibiting properties during the healing phase, characterised by an inhibition of the interleukins (IL)-6, IL-8, IL-10 and IL-33 as well as the matrix metalloproteases (MMP)1, MMP2, MMP3 and MMP9. At the same time, the activation and migration of Langerhans' cells into adjacent lymph nodes was suppressed. The results cannot be attributed per se to the moist wound treatment: in direct comparison to the identical hydrogel without octenidine, only the combination with octenidine demonstrated additional immunomodulatory properties. Moreover, octenilin® wound gel maintained the morphology of the skin and had no toxic effect on human skin cells.[45,46]

Fig. Method



Human skin explants (8 mm biopsies)

Superficial wounding through removal of the *stratum corneum*

Application of octenidine* and subsequent incubation in cell culture medium for 48 hours

* octenidine-containing hydrogel

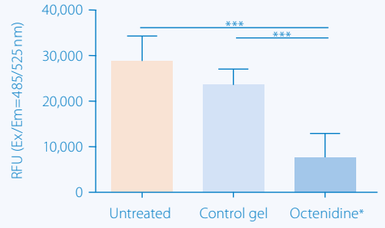


Fig.: Enzymatic activity of MMPs measured in culture supernatants of wounded skin explants treated with octenidine* in comparison to the controls (untreated and control gel), indicated as relative fluorescence unit (RFU). *** $p \leq 0.001$

CYTOKINE MODULATION

Reduction in the concentration of IL-6, IL-8, IL-33, IL-10

MATRIX METALLOPROTEASES

Reduction in the concentration of MMP1, MMP2, MMP3, MMP9 and MMP activity

OCTENIDINE

LANGERHANS' CELLS

Preservation of the cell morphology, no maturation and migration to adjacent lymph nodes

CELLS OF THE EPIDERMIS AND DERMIS

Intact morphology and architecture of the cell layers, no induction of apoptosis

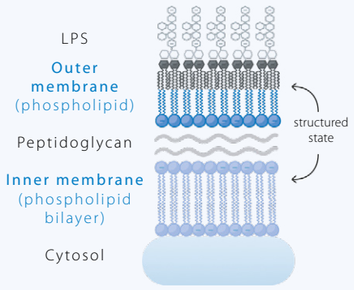
The use of an octenidine-containing hydrogel controls the inflammatory reaction in the wound and triggers a series of immunomodulatory events which may carry the healing process from the inflammatory to the proliferative phase.

NONSPECIFIC MECHANISM OF ACTION

Despite its long and successful history, basic discoveries through complex biophysical investigations on the detailed mechanism of action of octenidine in Gram-negative and Gram-positive bacteria on the cellular and molecular level were published only recently.[32, 33]

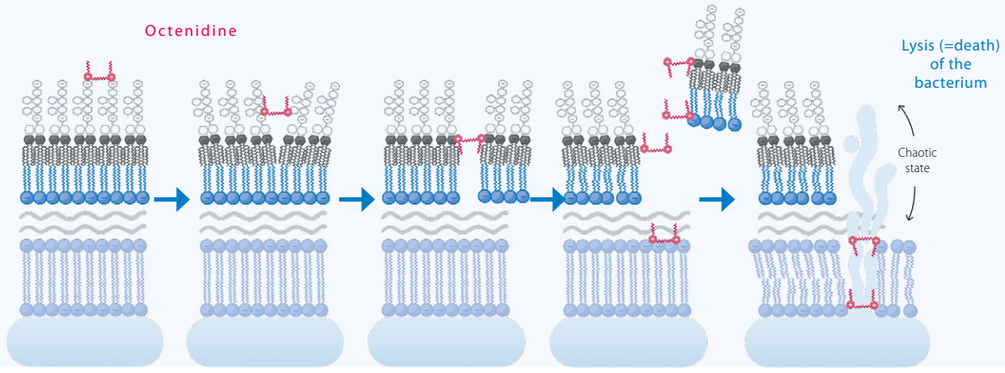
Because of electrostatic interactions, the molecule immediately attaches to the outer membrane of the bacteria. Due to hydrophobic interactions hydrocarbon chains from octenidine probably rush between the bacteria lipids and break up the structure of the outer membrane. Consequently, additional octenidine molecules can penetrate the inner membrane from the outside and create a chaotic state in an analog manner. Within a very short time, the bacteria gets lysed. Even though the membrane structure of gram positive bacteria differs the effect of octenidine is identical. The molecule permeates the cell wall and destabilises the cytoplastic membrane due to physical interactions.

Fig.: Membrane structure of Gram-negative bacteria.



The mechanism of action of octenidine explained in 2 minutes.

Fig.: Mechanism of action of octenidine in Gram-negative bacteria.



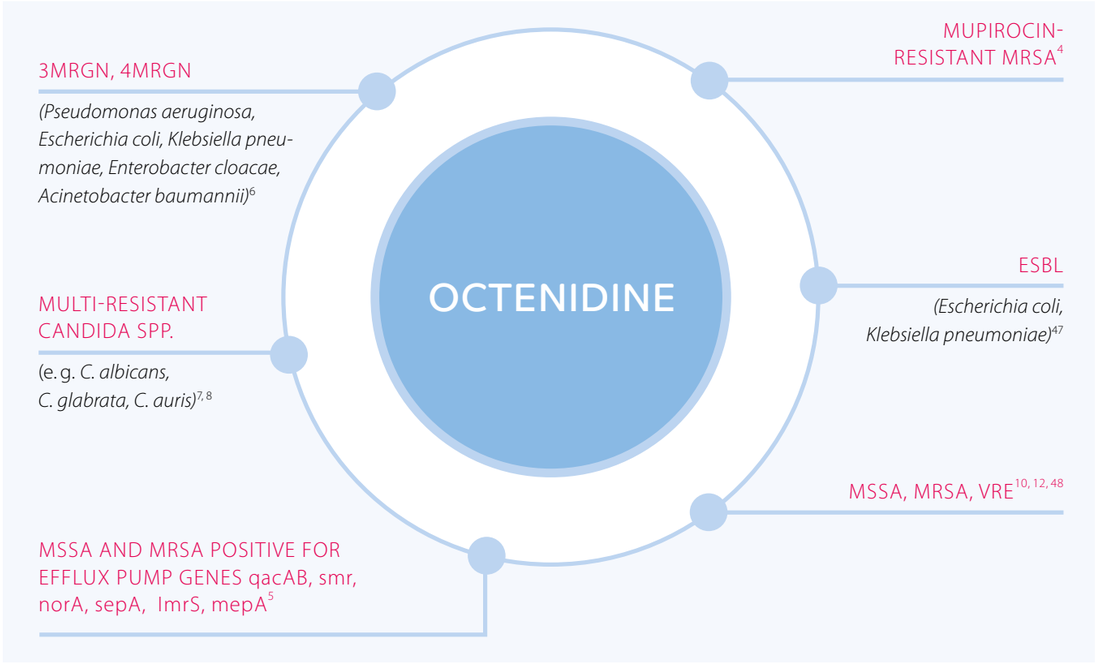
Octenidine acts quickly and effectively. Because of the unspecific mechanism of action – based on purely physical interactions – the development of resistance is highly unlikely!

RAPID AND STRONG EFFICACY AGAINST PROBLEMATIC MICROBES

Because of the increasing global problem of (multi)-resistant pathogens and the associated limited therapeutic options, antiseptics such as octenidine with alternative mode of action play an important role in local wound care.

In principle, every open wound harbours the risk of an infection. While *Staphylococcus aureus* is considered to be one of the most important cause of postoperative wound infections, there is a greatly differentiated spectrum of pathogens in acute and chronic wounds. Along with bacteria, potentially dangerous infections can also originate from fungi. In recent years, there have been increasing numbers of publications on various yeast fungi, moulds, and dermatophytes which were isolated from poorly healing wounds. However, because of the traditional focus on bacterial species as well as the more complicated diagnostic laboratory measures, fungal infections often remain undetected. Their role as a causal pathogen of serious infections is thus highly underestimated. Particularly in the case of severely burned patients, the incidence of wound infections with various *Candida* species has greatly increased in recent decades. Its prevalence has been reported with worldwide values of up to 40%, thus leading to new challenges in diagnostic and therapeutic approaches.

The broad and comparatively rapid efficacy of octenidine against bacteria and fungi, including (multi)resistant clinical isolates, has been extensively proven in numerous investigations. Octenidine is even highly effective in the presence of interfering substances like blood, protein, mucin, human wound exudate.[4–13]



It is particularly important to always keep the wound healing process under control. Acute as well as chronic wounds always harbour the risk of an infection which prolongs the healing process. The consequences are a significantly reduced quality of life of the patient and increased amount of care.

HIGH LEVEL OF EFFICACY AGAINST (POLY)MICROBIAL BIOFILMS

Microorganisms in the wound do not always necessarily lead to an infection. Various species of bacteria and/or fungi can surround themselves even within a short time with a common, mucous matrix made of biopolymers and thus unite in a (poly)microbial biofilm.

The formation of a biofilm offers the involved micro-organisms numerous advantages: In the common layer, they are extremely resistant to therapeutic agents, can exchange (resistance) genes and enter relationships for mutual benefit. For the patients affected by a biofilm, by contrast, the development of a biofilm in the wound is less positive. Biofilms represent a major challenge for the body's own immune system, particularly in the case of existing underlying diseases. The physiological wound healing is consequently delayed and as a result, chronic wounds can manifest.

In practice, it is often difficult to identify and diagnose a biofilm: various study data suggest that biofilms themselves are found even in acute wounds but at a higher percentage particularly in chronic wounds. Microorganisms in biofilms can evade the efficacy of antimicrobial substances. In order to combat existing biofilms in a reliable and lasting way an appropriate approach and sound knowledge about the application of the products used and their mode of action is required.

This includes, first of all, careful wound cleaning in which antimicrobial active substances can also already be used, and debridement, in which debris, necrotic tissue, and a majority of the biofilm is removed efficiently and as painlessly as possible. To further optimally support the healing process, an active substance with a broad antimicrobial spectrum should ideally be used prior to placing a dressing which can kill microorganisms in remaining remnants and also in the mature biofilm.

Octenidine is able to penetrate (poly)microbial biofilms and efficiently eliminates the microbes concerned. This property has been proven in numerous *in vitro* models and also in clinical practice.[16–28]

05 Antisepsis with octenidine: For successful wound treatment

Every open wound harbours the risk of an infection. Therefore the right first aid as well as the further treatment are crucial for the success of the healing.

There isn't always time for comprehensive wound swabs to determine the microbiological status. On the other hand, however, infections occur repeatedly even though a previous wound swab was unremarkable. In addition, the prevention of wound infections is becoming more and more important, not least because of the increasing development of resistance of the pathogens involved.

In principle, every wound at risk of infection can be treated with octenidine in order to avoid wound infections. Octenidine-based products are colourless and therefore every change in the wound situation can be easily detected and documented.

For the important user information please see page 41

OPTIMAL TREATMENT FOR WOUND HEALING

With the comprehensive range from schülke for wound care, all wound situations can be treated easily and according to the indication and the natural healing process can be supported individually and specific to the phase.

octenisept®
Wound and mucous membrane antiseptic

YOUR ADVANTAGES

- broad antiseptic activity
- fast onset from 1 minute
- good dermal and mucosal tolerability
- suitable for infants & premature babies*
- can be used during pregnancy*
- colourless
- supports wound cleaning
- ready to use (not suitable for dilution)
- stable for 3 years after initial opening (however do not use beyond the expiration date)

APPLICATION

Wound treatment:

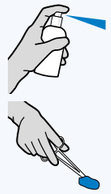
Antiseptic treatment of acute, chronic and surgical wounds and burns.

Mucosal antisepsis:

Prior to diagnostic and surgical interventions in the anal and urogenital areas (e.g. before placing IUDs, prior to pre-, intra- and post-partum manipulations or before obliteration of haemorrhoids) and in the oral area (e.g. before tooth extractions or curettage).

Before insertion of transurethral single-use and permanent catheters.

For preoperative antisepsis of the skin adjacent to mucosal areas (e.g. prior to caesarean section).



octenilin®
wound gel

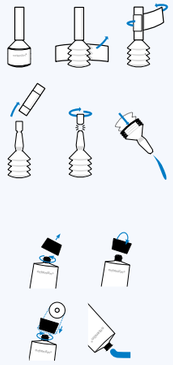
YOUR ADVANTAGES

- keeps the wound moist and promotes the natural healing process
- prevents bacterial growth in the gel and wound dressing
- painless, colourless and odour-absorbent
- suitable for long-term and large-scale use
- sterile
- stable for 6 weeks after initial opening (20 ml bellows bottle)
- stable for 8 weeks after initial opening (250 ml tube)

APPLICATION

For moisturising and cleansing of acute and chronic wounds (e.g. to loosen persistent wound debris as well as to treat burn wounds).

Improves scar quality when applied to the surgical wound immediately after wound closure.



octenilin®
wound irrigation solution

YOUR ADVANTAGES

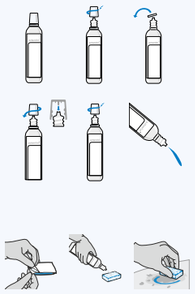
- excellent cleansing performance
- especially compatible with skin and tissue
- suitable for all wound situations
- rapid elimination of unpleasant wound odour
- painless, colourless
- for repeated and long-term use
- for combined use in vacuum therapy (V.A.C.Ulta™, KCl)
- can be combined with the schülke wound pad to enhance the cleaning effect
- sterile, stable for 8 weeks after initial opening

APPLICATION

Fast and effective wound cleansing, e.g. for removal of wound debris, necrotic tissue, biofilm and fibrin. Also suitable for hard-to-reach wound surfaces.

For moisturising the wound and keeping it moist and for gentle removal of persistent, crusted dressings/bandages.

In combination with the schülke wound pad for painless removal of fibrin and debris and to stimulate local circulation of the wound area.



* please refer to the Summary of Product Characteristics

For the important user information please see page 41

RECOMMENDED PROCEDURE

* Where applicable, wound swab or tissue sample (in this case, the wound cleansing should be performed using Ringer's solution or the like).

** The secondary dressing is always based on the nature and condition of the wound. Apart from PVP-iodine-coated dressing materials, products containing octenidine can be combined with all conventional wound dressings. If ointment gauze and octenilin® wound gel are used, the dressing should be changed daily and the wound cleansed. The octenilin® wound gel remains on the wound until the next dressing change. The frequency of the dressing change depends on the condition of the wound and the amount of exudate and should be adapted to the respective wound situation, however it should be performed after max. 3 days. The combination with other antimicrobial active substances does not provide any additional clinical benefit.

For the important user information please see page 41

06 Protection and care for irritated skin: octenicare® repair creme

The active complex of panthenol, bisabolol and octenidine supports the resilience of the skin and at the same time helps prevent infections and reduce unpleasant odours.

Human skin can be exposed to various and at times significant stressors which reduce the integrity of the epidermis. Essential protective functions can then no longer be adequately performed and the risk of the development of skin irritation, wounds and infections is consequently greatly increased.

Another product has recently been added to the octenidine range: the octenicare® repair creme, which strengthens the natural barrier of the skin through an innovative formulation. The cream forms a thin, oily film which protects the patient from outside influences and moisture (such as, for example, wound exudate, urine, sweat).

Because it does not contain fragrances or dyes, octenicare® repair creme is also highly compatible for sensitive skin.

Strengthening the integrity of the skin is not only important for preventive reasons. **Following wound closure, the newly formed epidermis also benefits from special care.** octenicare® repair creme can be used as aftercare for a wide variety of wounds (such as abrasions, cuts, burns) to promote the regeneration of the skin.

Due to the **significant stress which the skin is exposed to in everyday work**, there is also a risk of developing contact dermatitis. Frequent handwashing with soap and water, the use of lower-quality disinfectants, as well as the increased use of personal protective equipment (such as gloves, face masks) is very detrimental to the skin and makes it dry, chapped and flaky. octenicare® repair creme can moisturise irritated areas of skin, calm them, and restore the natural protective function.

+ PANTHENOL

promotes skin regeneration, ensures suppleness & elasticity

+ BISABOLOL

has a skin-calming effect

+ OCTENIDINE

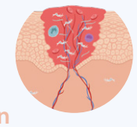
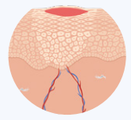
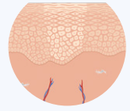
inhibits odour-causing germs

Successfully tested on children from 6 months[49]

Intact skin is the first line of defence against infections!

07 schülke: Wound care from a single source

Tailored to each phase of wound healing, products containing octenidine for cleansing, disinfection, promoting wound healing, and supporting regeneration are available.

WOUND HEALING PHASE		MEASURE	PRODUCT
1st phase: **Exudation and inflammation**		Cleansing	octenilin® wound irrigation solution schülke wound pad
		Antisepsis	octenisept®
2nd phase: **Proliferation and granulation**		Cleansing	octenilin® wound irrigation solution
		Moisturisation	octenilin® wound gel
3rd phase: **Epithelialisation**		Promotion of wound healing	octenilin® wound gel
4th phase: **Regeneration, prophylaxis and skin care**		Protection and care	octenicare® repair creme

Octenidine-based products have a special advantage: Because the same ingredient is used, they can be ideally combined. Adverse interactions between the products are thus excluded.

For the important user information please see page 41

08 From practice: Case studies

Case 1 | Chronic wound healing disorder – *Ulcus cruris*

Patient

Age 70, female

Clinical picture

Ulcus cruris venosum on the right external ankle

Medical history

- Chronic venous insufficiency
- Compression with compression stockings
- Wound existed at admission already for a year and had so far been dressed with foam

Products

Wound cleaned with octenilin® wound irrigation solution and treated with octenilin® wound gel

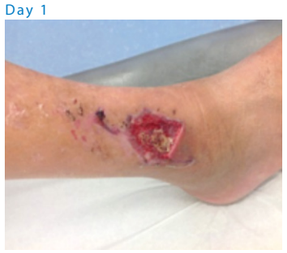
Length of treatment with octenidine

42 days

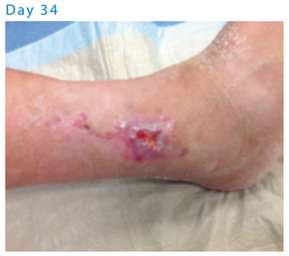
Wound dressing used

Spacer grid, non-woven fabric pad

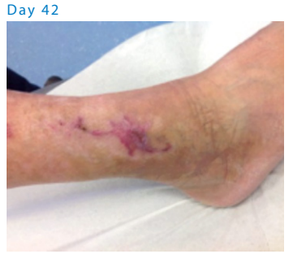
Day 1



Day 34



Day 42



Source: Assadian *et al.*, Journal of Wound Care 25(3), S1-S28, 2016

Case 2 | Chronic wound healing disorder – Decubitus ulcer

Patient

Age 85, female

Clinical picture

Sacral decubitus category 4, necrotic tissue

Products

Gauze impregnated with octenilin® wound irrigation solution, dressing change 3 x per day for 244 days

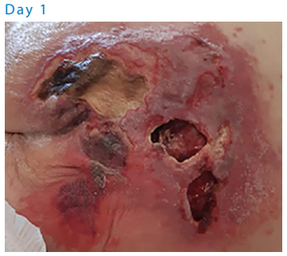
Length of treatment with octenidine

244 days

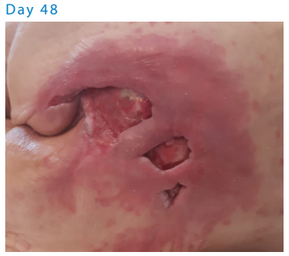
Wound dressing used

Gauze

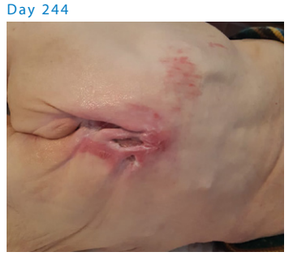
Day 1



Day 48



Day 244



Case 3 | Chronic wound healing disturbance and postoperative wound care

Patient

Age 78, male

Clinical picture

Diabetic foot syndrome (left)

Medical history

- Type 2 *Diabetes mellitus*
- On admission diabetic gangrene and osteolysis of the second toe
- Infection and necrosis of the big toe
- Subsequent amputation of the second toe and surgical debridement of the big toe

Product

- octenilin® wound gel, Dressing changes and treatment every 3 days
- No antibiotic therapy!

Length of treatment with octenidine

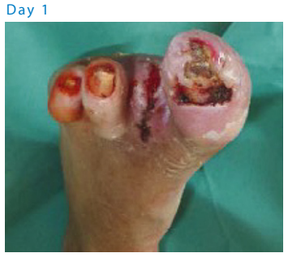
21 days

Wound dressing used

Foam, compresses, hydro fibre

Upon admission

Day 1



Day 21

Source: Assadian *et al.*, Journal of Wound Care 25(3), S1-S28, 2016

Wound management in the palliative setting

In the field of palliative wound care, the primary aim is not the rapid and aesthetically acceptable healing of a wound, but rather the reduction and control of symptoms and pain in order to maintain or improve quality of life and social integration for the person affected.

As well as chronic wounds, ulcerating cancer wounds in particular constitute an enormous physical and psychological burden for affected patients. In such cases, octenidine-based products, applied topically, have been shown not only to make a significant contribution in improving the clinical condition of the wound but also to have positive effects on the general wellbeing of the patient.[50, 51]

Case 4 | Postoperative wound healing disorder

Patient

Age 57, male

Clinical picture

Postoperative wound healing disorder at the harvesting site of a vessel in the forearm (by-pass operation)

Medical history

- Type 2 *Diabetes mellitus*, severe obesity
- Initially: Treatment with povidone-iodine spray and dry dressing
- **Until day 15:** systemic antibiotic therapy
- **Day 16:** severe redness and dehiscence
- **From day 35 on:** Therapy with silver-containing hydrofiber
- **From day 39 on:** Treatment with medical honey, foam dressing containing silver

Products

- **Day 41:** starting therapy with octenilin® wound gel and Mepilex®Ag dressings
- **Day 49:** reduced dehiscence and redness, continued wound care with octenilin® wound gel

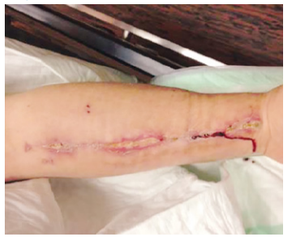
Length of treatment with octenidine

22 days

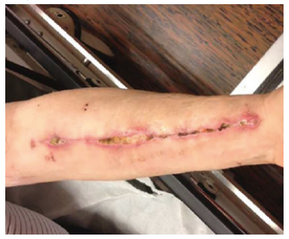
Wound dressing used

Compresses, film for fixation of bandages, silver-containing foam dressing, hydro fibre + silver

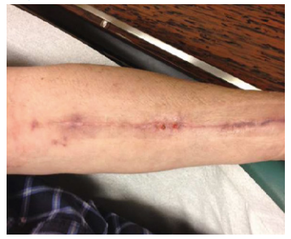
Day 16



Day 35



Day 62



Source: Assadian *et al.*, Journal of Wound Care 25(3), S1-S28, 2016

Case 5 | Postoperative wound healing disorder

Patient

Age 23, male

Clinical picture

Postoperative wound healing disorder after *sinus pilonidalis*

Medical history

Coccygeal fistula excised and primarily closed 3 years ago

Products

- Daily flushing of the wound with octenilin® wound irrigation solution
- **From day 21 on:** Wound sprayed 2 – 3 × per day with octenisept® for 28 days

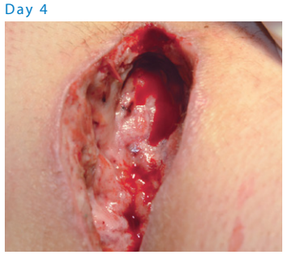
Length of treatment with octenidine

49 days

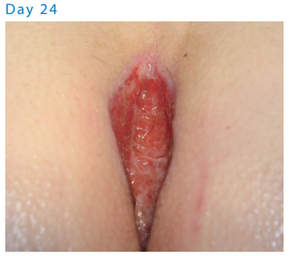
Wound dressing used

Haemostatic, bacteria-binding pad, closure with an absorbent dressing

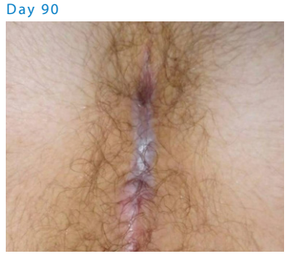
Day 4



Day 24



Day 90



For the important user information please see page 41

Case 6 | Postoperative wound healing disorder

Patient

Age 72, female

Clinical picture

Postoperative wound healing disorder after implantation of a knee endoprothesis

Medical history

- Superficial infection with wound edge dehiscence
- The wound was partially opened, the haematoma was drained, and signs of infection were found
- **From day 6 on:** Biological debridement (two bio-bags with 100 larvae each)

Product

From day 10 on: prophylactic treatment with octenisept® for 25 days

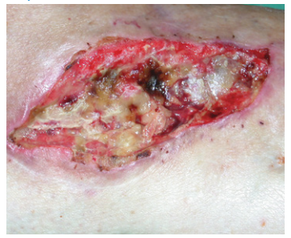
Length of treatment with octenidine

25 days

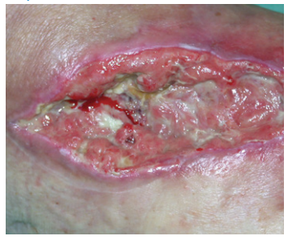
Wound dressing used

Superabsorbent foam dressings

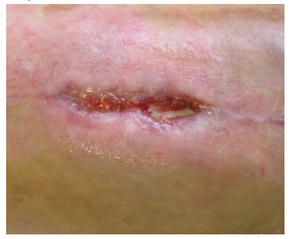
Day 6



Day 10



Day 56



Case 7 | Postoperative wound healing disorder

Patient

Age 68, male

Clinical picture

Postoperative wound healing disorder after plate osteosynthesis on the right outer ankle

Medical history

Cerebral infarction

Products

- Debridement and subsequent treatment of the wound with octenisept®
- Oral antibiotics; consequent elevation of the extremity
- Exudate management with antimicrobial wound dressing
- **From day 43 on:** Wound irrigation with Ringer's solution and exudate management with a highly absorbent foam dressing

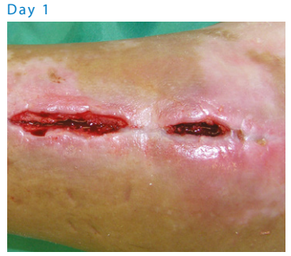
Length of treatment with octenidine

43 days

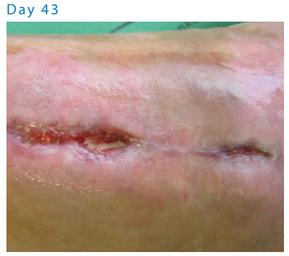
Wound dressing used

Superabsorbent foam dressings

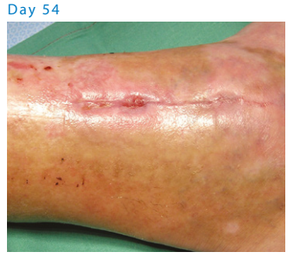
Day 1



Day 43



Day 54



Case 8 | Postoperative wound treatment

Patient

Age 37, female

Clinical picture

Postoperative wound treatment after abdominoplasty

Medical history

Removal of *cutis laxa abdominis* after massive weight loss

Product

octenilin® wound gel directly postoperatively, dressing change every 2 – 3 days

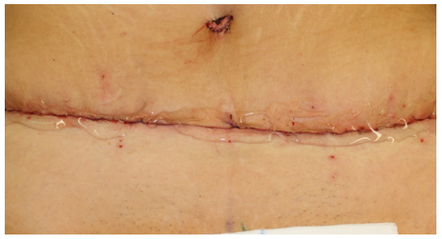
Length of treatment with octenidine

14 days

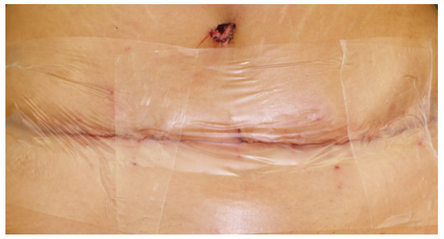
Wound dressing used

Film dressing

Day 1



Day 1



Case 9 | Postoperative wound treatment after amputation

Patient

Age 71, female

Clinical picture

Diabetic foot syndrome

Medical history

- Type 2 *Diabetes mellitus*
- Atherosclerosis
- Endovascular angioplasty / diabetic gangrene of the 1st – 4th toe sinistrally, amputation of the affected toes

Products

octenisept®, dressing changes every 2 – 3 days

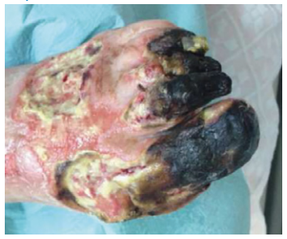
Length of treatment with octenidine

42 days

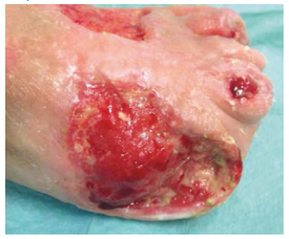
Wound dressing used

Hydro fibre

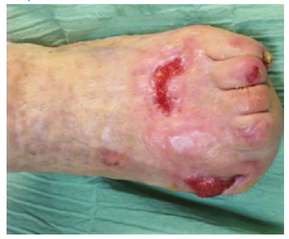
Day 1



Day 14



Day 42



Source: Assadian *et al.*, Journal of Wound Care 25(3), S1-S28, 2016

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Case 10 | Postoperative wound treatment after split-thickness skin grafting

Patient

Age 87, female

Clinical picture

Skin necrosis on the right leg

Medical history

- Type 2 *Diabetes mellitus*, rheumatoid arthritis
- Chronic renal insufficiency;
- Right-heart failure
- s/p deep vein thrombosis
- Long-term cortisone treatment
- 4 weeks of treatment with a PVP-iodine wound gel

Products

- **Day 1:** Split skin grafting, tie-over dressing left on for 5 days (wetted with octenisept®)
- **Day 5–14:** cleaning of the wound with octenisept® upon each change of dressing
- **Day 15–21:**Treatment of the wound with dexpanthenol

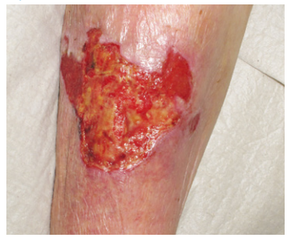
Length of treatment with octenidine

14 days

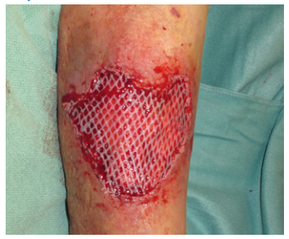
Wound dressing used

Foam compresses

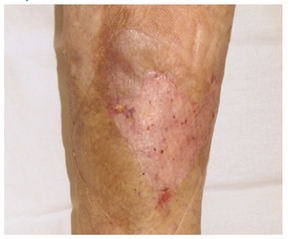
Upon admission



Day 1



Day 35



Source: Matiasek *et al.*, Journal of Wound Care 2015

Case 11 | Negative Pressure Wound Therapy with Instillation (NPWTi)

Patient

Age 74, male

Clinical picture

Gluteal decubitus category 4

Medical history

Paraplegia, surgical debridement

Products

- **Day 1:** Surgical debridement and wound bed preparation using V.A.C.Ulta™ and octenilin® wound irrigation solution
- **Day 1–5:** Instillation of the wound with octenilin® wound irrigation solution
- **Day 6:** Defect coverage by flap surgery

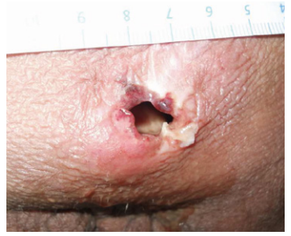
Length of treatment with octenidine

5 days

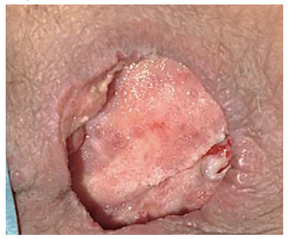
Wound dressing used

V.A.C.Ulta™

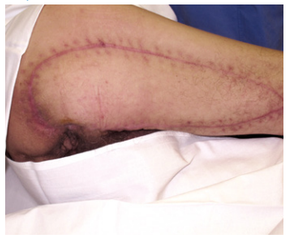
Day 1



Day 5



Day 90



Source: Matiasek *et al.*, Journal of Wound Care 2014

Case 12 | Wound antisepsis in surgery

Patient
Age 4, male

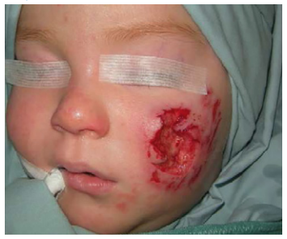
Clinical picture
Contaminated skin and soft tissue defect after dog bite

Product
- Pre-, intra- and postoperative antisepsis with octenisept®
- Debridement and systemic antibiotic therapy
- Drainage removed on the next day

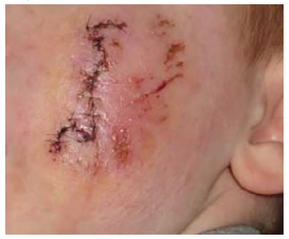
Length of treatment with octenidine
6 days

Wound dressing used
Sterile wound closure strips, patches

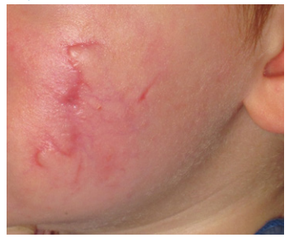
Day 1



Day 7



Day 30



Case 13 | Burn

Patient
Age 48, male

Clinical picture
Acute burn trauma of the left forearm

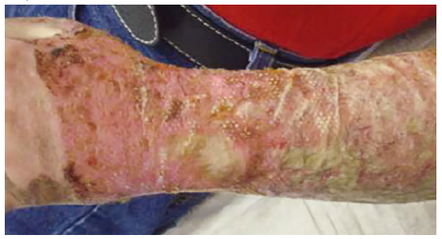
Medical history
- Therapy with fatty gauze over 2 weeks
- Encrusted coating on the entire forearm

Product
octenilin® wound gel, dressing changes every 2 days

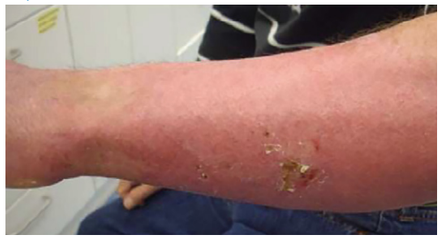
Length of treatment with octenidine
14 days

Wound dressing used
Foam dressing

Day 1



Day 14



For the important user information please see page 41

Case 14 | Burn

Patient
male

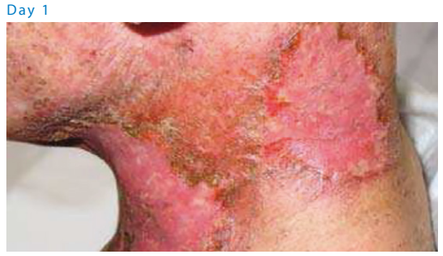
Clinical picture
Skin ulcerations after radiotherapy

Product
octenilin® wound gel, dressing change daily

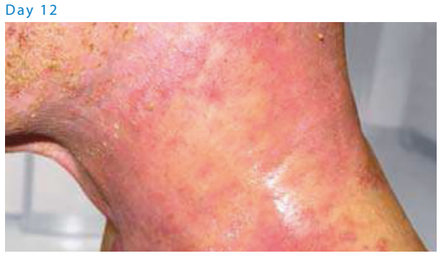
Length of treatment with octenidine
12 days

Wound dressing used
Film dressing

Day 1



Day 12



Case 15 | Burn

Patient
Age 69, female

Clinical picture
Burn trauma, grade 2a, caused by a baking sheet on the left lower arm

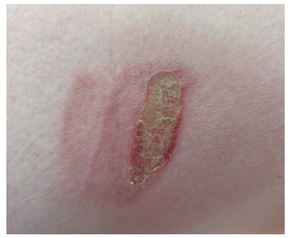
Medical history
Directly after the trauma cooling of the wound under cold water

Product
- octenilin® wound gel*, dressing change every 2–3 days until day 33
- No antibiotic therapy!

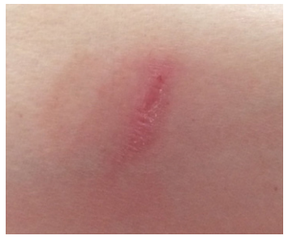
Length of treatment with octenidine
33 days

Wound dressings used
Mepilex® XT, elastic gauze

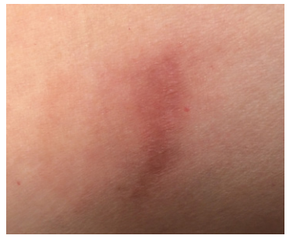
Day 1



Day 15



Day 43



*For the therapy at home octenisept gel can be used as an equivalent product.

Case 16 | Burn

Patient

Age 18, male

Clinical picture

82% of body surface burned due to deflagration (room spray), grade 2a/b, grade 1 inhalation trauma

Products

- **Day 1:** placement of the epicite[hydro] face mask in octenisept® for 20 minutes; the soaked mask remains on the patient's face for 14 days without further manipulations
- **Day 14:** small pieces of the face mask which still adhere are removed
- **Day 20:** epithelialisation nearly complete
- **Day 43:** face completely healed

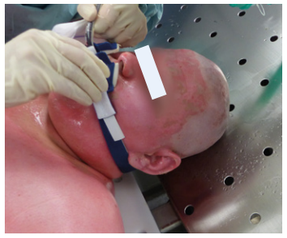
Length of treatment with octenidine

14 days

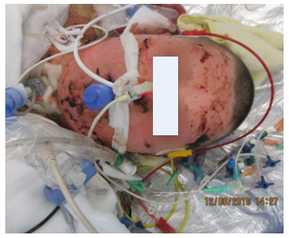
Wound dressing used

epicite[hydro] face mask

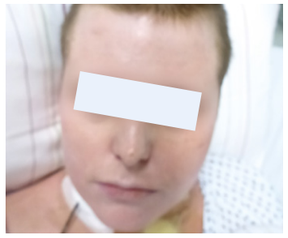
Day 1



Day 14



Day 43



Source: Burn Centre BG Bergmannstrost Halle / Saale, Prof. F. Siemers and Dr. I. Nietzschmann

Case 17 | Burn

Patient

Age 2, female

Clinical picture

Extensive burns due to fire, grade 2a/2b (partially grade 3), inhalation trauma

Medical history

- Systemic antibiotics & antimycotics, local therapy with 10% PVP-iodine and 0.3% chlorhexidine
- **Day 3:** xenotransplantation (600m²)
- Very poor overall condition
- **Starting on day 15:** change in local therapy

Products

- **Starting on day 1:** Removal of the xenotransplant and local therapy with gauze impregnated with octenisept® (8-10 layers), dressing change every 2 days
- **Starting on day 3:** significantly improved overall condition, visible insular epithelialisation of the wounds
- **Starting on day 5:** split skin transplant (autologous), additional dressing changes every 2 days with gauze impregnated with octenisept®; blood count returned to normal
- **Starting on day 23:** complete wound healing

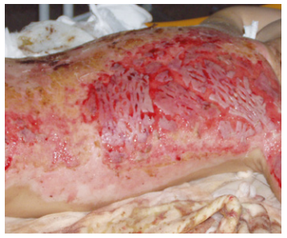
Length of treatment with octenidine

23 days

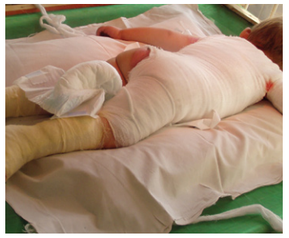
Wound dressing used

Grassolind® ointment compresses, Omiderm®, gauze

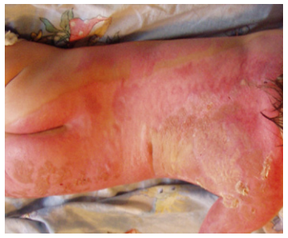
Day 3



Day 3



Day 23



Source: Dr. S. Smirny, Department of Thermal Injury, City Hospital No. 3, Nikolaev, Ukraine

For the important user information please see page 41

Case 18 | Genetic skin disease – *Epidermolysis bullosa*

Patient

Age 7, female

Clinical picture

Accidental detachment of the skin of the thumb

Medical history

Dystrophic *epidermolysis bullosa*

Product

octenilin® wound irrigation solution

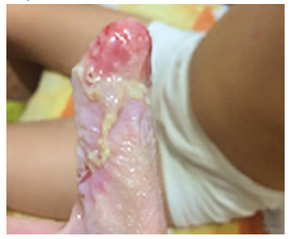
Length of treatment with octenidine

7 days

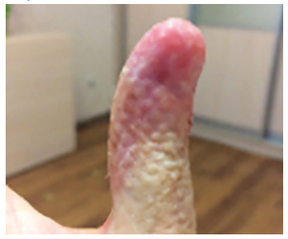
Wound dressing used

Ointment gauze

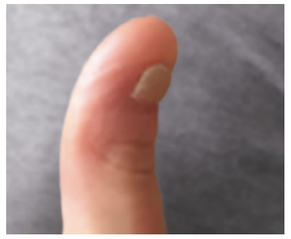
Day 1



Day 7



6 months



Case 19 | Debridement – wound pad

Patient

Age 64, male

Clinical picture

Post-thrombotic ulcer at the lower leg left inside

Medical history

Surgical debridement with sharp spoon according to Volkmann's method

Products

schülke wound pad and octenilin® wound irrigation solution

Length of treatment with octenidine

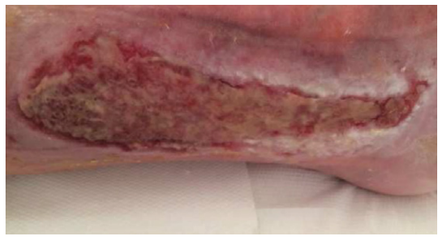
2 minutes

"Method preserves vital tissue"

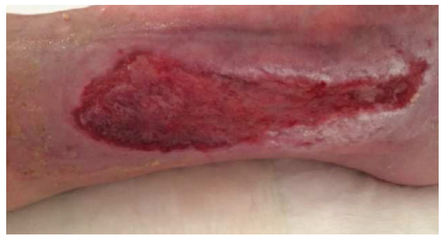
"Debris and fibrin bind well to the sponge"

"Significant pain reduction compared to the sharp spoon"

before



after



Source: Dr. E. Lahnsteiner, management of medical team wound healing, A-1090 Vienna
Assadian *et al.*, Journal of Wound Care 25(3), S1-S28, 2016

Case 20 | Wound infected with multi-resistant pathogens

Patient
Age 73, female

Clinical picture
Local wound infection on the left lower leg after split skin transplantation; necrotic routes, super infection with *E. coli* (ESBL), MRSA, *P. vulgaris*, *P. aeruginosa* and *E.faecalis*

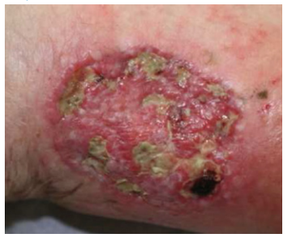
Medical history
- Type 2 *diabetes mellitus*
- Initial removal of a squamous cell carcinoma on the left lower leg (split-thickness skin transplantation)
- 6 days later first signs of a local infection, therapy with medical honey and gauze dressing for 10 days (dressing changes every 2nd day)

Products
- **Day 1–25:** Cleaning and disinfection with octenisept® (3–5 minutes), subsequently dressing with octenilin® wound gel, daily dressing changes for 5 days, subsequently every 2 days
- **Day 1:** additional daily whole-body decontamination with octenisan® wash lotion and octenisan® md nasal gel for 5 days to reduce the risk of recontamination
- No antibiotic therapy!

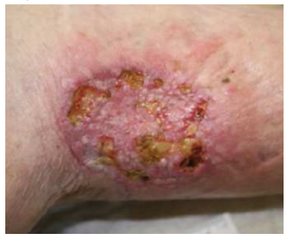
Length of treatment with octenidine
24 days

Wound dressing used
(soaked) compresses, hydro fibre dressing

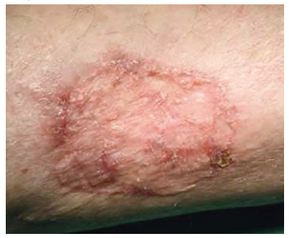
Day 1



Day 5



Day 25



Source: Matiasek *et al.*, Biomed Journal of Scientific & Technical Research 2018

Case 21 | Bullous erysipelas

Patient
Age 45, female

Clinical picture
Bullous erysipelas; streptococcal infection on the left lower leg

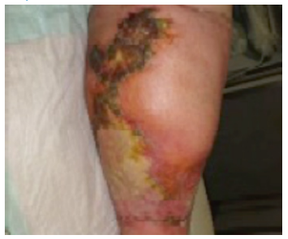
Medical history
- Type 2 *diabetes mellitus*, *Adipositas permagna*
- Progression despite systemic antibiotic therapy, amputation considered

Products
Wound debridement using a Versajet and subsequently daily therapy with octenisept®-soaked compresses

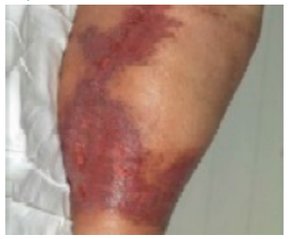
Length of treatment with octenidine
10 days

Wound dressing used
(soaked) pads

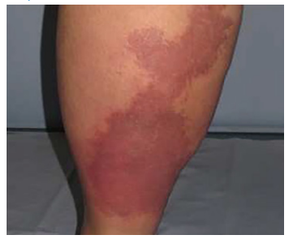
Day 1



Day 5



Day 21



For the important user information please see page 41

Case 22 | Infected haemorrhagic skin lesions

Patient
Age 15, male

Clinical picture
Meningococcal septicaemia, necrosis and superinfection (including *S. aureus, P. aeruginosa, Candida spp. on arms and legs*)

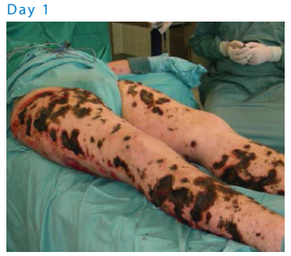
Medical history
High dose analgesics, systemic antibiosis, surgical debridement

Products
- **Day 1–4:** Daily after-treatment of the skin lesions with octenisept® and octenilin® wound gel with the purpose of wound bed conditioning for skin grafting on day 5
- **Day 5–23:** Therapy of the remaining wounds with octenilin® wound gel; dressing changes (every 2 days) were increasingly facilitated by the gel, the pain reduced, the need for analgesics reduced.

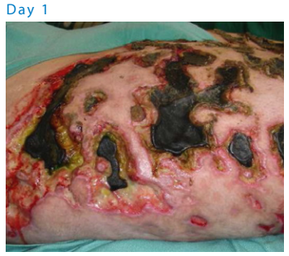
Length of treatment with octenidine
23 days

Wound dressing used
Initially superabsorbent; after abatement of the exudation, normal sterile compresses with folded edges

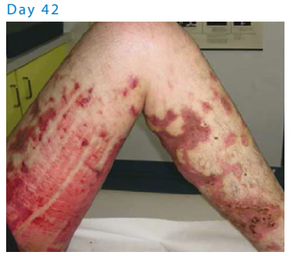
Day 1



Day 1



Day 42



Source: M. Hintner – Wundmanagement 2010

Case 23 | Chronic inflammatory skin disease

Patient
Age 3, female

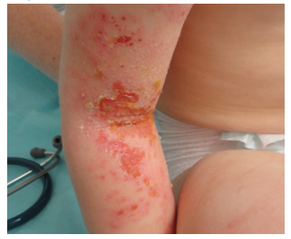
Clinical picture
Atopic dermatitis with *impetigo contagiosa* on the right arm

Products
- Intensive care of the noninfected skin with professional care products
- Treatment of the infected skin sites with a topical corticosteroid from the active substance group mometasone as an ointment as well as octenilin® wound gel* (3 x daily)

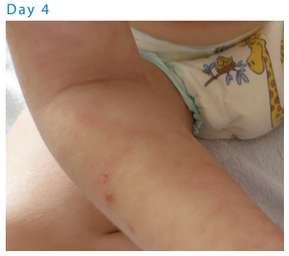
Length of treatment with octenidine
5 Days

Wound dressing used
Tubifast® Garments tube dressing

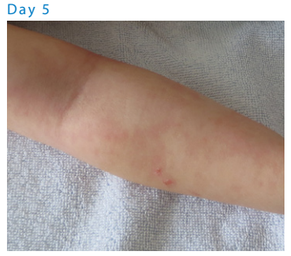
Day 1



Day 4



Day 5



*For the therapy at home octenisept gel can be used as an equivalent product.

Case 24 | Acute inflammatory skin disease

Patient

Age 6 months, male

Clinical picture

Diaper rash after RSV infection

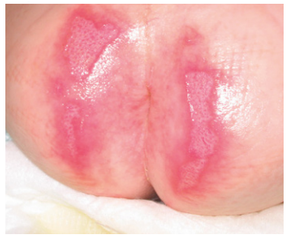
Products

- Regular, thorough washing of the diaper area with soft baby wipes
- After each cleaning treatment with octenilin® wound gel* (several times per day)

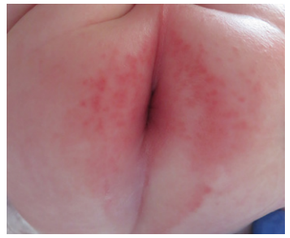
Length of treatment with octenidine

4 days

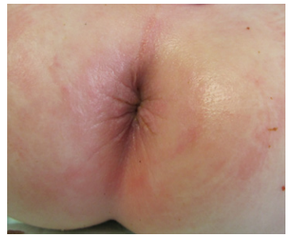
Day 1



Day 2



Day 4



*For the therapy at home octenisept gel can be used as an equivalent product.

Case 25 | Acute abrasion

Patient

Age 9, female

Clinical picture

Abrasion on the left shin after falling on asphalt

Medical history

- Hydrocolloid dressing (Varihesive extra thin) for the first 4 days
- Removal due to significant odour and detachment at the edges, visible signs of a local infection

Products

- **Day 1:** Disinfection with octenisept® and therapy with octenilin® wound gel*, daily dressing change for a total of 7 days
- **Starting on day 7:** Care of already closed sites with octenicare® repair creme, therapy of the remaining areas with octenilin® wound gel, daily dressing change for another 9 days
- **Starting on day 16:** Care of the entire wound with octenicare® repair creme (1x daily in the evening, without secondary dressing) until visible healing

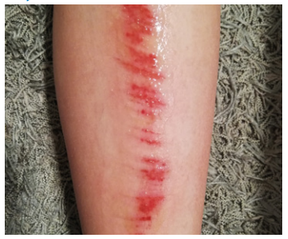
Length of treatment with octenidine

16 days (plus approx. 21 days octenicare® repair creme)

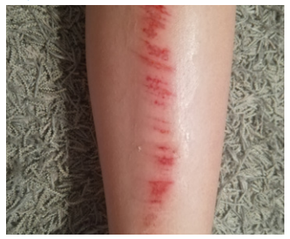
Wound dressing used

Hansaplast classic bandage

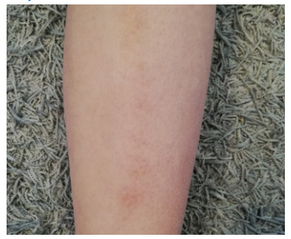
Day 1



Day 7



Day 40



*For the therapy at home octenisept gel can be used as an equivalent product.

For the important user information please see page 41

Case 26 | Tattoo care

Patient

Age 30, female

Clinical picture

Extensive black/white tattoo on left upper arm

Execution

- Prior to tattooing, treatment and disinfection of the shaved area of skin with octeniderm® colourless
- Then washing of the tattoo with pH-neutral soap
- Complete covering with Suprasorb® F film dressing for 5 days

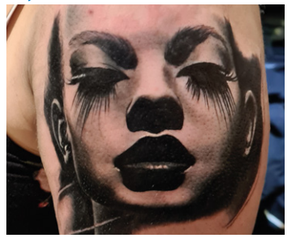
Product

Starting on day 5: octenicare® repair creme (2-4 x daily, depending on dryness)

Protection and care with octenidine

38 days

Day 1



Day 7

Day 42

Source: M. Luders, Milan's Bodyshop, Hamburg (www.hamburg-piercingstudio.de)

Case 27 | Tattoo care

Patient

Age 42, male

Clinical picture

Colourful tattoo in red tones with coronavirus motif on the left thigh

Execution

- Prior to tattooing: treatment and disinfection of the shaved skin site with octeniderm® colourless
- Covering directly after the tattooing with plastic wrap for approx. 5 hours
- Then washing of the tattoo with pH-neutral soap

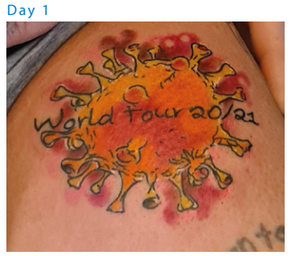
Products

Starting from day 1: octenicare® repair creme (2-4x per day, depending on dryness)

Protection and care with octenidine

28 days

Day 1



Day 14

Day 28

Source: M. Luders, Milan's Bodyshop, Hamburg (www.hamburg-piercingstudio.de)

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Literature can be provided on request

Important user information

octenisept® Wund-Desinfektion • Active substances: octenidine dihydrochloride, phenoxyethanol (Ph.Eur.). • **Composition:** 100 g solution contain 0.1 g octenidine dihydrochloride, 2.0 g phenoxyethanol (Ph.Eur.). Other ingredients: cocamidopropylbetaine , sodium D-gluconate, glycerol 85%, sodium chloride, sodium hydroxide, purified water. • **Indications:** Antiseptic for the repeated, temporarily limited adjuvant antiseptic wound treatment. • **Contraindications:** Hypersensitivity (allergy) to the pharmaceutically active ingredients or any of the other ingredients. Rinsing the abdominal cavity (e.g. during surgery) or the urinary bladder. Do not apply to the eardrum. • **Undesirable effects:** A subjective symptom of transitory burning sensation might occur in rare cases. In very rare cases allergic contact reactions, e.g. temporary redness, occur at the application site. Effective 03/20
If any of the side effects get serious, or if you notice any side effects not listed in this user information, please tell your doctor or pharmacist.

octeniderm® colourless • Active substances: octenidine dihydrochloride, 1-propanol (Ph.Eur.), 2-propanol (Ph.Eur.). • **Composition:** 100 g solution contain: 0.1 g octenidine dihydrochloride, 30.0 g 1-propanol (Ph.Eur.), 45.0 g 2-propanol (Ph.Eur.). Other ingredients: purified water. • **Indications:** Skin disinfection prior to surgical procedures, catheterization, blood and liquor collection, injections, punctures, excisions, cannulations, biopsies and for antiseptic care of sutures. If no special hand disinfectant is available, octeniderm® colourless can also be used for hygienic and surgical hand disinfection. • **Contraindications:** octeniderm® colourless should not be used in case of hypersensitivity to any of the components of the preparation. • **Undesirable effects:** Particularly in cases of frequent use, skin irritation such as redness, burning and itching may occasionally occur. In rare cases allergic reactions (e.g. contact eczema) are possible. Revision 03/18.
If any of the side effects gets serious, or if you notice any side effects not listed in this user information, please tell your doctor or pharmacist.

octenisept® • Active substances: octenidine dihydrochloride, phenoxyethanol (Ph.Eur.). • **Composition:** 100 g solution contain: 0.1 g octenidine dihydrochloride, 2.0 g phenoxyethanol (Ph.Eur.). Other ingredients: cocamidopropylbetaine, sodium D gluconate, glycerol 85%, sodium chloride, sodium hydroxide, purified water. • **Indications:** For repeated, short-term antiseptic treatment of mucous membranes and adjacent tissues prior to diagnostic and surgical procedures - in the ano-genital region including the vagina, vulva and glans penis as well as prior to bladder catheterization - in the oral cavity. For short-term supporting therapy of interdigital mycotic infections and adjuvant antiseptic wound treatment. • **Contraindications:** octenisept® may not be used in cases of hypersensitivity to any of the components of the preparation. octenisept® should not be used for rinsing the abdominal cavity (e.g. intra-operatively) or the bladder, nor the tympanic membrane. • **Undesirable effects:** rare: burning, redness, itching and warmth at the application site, very rare: allergic contact reaction, e.g. temporary redness at the application site; frequency unknown: after lavage of deep wounds with a syringe, persistent edema, erythema and also tissue necrosis have been reported, in some cases requiring surgical revision. Rinsing of the oral cavity may cause a transitory bitter sensation. Revision 11/18

To prevent possible tissue injury, the product must not be injected into the deep tissue using a syringe. The product is intended for superficial use only (application by swab or spray pump).

Schülke & Mayr GmbH, 22840 Norderstedt, Germany, Tel. +49 40 52100-666, info@schuelke.com

schülke worldwide:

Australia
Schulke Australia Pty Ltd
Macquarie Park NSW 2113
Phone +61 2 8875 9300
Fax +61 2 8875 9301

Austria
Schülke & Mayr Ges.m.b.H.
1070 Vienna
Phone +43 1 523 25 01 0
Fax +43 1 523 25 01 60

Brazil
Vic Pharma Indústria e
Comércio Ltda.
Taquaratinga/SP – CEP
15900-000
Phone +16 3253 8100
Fax +16 3253 8101

Czech Republic
Schulke CZ, s.r.o.
73581 Bohumín
Phone +420 558 320 260
Fax +420 558 320 261

France
Schülke France SARL
71100 Chalon sur Saône
Phone +33 3 85 92 30 00

India
Schulke India Pvt. Ltd.
Powai, Mumbai – 400076
Phone +91 22 61736600

Japan
Schulke Japan LLC
Shinagawa East One Tower
2-16-1 Konan, Minato-ku,
Tokyo 108-0075
Phone +81 3 6894 3335
Fax +81 3 3453 0207

Netherlands
Schülke & Mayr Benelux B.V.
2031 CC Haarlem
Phone +31 23 535 26 34
Fax +31 23 536 79 70

New Zealand
Schulke New Zealand Limited
Auckland 1010
Phone +61 2 8875 9300
Fax +61 2 8875 9301

Poland
Schulke Polska Sp. z o.o.
02-305 Warszawa
Phone +48 22 11 60 700
Fax +48 22 11 60 701

Singapore
Schulke & Mayr (Asia) Pte. Ltd.
Singapore 159410
Phone +65 62 57 23 88
Fax +65 62 57 93 88

Slovakia
Schulke SK, s.r.o.
97101 Prievidza
Phone +421 46 549 45 87
Fax +420 558 320 261

Switzerland
Schülke & Mayr AG
8500 Frauenfeld
Phone +41 44 466 55 44
Fax +41 44 466 55 33

United Kingdom
Schulke & Mayr UK Ltd.
Sheffield S9 1AT
Phone +44 114 254 35 00
Fax +44 114 254 35 01

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