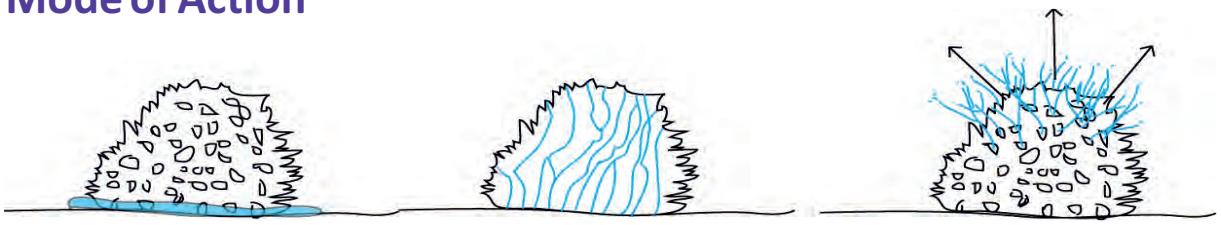
Acapsil® Information Sheet

WOUND CARE

Introduction

- First-in-Class, low risk medical device to support the healing of wounds to close by secondary and tertiary intention.
- White, odourless powder to be applied topically to the wound. A very light, permeable dressing is recommended but can be omitted altogether in difficult-to-dress and moving areas.
- Applicable to all wound types. It can be used on acute and chronic wounds and ulcers with low to high levels of exudate including wounds with infection or necrosis, eg infected post-surgical wounds, trauma wounds, abscesses, burns, diabetic foot ulcers, venous leg ulcers, pressure ulcers etc.
- Wounds halted in the inflammatory wound healing phase exit this phase 60% faster. This leads to an overall reduction in hospital bed days of 31%.
- An average of 3 applications have shown to be sufficient to obtain a clean wound and for the wound to progress into the proliferative stage for healing to proceed.
- Acapsil® strips bacteria of their defences by removing toxins released by pathogenic bacteria and disrupting biofilm. This allows the immune cells to selectively kill the pathogenic bacteria without damaging the healthy (and necessary) micro-flora of the wound.
- This support of the immune system allows for the removal of antibiotic resistant infections without creating new resistant strains.
- Acapsil® supports autolytic debridement.
- Acapsil® should always be stored in a refrigerator (2° to 10°C)

Mode of Action



Absorption **Transport by capillary action** **Evaporation**

Acapsil® consists of tiny, highly porous microspheres that can access all crevices in the wound surface. The exudate is absorbed into the microspheres where strong capillary forces pump it to the Acapsil® surface. Here, the exudate evaporates effectively due to an enlarged surface area. An enzyme lining the pores prevents obstruction.

The microspheres auto-regulate the moisture level on the wound surface ensuring a moist, but not wet, environment thereby protecting the wound against maceration and over-drying.

Similar to Topical Negative Pressure but without the drawbacks

TNP and Acapsil® both remove wound exudate by pumping it away from the wound surface, but Acapsil® is only active if exudate is present. This avoids the risk of vacuum harming the wound bed and causing bleeding complications.

Acapsil® can be used on all wounds from low to highly exuding. It is easy and fast and does not cause pain. It does not require extensive handling, huge dressings, airtight seals, pumps, tubing and canisters. It thus offers the benefits of TNP to wounds not eligible for TNP.

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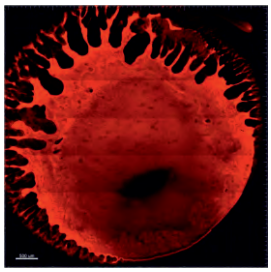
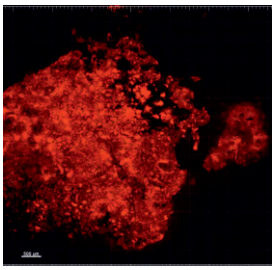
Acapsil® breaks up biofilm - new and mature exposing the bacteria to the immune system





Control - No Acapsil® **Acapsil® applied at 24h**

48 hours old *P. aeruginosa* biofilms

Acapsil® removes bacterial toxins and damages the biofilm.

The immune system can now selectively kill the pathogenic bacteria, while preserving the beneficial natural micro-flora of the wound.

This approach does not rely on antibiotics.

This removes antibiotic resistant infections without creating new resistant strains.

Randomised Clinical Study - 266 Patients

Study design

Wide range of wounds and ulcers with necrosis and tissue infiltration
Comparators: Gentaxane (hydrogel with antibiotic) and Ioddicerin (iodine dressings)
Daily application until achieving a clean wound, ie free of necrosis, pus and excess exudate

Reduction in number of applications to reach clean wound

Acapsil® required only 3 applications compared to 7 for Gentaxane and 8 for Ioddicerin.

60% Acceleration

Wounds and ulcers reach clean state, ie enter Proliferative Healing Phase, 60% faster.
No severe adverse events, wound irritation or sensitisation.

Reduction in Bed-days

	Acapsil® vs. Gentaxane	Acapsil® vs. Ioddicerin
Wounds and ulcers	31%***	39%***
Wounds as sub-group	41%***	44%***