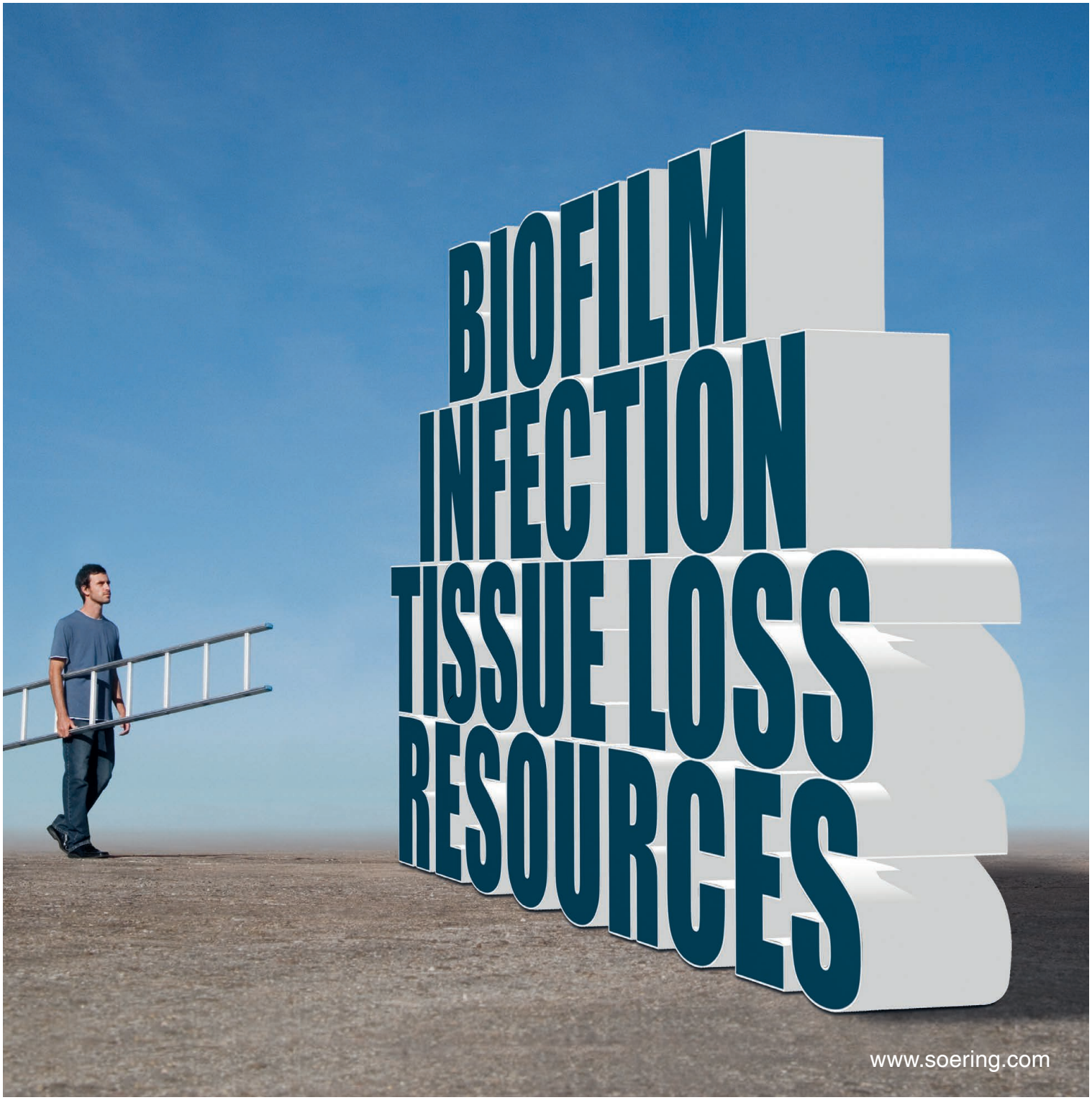
Söring
INNOVATIVE SURGERY

Challenges require effective tools:
How Söring UAW can support you in overcoming barriers to DFU healing.



→ Diabetes: **a severe problem ...**

370 Million

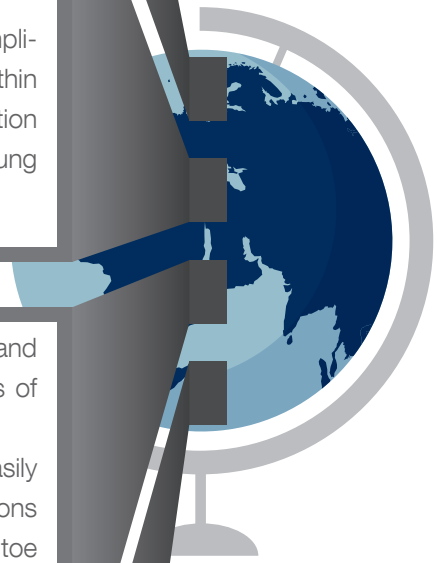
Globally, 370 million people are affected by diabetes mellitus (DM) and the number of affected people with this disease is increasing in every country. Being the 5th leading cause of death (5.2%), diabetes kills more people per year than breast cancer and AIDS together. Studies estimate that by 2040, 642 million people will suffer from diabetes impacting patient morbidity, mortality and quality of life. (1) (2) (3) (4)

"If Diabetes were a country, it would be the 4th largest in the world." (5)

One out of seven patients diagnosed with diabetes will develop a Diabetic Foot Ulcer (DFU). Without proper intervention, a DFU can lead to amputation. Additionally, DFU patients are at great risk of myocardial infarction, fatal stroke and premature death. (3) (6) (7)

Estimates assume that every 20 seconds a lower limb is amputated due to complications of diabetes and 50% of amputees will have their other limb amputated within 2 years after the first major amputation. The relative mortality rate after limb amputation is at alarming 68% after 5 years, bearing the second highest mortality rate after lung cancer (86%). (8) (9) (10)

The American Diabetes Association (ADA) has documented in a series of rigorous and exhaustive descriptive cost analyses studies that there is an increase in the costs of diabetes.
An US study has shown the average outpatient costs for treating one DFU can easily reach $28,000 (US $) for a 2-year period. Inpatient costs for lower limb complications were reported at an average of $16,580 (US $) for DFUs, $25,241 (US $) for toe or toe plus other distal amputations and $31,436 (US $) for major amputations. On basis of existing prevalence data, it can be estimated Europe alone will be confronted with costs associated with DFU treatment as high as 10 billion Euros per year. (11) (12) (13) (14) (15)



QOL

Diabetes patients' quality of life (QOL) is severely affected by the disease. Studies estimate that 50% of patients showing DFUs are no longer in work because of their ulcer. Furthermore, suffering from a DFU restricts patients in participating and enjoying their hobbies. Mobility difficulties and treatment requirements cause negative psychological effects and increased depression lowering patients` satisfaction with their personal lives. (16) (17)

The long-term consequences of diabetes include health complications, such as eye disease, circulatory problems and kidney failure, resulting in decreased QOL for patients and increased costs for health services. In general, people with diabetes have a significantly lower QOL than people without diabetes (mean health utility index: 0.78 vs. 0.88, P <0.01). (18)

… with major challenges …

Treating DFUs presents a major challenge. The first step is wound bed preparation to thoroughly clean the wound by removing devitalized tissue, debris and biofilms creating a healing-friendly environment and to manage wound infection. Appropriate DFU treatment involves a multidisciplinary approach and should proceed in a coordinated manner, considering local wound conditions, available resources, as well as patients´ compliance.

In most of DM patients, peripheral neuropathy and arterial disease (or both) play a central role in developing DFUs, which can therefore be classified as neuropathic, ischemic or neuroischemic.

In ischemic and neuroischemic DFUs macrovascular disease, and in some instances microvascular dysfunction, impair perfusion in the diabetic foot. (19) (20)

Treatment of ischemic ulcers is particularly challenging since these wounds often present local or systemic infection, with patients requiring systemic antibiotic therapy. However, provided antibiotics might not reach the wound bed because of poor vascular supply increasing the risk of wound infection to spread out.

INFECTIONS

A Pan-European study showed that 58% of patients attending a foot clinic with a new ulcer presented a clinically infected wound. Diabetic foot infections can result from uncontrolled bacterial presence and are the leading cause of amputations in patients with DFUs. Besides increasing time for healing and the risk for amputation, wound infections impact patients' quality of life and have a deleterious influence in wound healing. (21) (22)

A further study confirmed approximately the same numbers for the United States, reporting the risk for hospitalization and lower-extremity amputation to be 56-155 times greater for diabetes patients with a foot infection compared to those without infection. (23)

BIOFILMS AND MULTI-RESISTANT STRAINS

Clinical experience in DFU treatment has demonstrated, locally infected DFUs are difficult to treat showing polymicrobial bacteria presence including biofilm building species which interfere with local antimicrobial dressing therapy and lower the efficacy of systemic antibiotic therapy. (22)

Bacteria in biofilms are embedded within an extracellular polymeric substance (EPS) matrix that acts as a protective shield against topical antimicrobial therapy. Furthermore, bacteria in biofilms change their metabolism, meaning they can live without dividing. As certain antibiotics used for local wound infection only attack dividing bacterial cells, these measures result ineffective for biofilm treatment. One example is methicillin resistant Staphylococcus aureus (MRSA), which resides in a complex biofilm, that systemic antibiotics, including Vancomycin, can reduce but not eradicate the bacteria. (24)

Removal of bacteria and debris is part of wound bed preparation and represents an integral part of biofilm based wound care (BBWC) to treat the biofilm and inhibit its reformation. (25)

POOR WOUND CONDITIONS WITH ONLY MINIMAL TISSUE LEFT

A clean and viable wound bed as a result of effective wound debridement is an integral part of DFU treatment. The wound bed in DFUs can often present only minimal tissue left, making wound debridement of these wounds particularly challenging. Clinical experience of DFU treatment has shown, sequential wound debridement plays a significant role in the healing of DFU. (26) (27) However, a too aggressive debridement procedure, involving damage of healthy tissue, could delay the healing process in DFU. (27)

CONSTRAINTS

The individual patient situation might limit the options for wound debridement strategies to be used and therefore a careful risk/benefit assessment is needed. Severe comorbidities might influence patients' tolerance to the applied debridement procedure. It also might be, patients are not willed or do not tolerate wound debridement that needs to be conducted in the operating room (OR) requiring systemic anesthesia or they refuse hospital admission for surgical debridement.
Especially in times of economic constraints as a result of increased pressure on health care systems to reduce treatment costs, treatment choice is often also reduced by restricted availability of personnel and technical resources.

A debridement technique that provides effective wound debridement and helps to overcome the above listed challenges, without requiring use of systemic anesthesia, which is safe and easy to perform and can be carried out by all medical personnel, even outside the OR, can be considered a useful measure for BBWC, thus representing a beneficial adjunct to caregivers´ wound care tool box.

… that requires safe and effective solutions: Söring UAW

Söring attempts to overcome those challenges with the Söring UAW (Ultrasonic-Assisted Wound Debridement), an innovative addition to existing debridement techniques.

Gentle mode of wound debridement

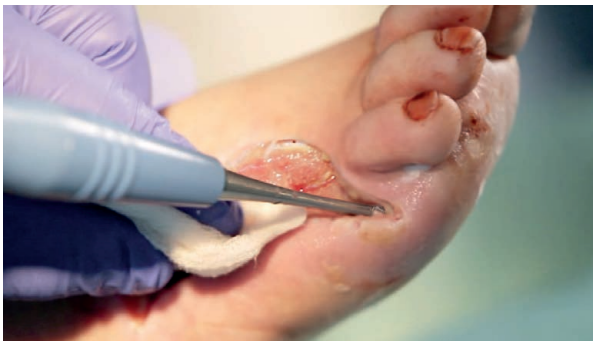
The efficacy of wound debridement as a result of Söring UAW can be explained by cavitation, an effect produced by the device. Söring UAW vibrates at an ultrasonic frequency of 25 kHz and forms micro-gas bubbles in a cavitation media that implode and disrupt the devitalized tissue. The cavitation bubbles have no detrimental impact on healthy tissue as these cells have a different mechanical strength and resist pressure changes due to UAW application. The unhealthy tissue is dissolved by the cavitation bubbles and the healthy tissue is "stimulated" into an inflammatory process or healing cascade. (28)

Söring UAW's mode of action therefore differs from other techniques likely to be described as more

aggressive, such as Waterjet-debridement or other forms of surgical debridement. The cavitation media in UAW is only required to ensure cavitation and enhanced cleansing of the ulcer bed from any residual debris through the continuous irrigation flow. (29)
Typical fluids used in combination with UAW in daily clinical practice are saline solution, polyhexamethylene biguanide (PHMB) - or hyperoxidized wound rinsing solutions.

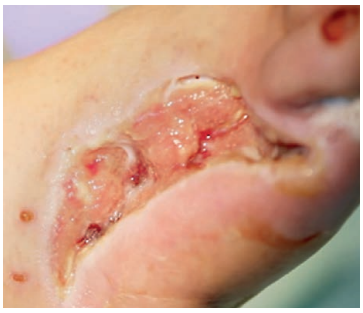
As with any other debridement procedure, treatment modalities of UAW should be adapted to the individual wound situation. Caregivers can adjust Söring UAW to various wound situations choosing different power levels and selecting instruments, thereby facilitating debridement. Söring UAW`s tissue selectivity makes it highly effective in deep wound tunnels, fistulas or areas with only minimal tissue left.

Frequency of UAW sessions depends on how fast slough in the wound bed rebuilds and needs to be removed. Clinical practice has shown that a debridement procedure with Söring UAW usually takes around 5 minutes. (24) (30)
The presence of a clean, viably rosy pink wound bed with no visible signs of slough or fibrin residue are the clinical markers one will see in witnessing the effectiveness of Söring UAW. This has been confirmed by experts using Söring UAW in clinical practice. (31)

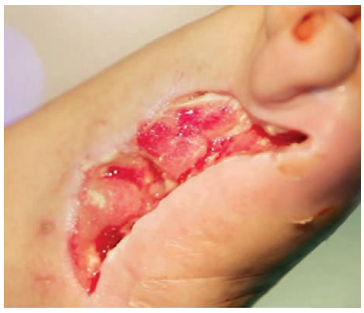


*UAW Instrument Double-Ball: Ideal for debridement of wound pockets **

Case example:



*Wound prior to Söring UAW **



*Wound after Söring UAW **

Exceptional tissue protection

The selective mode of action of Söring UAW represents a gentle option for wound debridement, removing only devitalized tissues, cell remnants, biofilms, and contaminations, whereas vital tissue is hardly affected. (32) Wound debridement with Söring UAW can therefore be considered as an appropriate measure to conduct wound bed preparation in DFU treatment.

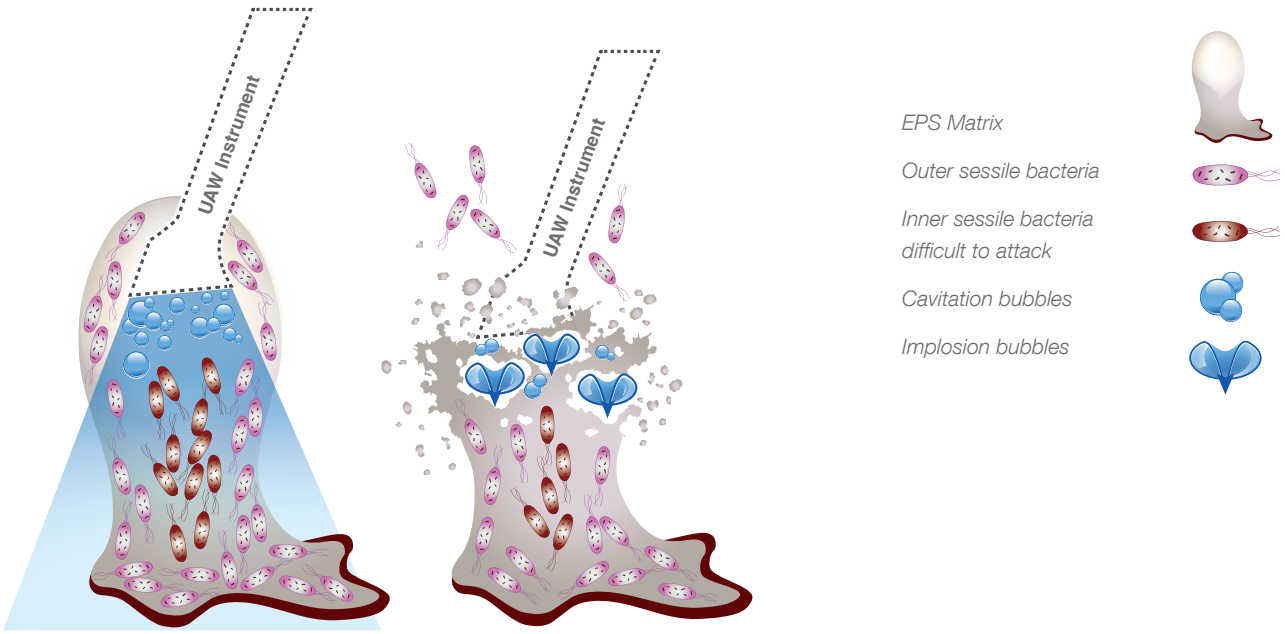
* Source: Südharz Klinikum Nordhausen, Nordhausen, Germany

Management of biofilms, bacteria and multi-resistant strains

But Söring UAW is more than a wound debridement technique which can be used for effective wound cleansing, removing devitalized tissue debris and bacteria present at wound site. Use of Söring UAW also facilitates removal of biofilms, disrupting the EPS protecting shield through a purely physical mode of action, thus supporting further treatment of these wounds. The bacteria previously protected by the EPS in biofilms break apart making them vulnerable for antimicrobial therapies or assistance from the host's immune system. (33)

In addition, results derived from recent research have suggested that Söring UAW influences biofilm rebuilding capacity of detected bacteria. (34) (35)

DFU experts emphasize the risks derived from failure to effectively treat the infection in DFU as this leads to progressive tissue damage, disrupted wound healing, and serious complications such as osteomyelitis. Clinical practice of DFU treatment involving sequential wound debridement sessions with Söring UAW has shown significant reduction of bacteria load, not only right after debridement but also during the complete period of treatment in a cumulative way. UAW is effective against every type of bacteria, also against multi-resistant bacteria. Furthermore, it has been suggested that sequential use of UAW for DFU treatment might help to reduce use of systemic antibiotics in DFU patients. (22) (36)



A kick-start towards wound healing

The combination of effective wound cleansing, biofilm removal and exceptional protection of healthy tissue as a result of Ultrasonic-Assisted Wound Debridement (UAW) leads to wound conditions favorable to kick-start healing of complicated DFUs *(37) (38) (39)* ***and might therefore offer advantages over use of other debridement methods.***

As effective as surgical debridement, but making a difference

Despite its gentle and selective mode of action Söring UAW has shown to be as effective as surgical wound debridement but with a favorable risk profile.
Successful surgical debridement is highly dependent on the surgeon`s skills and their ability to distinguish between tissue types and might therefore be associated with certain procedural risks such as patients' pain, wound bleeding, damage to underlying tissue with a potential functional loss, post-surgical infection, as well as the use and associated risks of general anesthesia. (40) (41) (42) (43)

In contrast, Söring UAW is easy to learn and to handle by both, physicians and nurses, does not necessarily require anesthesia and might be carried out in or outside of the OR. Its use is a procedure that can easily be integrated in daily clinical practice and might facilitate utilization of limited personnel and OR resources. (32) (38) (40) (44)

To prevent discomfort in patients, a topical anesthesia (like lidocaine cream) might be applied 30 minutes prior to treatment. Clinical practice has shown that this is usually sufficient for patients to tolerate pain without any other pain medication, causing no further stress on weakened patients and enabling treatment outside the OR. (45) (46)
Söring UAW is therefore an appealing therapy for debriding wounds in a relatively painless and bloodless manner and also provides a potential for global cost savings when factoring in lingering patient care and potential amputation costs. In addition, it offers patients with extensive medical histories, suffering from complex and delayed wound healing, an alternative treatment modality. Patients facing poor healing outcomes with a risk of amputation get the chance for an improved quality of life they may not have had prior to the DFU treatment using Söring UAW. (24) (45)

Facilitating a holistic treatment pathway for DFUs

Appropriate wound bed preparation, advanced wound care measures and treatment of the underlying disease, that is DM, and associated comorbidities are prerequisites for any wound to show progress in healing. Söring UAW can easily be integrated in different treatment pathways. The clean, viable wound bed as a result from wound debridement and gentle but effective wound bed preparation with Söring UAW represent a helpful measure to:

1. ***Support and potentially increase efficacy of topical wound irrigation solutions used, such as PHMB or superoxidized wound rinsing solutions*** *(22) (33)*
2. ***Prepare the wound bed for further topical wound treatment with appropriate wound dressings, including bacteria-binding dressings*** *(47)*
3. ***Further treatment with Negative Pressure Wound Therapy (NPWT)*** *(35) (47)*
4. ***Wound treatment and wound closure with skin grafting*** *(34)*

Clinicians achieve very good results when cleaning and preparing the wound bed with Söring UAW before skin grafting and observed an improvement in skin graft take rates and time-to-graft. These clinical observations can be explained by Söring UAW's efficacy in biofilm removal and control of bacteria present at wound site both of which exert a considerable impact on take or rejection of the graft. (34) (48)

Depending on wound conditions Söring UAW can also be used in combination with other debridement methods. In case of very dry, large, black necrosis, the tandem use of initial sharp debridement followed by Söring UAW might be an effective and beneficial treatment. An useful treatment pathway may involve first use of sharp wound debridement to remove the dead unhealthy tissue, followed by Söring UAW to remove the remaining slough and devitalized tissue without damaging the wound bed whilst kick-starting healing in these wounds. (28)

Several studies confirm the efficacy and safety of Söring UAW, such as:

Reference	Key findings
Crone S, Garde C, Bjarnsholt T, Alhede M: ***A novel in vitro wound biofilm model used to evaluate low-frequency ultrasonic-assisted wound debridement.*** **Journal of Wound Care 2015** In-vitro study conducted at Costerton Biofilm Center, Copenhagen, Denmark (Interdisciplinary research center exploring the field of chronic bacterial infections)	• *Application of 10 seconds of moderate-intensity Söring UAW could effectively disrupt semi-solid biofilms in vitro. This treatment only had a small effect on the cell viability.* • *Significant improvement in reducing the number of viable bacteria when applying Söring UAW before administration of a PHMB solution.* • *Applying Söring UAW in the presence of PHMB further improved the efficacy.* • *Combining UAW with a PHMB containing antiseptic has potential as an anti-biofilm strategy in wound care.*
Herberger K, Franzke N, Blome C, Kirsten N, Augustin M: ***Efficacy, tolerability and patient benefit of ultrasound-assisted wound treatment versus surgical debridement: a randomized clinical study.*** **Dermatology 2011** Monocentric prospective randomized-controlled clinical study conducted at University Medical Center Hamburg-Eppendorf (UKE), Hamburg, Germany	• *Debridement of Venous Leg Ulcers (VLUs) with Söring UAW displays the same high efficacy, a comparable patient benefit and improved quality of life when compared to gold standard, i.e. surgical wound debridement.* • *Both procedures are equally suitable for highly beneficial guideline-based treatment of chronic wounds.* • *Söring UAW is a simple time-saving alternative to surgical wound cleansing with a favorable risk profile.* • *Delegation of the treatment to trained medical personnel is conceivable because of the simplicity of the procedure. This may reduce direct costs for staff.* • *Söring UAW enjoys high patient acceptance and can easily be performed on an outpatient basis.*

Reference

Yarets Y, Rubanov L, Novikova I, Shevchenko N:
The Biofilm-forming capacity of staphylococcus aureus from chronic wounds can be useful for determining Wound-Bed Preparation methods.
EWMA Journal 2013 Vol 13 No 1

Clinical case series with ulcers of mixed etiologies where UAW treatment followed by NPWT was an integral part of wound bed preparation before skin grafting. Study conducted at the Regional Centre for Thermal Injury and Reconstructive Surgery, in collaboration with the Clinical Laboratory Diagnostic Department, Gomel State Medical University (Gomel, Belarus). Staphylococcus aureus was isolated from chronic wounds to investigate effects on biofilms in vitro.

Key findings

- *The presence of bacterial biofilms impacts the surgical closure of skin grafted wounds.*
- *The treatment of chronic wounds with Söring UAW followed by NPWT reduced the capacity of staphylococcus aureus to synthesize a major biofilm substance.*
- *Staphylococcus aureus isolates from patients with favorable skin-grafting results had a lower capacity to form biofilms in vitro compared with isolates from patients with poor skin-grafting results.*
- *The use of Söring UAW followed by NPWT for surgical closure reduced the length of the skin-graft healing process compared with the use of standard bandages.*

Yarets Y, Rubanov L:
Clinical Experiences with Ultrasonic-Assisted Wound Debridement (UAW) used for wound bed preparation before skin grafting.
Free Paper Session Infection and Antimicrobials, EWMA Conference, May 14, 2015; London UK

Follow-up study on 140 chronic wounds to evaluate efficacy of one or two Söring UAW debridement sessions used for wound bed preparation prior to skin grafting and its effect on skin graft take rates in a practical clinical setting

- *A single Söring UAW application showed to be effective in removing necrotic tissue and wound debris in patients with colonized wounds showing a significant reduction of bacterial burden.*
- *Patients with locally infected wounds required two procedures of Söring UAW before a significant reduction of bacteria, especially of biofilm building species, was detected. These wounds showed good granulation and best take rates of skin grafting, with no complications noted.*

Lázaro-Martinéz JL, García-Álvarez Y, Aragón-Sánchez J, García-Morales E, Molines-Barroso R, Álvaro-Afonso FJ:
Preliminary case series results evaluating Ultrasonic-Assisted Wound Debridement (UAW) for treatment of complicated diabetic foot ulcers (DFU).
Poster presentation, ISDF conference, May 20-23, 2015; The Hague, Netherlands

Pilot study with DFU patients conducted at Diabetic Foot Unit, University Podiatry Clinic, Complutense University, Madrid, Spain

- *Sequential wound debridement with UAW used in combination with a super-oxidized antiseptic solution resulted in safe and effective wound cleansing, removal of biofilms and significant reduction of bacterial presence of complicated DFU, thus controlling wound infection.*
- *The wound bed of UAW debrided DFU showed fast granulation and kick-started healing of these wounds.*

Reference

Lázaro-Martinéz JL, Álvaro-Afonso FJ, García-Álvarez Y, García-Morales E, Sanz-Corbalán I, Tardáguila-García A:
Improved Wound Conditions and Reduced Bacterial Load as a Result of Sequential Low-Frequency Ultrasound Wound Debridement in Neuroischemic Diabetic Foot Ulcers
Poster presentation, SAWC Spring conference, April 13-17, 2016; Atlanta, US

Selected results derived from a monocentric, controlled clinical study conducted at Diabetic Foot Unit, University Podiatry Clinic, Complutense University, Madrid, Spain

Key findings

Sequential wound debridement with UAW ...

- *leads to significant reduction of bacterial load in tissue samples, not only right after debridement but also during the complete period of treatment in a cumulative way.*
- *improves wound conditions which can be associated with a decreased bacterial load detected in tissue samples.*
- *appears to prevent the reformation of biofilms by disrupting the bacterial communities and avoiding spread of bacteria and infection.*
- *could reduce the probability of bacteria to develop resistance because overuse of antimicrobials and antibiotics can be avoided.*
- *kick-starts healing in DFUs showing improved granulation as a result of changing the wound environment to healing friendly conditions.*

- *Measured effects of Söring UAW are independent to the bacterial species, acting in the same way against every type of bacteria independently of whether there is presence of resistant bacteria on the wounds or not.*

About Söring

Söring has been developing innovative medical technology "Made in Germany" for various surgical disciplines for over 30 years. The family-run business, founded and still located in Quickborn (near Hamburg), utilizes extensive experience in ultrasonic technology, a dedicated in-house R&D Team and close clinical collaborations for new solutions to support clinicians in their daily clinical practice.

The Söring UAW generator SONOCA 185 and the UAW instruments are made in Germany, they are reusable and known for their long-lasting quality. Söring offers different options to enhance hospitals' access to this innovative technology.

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Söring UAW:
your support in daily clinical practice

No two patients are the same, and no two wounds are the same. The whole patient must be treated on an individual prospective, from nutrition, to smoking cessation, to off-loading, to vascular perfusion, to wound management.
DFU treatment should follow a holistic approach, applying appropriate therapies and this always considering the wound status and patients compliance. Nussbaum et al (2002) have listed essential characteristics to describe the “ideal” debridement technique: (49)

1. ***Ease of use***
2. ***Precision***
3. ***Speed***
4. ***Safety and efficiacy***
5. ***Selective removal of necrotic tissue***
6. ***Capability to reduce wound-associated biofilm***

Are you interested in finding out whether Söring UAW can meet your expectations on the ideal debridement technique?

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