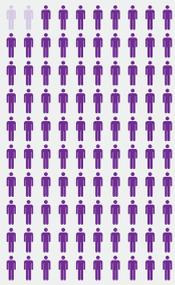


Introducing the ChloraSolv® Wound Debridement Gel White Paper

Improving outcomes for patients with hard-to-heal leg ulcers (LUs) and diabetic foot ulcers (DFUs)



Hard-to-heal wounds impose a substantial burden for individuals and society

- 1-2% of people at some point in their lives,^{1,2} with this figure expected to rise in the future³
- The most frequent aetiologies are LUs and DFUs¹

For society, costs for managing hard-to-heal wounds are a major healthcare burden:



£5.6 billion

National Health Service costs for unhealed wounds in 2017/18 were estimated at **£5.6 billion** per year⁷



£3.1 billion

In 2019, there were an estimated **739,000** leg ulcers in England, with estimated healthcare costs of **£3.1 billion** per year⁸

For affected individuals, hard-to-heal wounds, such as LUs and DFUs, have a profound impact:^{4,5}



Severe pain



Emotional and physical distress



Reduced mobility



Impaired quality of life



Detriment to finances



Emotional trauma to caregivers



DFUs can lead to lower limb amputations, which are associated with a potential reduction in life expectancy of up to **5 years**⁶

Responding to the clinical challenge of hard-to-heal wounds

Why don't some wounds heal properly?



Age-related factors

Individuals aged >60 years may have delayed wound healing^{9,10}



Inflammation

Infiltration of inflammatory cells and mediators as well as changes in immune cell function contribute to poor healing¹¹



Chronic disease - diabetes

Reduced capacity for wound healing in people with diabetes can lead to DFUs¹²



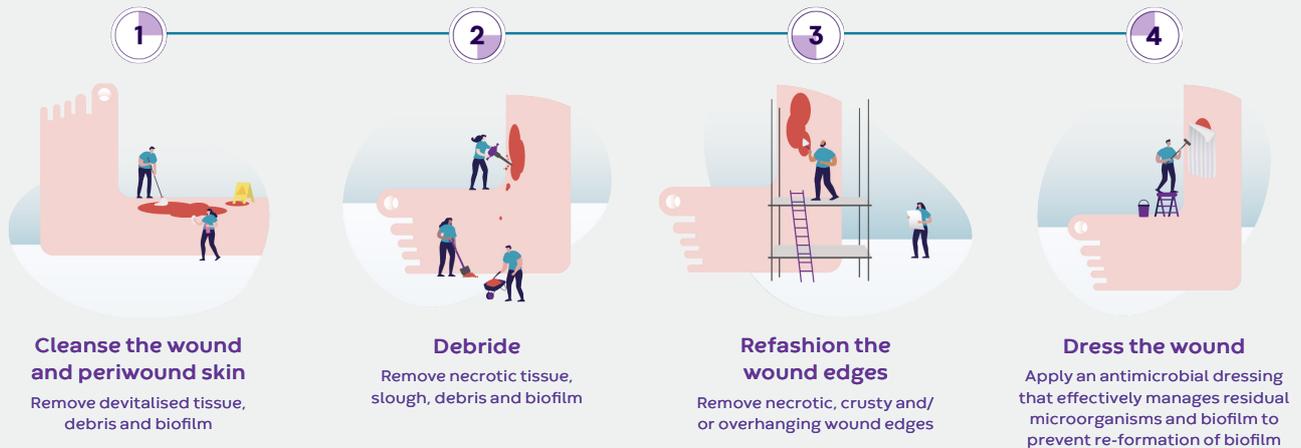
Biofilm and local infection

Extensive microbial colonisation that cannot be cleared by the innate immune system leads to the formation of a biofilm - a polymicrobial community of microorganisms in a protective matrix^{11,13,14}

The concept of Wound Hygiene

Wound Hygiene is a biofilm-based wound-care strategy, highlighting the importance of regularly removing biofilm to facilitate wound healing¹⁵

Wound Hygiene comprises four key steps¹⁶



You can learn more about implementing Wound Hygiene at: <https://www.woundhygiene.com>

The importance of frequent debridement



Biofilms can re-form in as little as 24 hours¹⁷



- More frequent debridement results in better healing outcomes;^{18,19} however, specialist training is needed to perform some debridement techniques (i.e. sharp), so bottlenecks can occur in accessing the most appropriate care
- There remains an unmet need for effective and easy debridement methods that can be undertaken by non-specialists and can be used frequently

ChloraSolv® Wound Debridement Gel enables rapid and effective debridement of hard-to-heal wounds

ChloraSolv® improves the healing of DFUs

- In 34 patients with diabetes and a DFU infected for >4 weeks, ChloraSolv® provided a significantly greater relative reduction in DFU area compared with standard treatment ($p=0.016$)²⁰
- ChloraSolv® in conjunction with weekly dressing changes improved absolute and relative DFU area and time to healing of DFUs compared with standard treatment²⁰



ChloraSolv® effectively softens and removes devitalised tissue in hard-to-heal LUs

After 5 weeks in 57 patients with hard-to-heal lower LUs:²¹

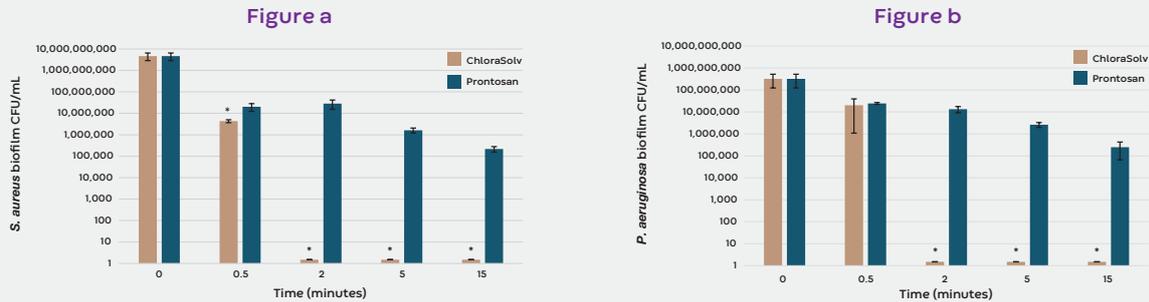
72.7% decrease in devitalised tissue ($p<0.0001$)

Complete debridement in 23.2% of wounds

ChloraSolv® eradicates biofilm rapidly

Biofilms grown on plates for 48 hours were exposed to treatment with ChloraSolv® or Prontosan® Wound Irrigation Solution. After 2 minutes of exposure to ChloraSolv®, both *Staphylococcus aureus* (Figure a) and *Pseudomonas aeruginosa* (Figure b) biofilms were completely eradicated to below the limit of detection with ChloraSolv® but not with Prontosan²²

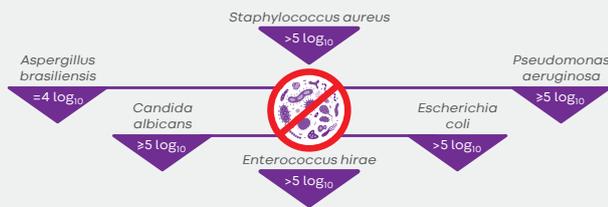
Mean biofilm cell counts (CFU/mL) (±SD) following treatment with ChloraSolv® and Prontosan®



*Statistically significant compared with Prontosan® (p=0.011 and p=0.004 with *S. aureus* and *P. aeruginosa*, respectively).
CFU, colony-forming unit.

ChloraSolv® has broad-spectrum antimicrobial activity

Antimicrobial effects of ChloraSolv® have been validated *in vitro*²¹



ChloraSolv® is effective against antibiotic-resistant bacteria

ChloraSolv® kills antibiotic-resistant biofilm bacteria (methicillin-resistant *Staphylococcus aureus* and resistant *Pseudomonas aeruginosa*) more effectively than antimicrobial solution soaks or debridement pads/wipes in a challenging, validated gauze biofilm model²²



ChloraSolv® is convenient and easy to use

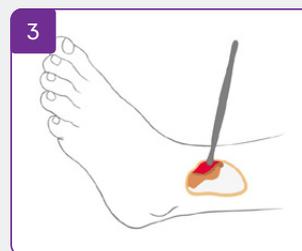
- ChloraSolv does not require any special training or qualifications, avoiding the need for specialist skills for effective debridement²³
- ChloraSolv® can be deployed in patients' homes or in a clinic/hospital setting²³, using the steps below²⁴:



Press the plunger downwards and apply a thin layer of the mixed gel directly to the wound bed. The gel should cover the wound completely when applied.



Leave the gel on the wound for 2-5 minutes.



Remove loosened necrotic tissue, using a gentle scraping action with a blunt instrument.



Rinse the wound area with water or isotonic saline solution and wipe dry. Complete the treatment by repeating steps 1-4 and then protecting the wound with a bandage or dressing appropriate for the state of the wound

ChloraSolv® is highly rated by patients and clinical staff

Patients



90%

ChloraSolv® rated as 'good' or 'very good' with regard to pain²¹

Clinical staff



94%

ChloraSolv® rated as 'easy' or 'very easy' to apply²¹

70%

ChloraSolv® made the debridement process easier²¹

ChloraSolv® Wound Debridement Gel has the potential to reduce costs in hard-to-heal wound management

Hard-to-heal wounds are costly to manage

UK community analyses: management costs



ChloraSolv® improves outcomes in hard-to-heal wounds

Debridement of hard-to-heal wounds with ChloraSolv® results in:

-  Shorter healing time vs standard of care in DFUs²⁰
-  Improvements in wound area in DFUs and LUs^{20,21}
-  Rapid and effective removal of devitalised tissue and biofilm²⁹

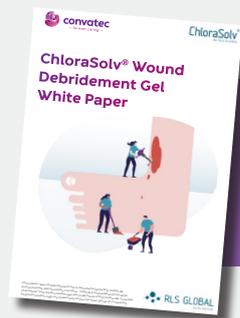
What impact could ChloraSolv® have in your wound care team?

- Mitigate the risk of biofilm and reduce the risk of complications of wound infection
- Promote faster healing in patients with DFUs and LUs, reducing the need for visits to patients and patient visits to clinics²⁹
- Offer a convenient, easy-to-use option for patients and clinical staff
- Avoid patient delays in accessing specialist care for sharp debridement
- Reduce the need for specialist staff training in sharp debridement



ChloraSolv® offers the potential to reduce the overall costs of managing hard-to-heal wounds

-  Requires little training to use
-  Can be deployed in patients' homes or in a clinic/hospital setting
-  Reduces the need for sharp debridement



Read our new White Paper highlighting the potential of ChloraSolv® Wound Debridement Gel in managing hard-to-heal LUs and DFUs

References

1. Gupta, S., Andersen, C., Black, J., de Leon, J., Fife, C., Lantis II, J.C., Niezgodna, J., Snyder, R., Sumpio, B., Tettelbach, W., Treadwell, T. Management of chronic wounds: diagnosis, preparation, treatment, and follow-up. *Wounds* 2017; 29(9):S19-S36; 2. Gottrup, F., Apelqvist, J. The challenge of using randomized trials in wound healing. *Br J Surg* 2010; 97(3):303-4; 3. Thomas, D.C., Tsu, C.L., Nain, R.A., Arsat, N., Fun, S.S., Lah, N.A. The role of debridement in wound bed preparation in chronic wound: a narrative review. *Ann Med Surg* 2021; 71:102876; 4. Järbrink, K., Ni, G., Sönnnergren, H., Schmidtchen, A., Pang, C., Bajpai, R., Car, J. The humanistic and economic burden of chronic wounds: a protocol for a systematic review. *Syst Rev* 2017; 6(1):15; 5. Olsson, M., Järbrink, K., Divakar, U., Bajpai, R., Upton, Z., Schmidtchen, A., Car, J. The humanistic and economic burden of chronic wounds: a systematic review. *Wound Repair Regen* 2019; 27(1):14-25; 6. Graves, N., Phillips, C.J., Harding, K. A narrative review of the epidemiology and economics of chronic wounds. *Br J Dermatol* 2022; 187(2):141-8; 7. Guest, J.F., Fuller, G.W., Vowden, P. Cohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018: update from 2012/2013. *BMJ Open* 2020; 10(12):e045253; 8. National Wound Care Strategy Programme (NWCSP) 2020. Preventing and Improving Care of Chronic Lower Limb Wounds- implementation case. Available at: <https://www.nationalwoundcarestrategy.net/wp-content/uploads/2021/04/NWCSPImplementing-the-Lower-Limb-Recommendations-15.12.20-1.pdf> (last accessed 19 May 2023); 9. Bonifant, H., Holloway, S. A review of the effects of ageing on skin integrity and wound healing. *Br J Community Nurs* 2019; 24(Sup3):S28-S33; 10. Moriya, J., Minamoto, T. Angiogenesis, cancer, and vascular aging. *Front Cardiovasc Med* 2017; 4:65; 11. Wilkinson, H.N., Hardman, M.J. Wound healing: cellular mechanisms and pathological outcomes. *Open Biology* 2020; 10(9):200223; 12. Burgess, J.L., Wyant, W.A., Abdo Abujajra, B., Kirsner, R.S., Jozic, I. Diabetic wound-healing science. *Medicina (Kaunas)* 2021; 57(10):1072; 13. Eming, S.A., Martin, P., Tomic-Canic, M. Wound repair and regeneration: mechanisms, signaling, and translation. *Sci Transl Med* 2014; 6(265):265sr6; 14. Schultz, G., Bjarnsholt, T., James, G.A., Leaper, D.J., McBain, A.J., Malone, M., Stoodley, P., Swanson, T., Tachi, M., Wolcott, R.D., Global Wound Biofilm Expert Panel. Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. *Wound Repair and Regen* 2017; 25(5):744-57; 15. Murphy, C., Atkin, L., Swanson, T., Tachi, M., Tan, Y.K., de Ceniça, M.V., Weir, D., Wolcott, R., Černohorská, J., Ciprandi, G., Dissemmond, J. Defying hard-to-heal wounds with an early antibiofilm intervention strategy: wound hygiene. *J Wound Care* 2020; 29(Sup3b):S1-S26; 16. Murphy, C., Atkin, L., Vega de Ceniça, M., Weir, D., Swanson, T., Walker, A., Mrozkiewicz-Rakowska, B., Ciprandi, G., Martine, J.L., Černohorská, J. Embedding wound hygiene into a proactive wound healing strategy. *J Wound Care* 2022; 31(Sup4a):S1-S9; 17. Mancl, K.A., Kirsner, R.S., Ajdic, D. Wound biofilms: lessons learned from oral biofilms. *Wound Repair Regen* 2013; 21(3):352-362; 18. Wilcox, J.R., Carter, M.J., Covington, S. Frequency of debridements and time to heal: a retrospective cohort study of 312 744 wounds. *JAMA Dermatology* 2013; 149(9):1050-8; 19. Tettelbach, W., Cazzell, S., Reyzelman, A.M., Sigal, F., Caporusso, J.M., Agnew, P.S. A confirmatory study on the efficacy of dehydrated human amnion/chorion membrane dHACM allograft in the management of diabetic foot ulcers: a prospective, multicentre, randomised, controlled study of 110 patients from 14 wound clinics. *Int J Wound J* 2019; 16(1):19-29; 20. Bergqvist, K., Almhöjd, U., Herrmann, I., Eliasson, B. The role of chloramines in treatment of diabetic foot ulcers: an exploratory multicentre randomised controlled trial. *Clin Diabetes Endocrinol* 2016; 2:6; 21. Eliasson, B., Fagerdahl, A.M., Jönsson, A., Apelqvist, J. Debriding effect of amino acid-buffered hypochlorite on hard-to-heal wounds covered by devitalised tissue: pilot study. *J Wound Care* 2021; 30(6):455-64; 22. Metcalf, D.G., Meredith, K., Olsson, S. The in vitro anti-biofilm performance of ChloraSolv® Wound Debridement Gel. *Wounds UK* 2023; 19(1):34-45; 23. Atkin, L. Introducing a new approach to debridement and wound bed preparation. *J Wound Care* 2022; 31(Sup8a):S5-S11; 24. RLS Global 2021. ChloraSolv® Instructions for Use. ChloraSolv 10703-ML VERSION: 2021-04-27. Available at: https://rls.global/wpcontent/uploads/2021/05/ChloraSolv_IFU_2021-04-27.pdf (last accessed 19 May 2023); 25. Guest, J.F., Fuller, G.W., Vowden, P. Diabetic foot ulcer management in clinical practice in the UK: costs and outcomes. *Int Wound J* 2018; 15(1):29-37; 27. Guest, J.F., Fuller, G.W., Vowden, P., Vowden, K.R. Cohort study evaluating pressure ulcer management in clinical practice in the UK following initial presentation in the community: costs and outcomes. *BMJ Open* 2018; 8(7):e021769; 28. Guest, J.F., Fuller, G.W., Vowden, P. Costs and outcomes in evaluating management of unhealed surgical wounds in the community in clinical practice in the UK: a cohort study. *BMJ Open* 2018; 8(12):e022591; 29. Atkin, L., Tickle, J., Wilde, K. Conclusion. *J Wound Care* 2022; 31(Sup8a):S22.