Formulary Information Pack DryMax®

Contents

Introduction

Exudate is produced as part of the inflammatory stage of the healing process to prevent the wound bed from drying out. When a wound is healing normally, the volume of exudate decreases as the wound heals, and is usually clear and straw or amber coloured.

Not all exudate is bad, and exudate is known to assist healing by:

- Providing the correct medium for tissue repairing cells to migrate across the wound bed
- Supplying essential nutrients for cell metabolism
- Enabling diffusion of growth factors for wound healing
- Promoting autolysis (WUWHS, 2007; Gardner, 2012).

In chronic wounds, exudate prolongs the inflammatory phase and can be detrimental to wound healing (Figure 1).

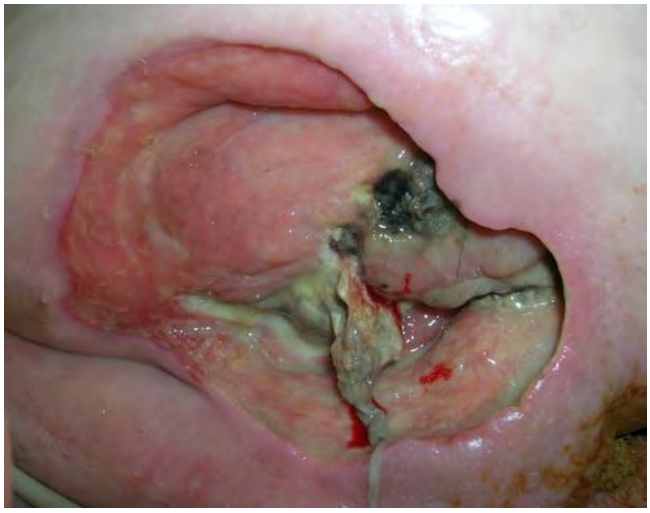

Figure 1. Chronic wound: pressure ulcer on the sacrum, with exposed bone, slough and granulation tissue.

Wound exudate, particularly from chronic wounds, contains not only water, but often cellular debris and enzymes (Chen and Rogers, 1992). This 'cocktail' can be corrosive to the intact skin surrounding the wound (Coutts et al, 2001). Certain MMPs present in chronic wound exudate are detrimental to the extracellular matrix, causing it to break down and preventing cells from migrating across the wound bed. Although present in the exudate of all wounds, these MMPs exist at elevated levels in chronic wounds (Schultz and Mast, 1999), which if left unaltered, can delay healing (Gibson et al, 2009). Chronic wound exudate also lacks the active growth factors found in acute wound exudate (White and Cutting, 2006).

Too much exudate, and/or its composition can delay or prevent wound healing, affecting patients' physical and psychological wellbeing, while placing increased demands on healthcare resources. Effective exudate management can reduce time to healing, reduce dressing change frequency and nurse input, thereby optimising healthcare efficiency (Romanelli et al, 2010). Appropriate choice of wound dressing and involvement of the patient in the plan of care can help to eliminate exudate-related problems (Dowsett, 2008; International Consensus, 2012).

Absorbest technology

Over the recent years there have been further cumulative improvements in DryMax wound care family. DryMax Super is the current formulation and the same product as DryMax Soft, which is an improvement on DryMax Extra. The performance criteria discussed in this Formulary Information Pack applies to DryMax Super. The additional products DryMax Blue and DryMax Border also have the Absorbest technology in their cores.

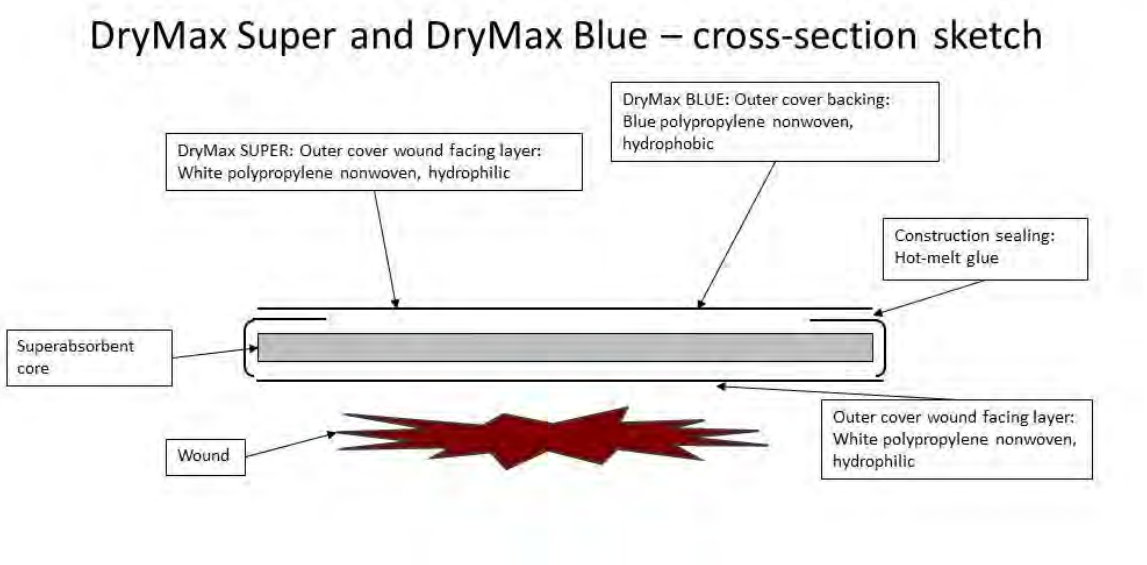

Figure 2. A schematic cross-section of DryMax Super and DryMax Blue

The contact layer absorbs and transports fluid vertically and distributes it evenly into the Absorbest core of superabsorbent polymers. The superabsorbent core absorbs and retains exudate thus minimizing the risk of maceration to the peri-wound skin while maintaining a moist wound environment.

An effective dressing to manage excess exudate should have a number of characteristics:

- High absorption and retention of wound fluid under pressure
- Ability to bind exudate into the dressing irrespective of viscosity
- Prevent wound edge maceration
- Promote wound healing

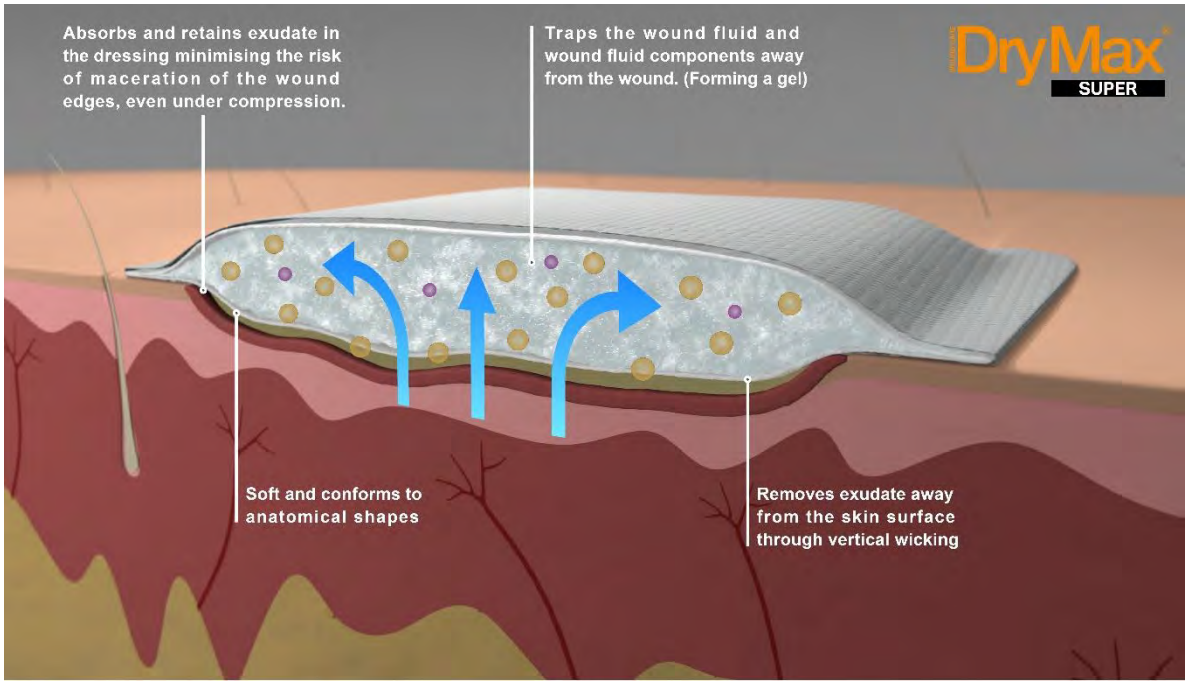

Figure 3. A schematic mode of action for DryMax Super.

DryMax - Absorbency and retention

Independent absorption tests by SMTL were performed and DryMax Super was analysed. The results are presented in table 1 (SMTL, 2020). The table below shows free swell absorbency according to EN 13726-1 and retention capacity according to TM-404 by SMTL.

Table 1 shows that DryMax Super retains 83% of wound fluid after 40mmHg pressure during the retention test.

Table 1. Absorbency and Fluid Retention - DryMax Super 11x10cm (core size 11x7cm).

Sample	Absorbency (g)	Absorbency (g/cm2)	Absorbency (g/g)	Retention (g)	Retention (g/cm2)	Retention (g/g)
1	129.2	1.69	26.31	107.19	1.40	21.83
2	129.37	1.69	26.73	107.10	1.4	22.13
3	131.20	1.71	26.67	108.93	1.42	22.14
Mean (SD)	**129.92 (1.1)**	**1.70 (0.0)**	**26.57 (0.2)**	**107.74 (1.0)**	**1.41 (0.0)**	**22.03 (0.2)**

The official free swell capacity value for DryMax Super is 1.8g/cm2. Free swell value in g/cm2 is less for smaller sizes and higher for larger sizes due to sealing constraints and core-area-ratio. Note: SMTL tests are performed on small size 11x10 cm.

DryMax - Absorption under load

Very often superabsorbent dressings are used under compression bandages in chronic venous ulcers. It is important to use a dressing that can both absorb and retain excess exudate, like a superabsorbent. If optimum compression of 40mmHg at the ankle is applied, this type of dressing is suitable to use underneath. Because under compression, the absorption capacity is reduced but the absorbed exudate will be retained.

In fact, DryMax Super can still absorb wound fluid under this pressure albeit reduced by 50% (SMTL, 2020).

Table 2. Absorbency under load (compression) - DryMax Super 11x10cm (core size 11x7cm).

Sample	Absorbency Under Compression (g)	Absorbency Under Compression (g/cm2)	Absorbency Under Compression (g/g of dressing)
1	57.37	0.75	11.85
2	61.58	0.80	12.22
3	62.50	0.82	12.94
4	69.27	0.90	13.72
5	61.76	0.81	13.06
Mean (SD)	**62.50 (4.3)**	**0.82 (0.1)**	**12.76 (0.7)**

The ability of DryMax Super to absorb large quantities of wound fluid and carry-on absorbing and retaining wound fluid under compression bandages or compression hosiery makes it an ideal dressing for managing venous leg ulcers.

"In the clinical use we could observe the effectiveness of a DryMax in combination with compression therapy on venous leg ulcers. We noticed advantages of comfort and remarkable effects on wound healing". (Meulniere F, EWMA 2012)

DryMax – Wicking exudate

Superabsorbent dressings can often wick vertically very quickly but the design of the dressing blocks further horizontal wicking, meaning a large area of the dressing is rendered unused. DryMax Super has been shown to wick vertically but because of the dressing design, it will wick horizontally as well. This can effectively allow greater intervals between dressing changes and potential for cost savings.

"A reduction of visits can enable the patient to have more independence, and allow clinicians to manage their workload appropriately, including out-of-hours services." (Stephen-Haynes J, 2012)

DryMax – Performance and competitor products

A summary of data on competitor superabsorbent dressings is given in Figure 4. In terms of free swell absorption, retention capacity and absorption of viscous fluid, DryMax Super shows superior or equal results to the compared superabsorbent dressings.

For example, DryMax Super shows higher free swell absorption and better retention than Curea P1 (blue and orange bars in Figure 4) and compared to the UK market leader KerramaxCare®, DryMax Super has 20% more absorption capacity in free swell testing according to EN 13726-1.

Exudate can vary in viscosity from very aqueous to very thick. In bench test with free swell absorption with high viscosity fluid components, the performance of DryMax Super was higher than for Kerramax Care. (grey bars in Figure 4 below).

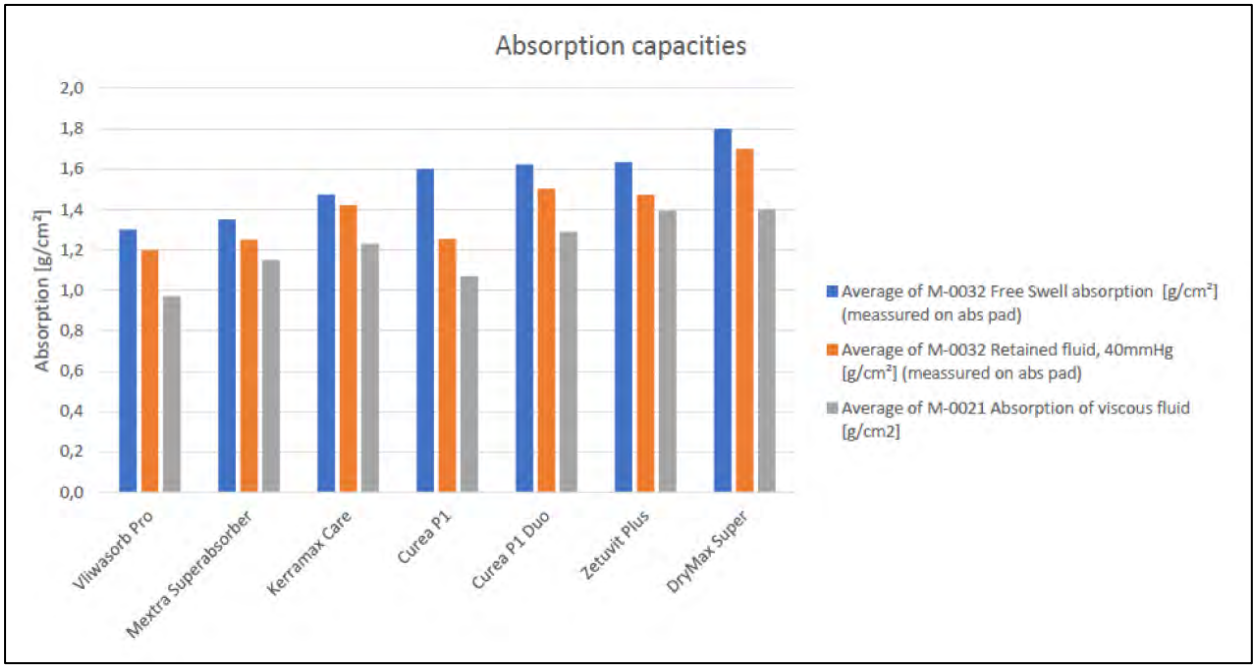

Figure 4. Summary free swell absorption capacities of superabsorbent dressings (according to international standard EN 13726-1 (Data on file, Absorbest).

DryMax – Biofilm and MMP

Biofilms

Wound healing can be impaired and delayed by the presence of microbial biofilms. Biofilms consist of grouped bacterial embedded in an extracellular polymeric substance (Davis L, 2008). Biofilms are difficult to remove physically and by the host defence mechanisms.

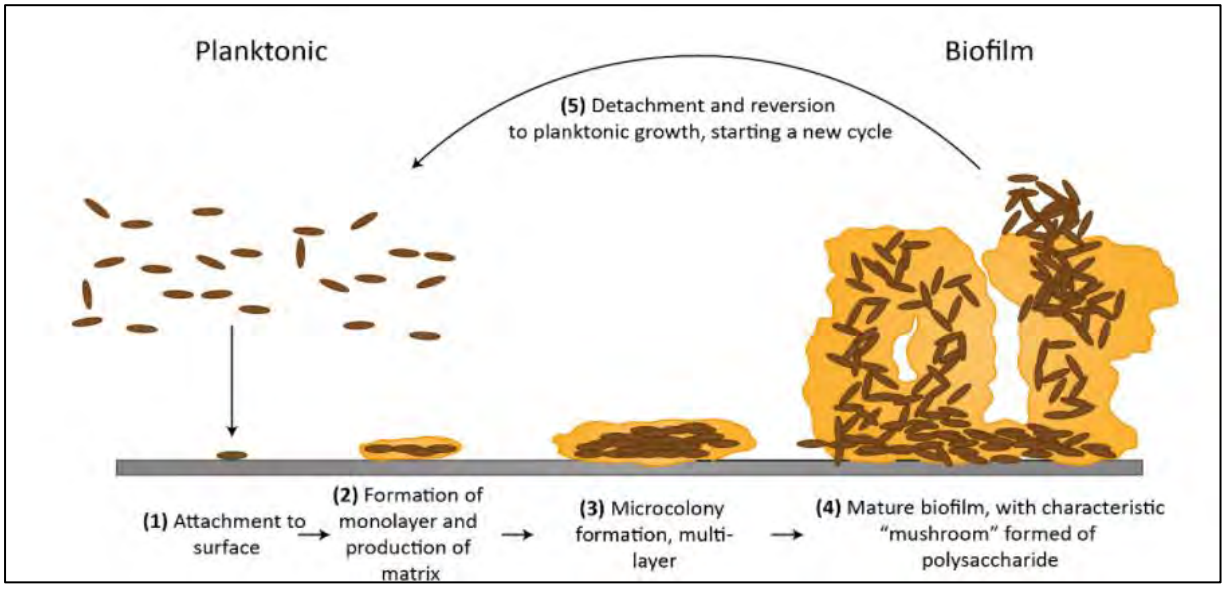

Figure 5. Schematic representation of a biofilm formation. *The formation begins with a reversible attachment of the planktonic cells (brown ovals) followed by the adhesion to the surface (grey)* ***(1)****. The bacteria then form a monolayer and irreversibly attach by producing an extracellular matrix* ***(2)****. Next, a microcolony is formed where multilayers appear* ***(3)****. During later stages, the biofilm is mature, forming characteristic "mushroom" structures due the polysaccharides (4). Finally, some cells start to detach and the biofilm (shown in yellow) will disperse* ***(5)****. (Adapted from Vasudevan, 2014), J Microbiol Exp 1(3): 00014. DOI: 10.15406/jmen.2014.01.00014.)*

Due to resistance issues related to the use of systemic or topical antibiotics, wound dressings have been designed with silver or iodine for example. These antimicrobials are not without concerns regarding resistance. Consequently, other methods have been used to try and reduce bacterial load and shifting a wound from stasis to healing. An example is Sorbact ® adsorption technology where hydrophobic moieties on bacteria are attracted to the hydrophobic material on the dressing. So, when the dressing is removed from the wound, bacterial load is claimed to be reduced (Gentili V. 2012) (Mosti G. 2015).

DryMax in a biofilm test model

In a laboratory study, superabsorbent dressings, including DryMax*, were compared to Sorbact® in their activity against *Pseudomonas aeruginosa* biofilms. This pathogen was selected together with *Staphylococcus aureus* as they tend to be the most common pathogens to delay wound healing (Larkö E, 2015).

The methodology employed investigated bacterial burden in the dressing itself after 24 hours incubation and in the surrounding (acellular) synthetic soft tissue (ASST) model (Figure 6).

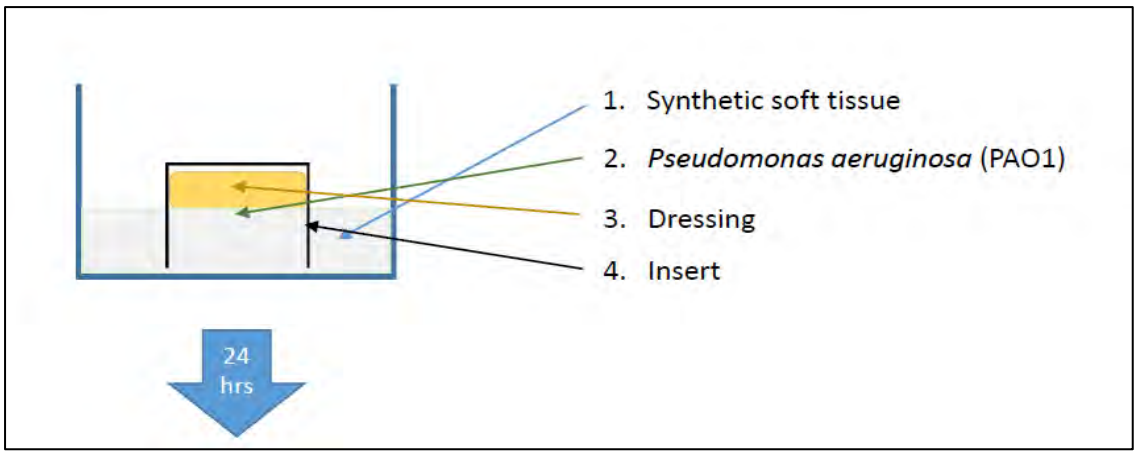

Figure 6. Diagram of methodology. Assessment of zone of inhibition (ZOI) and bacterial burden in the wound dressings and the synthetic soft tissue (ASST).

Test results – bacterial burden

In this test model, metallic silver showed significant reduction in bacterial load. The superabsorbent dressings including DryMax* showed same results as Sorbact.

Often Sorbact® is used as an alternative to silver or other antimicrobial dressings for local treatment of infected wounds. This publication in Journal of Wound Care (JWC), states that the same results were obtained for Sorbact and for DryMax*, when bacterial burden was measured in the wound dressing as well as in the synthetic soft tissue (Figure 7). Further stated in the JWC-publication; to obtain log reduction in bacterial load in the soft tissue, an antimicrobial substance must be added.

The sequestration of bacteria into the dressing and away from the wound bed is purely due to the absorption and retention of wound fluid and the hydrophilic design of the dressing. DryMax* unlike Sorbact® and some superabsorbent dressings, does not claim reduction of bioburden in the wound.

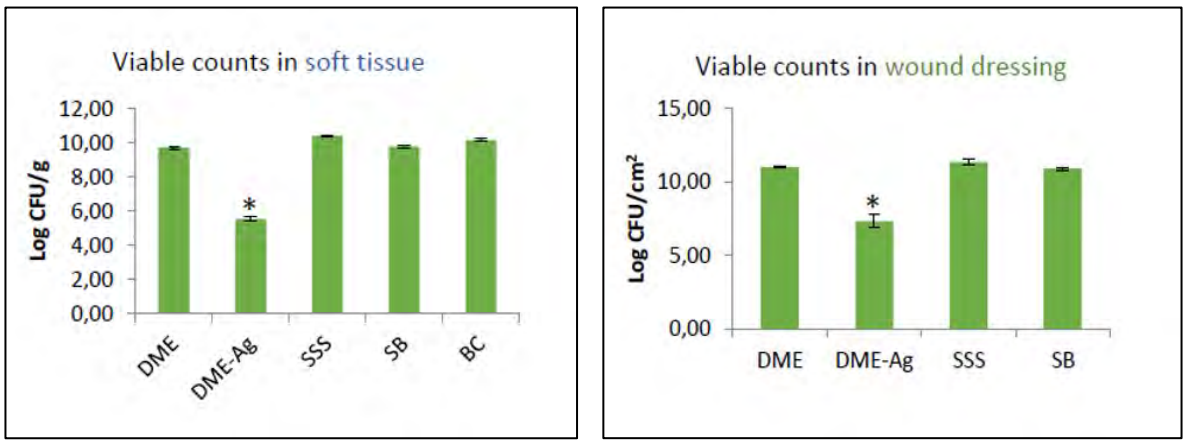

Figure 7. Bacterial load in wound dressings and synthetic soft tissue after 24h's incubation. Results are shown as mean +or- -standard error of the mean. N=3. *DME = DryMax®Extra, DME-Ag = DryMax Extra with silver net, SSS= Sorbion Sachet S, SB= Sorbact®, BC = bacterial control.

Test results – Zone of inhibition (ZOI)

In this model ZOI demonstrates the absorption effect of superabsorbent dressings compared with Sorbact ®. The superabsorbent dressings, including DryMax*, demonstrate that the inoculation of *Pseudomonas aeruginosa* remain in the dressing and not in the surrounding tissue.

Complete ZOI was seen with the superabsorbent dressings. Noticeable was that no ZOI was detected for Sorbact® dressing, indicating bacterial movement and biofilm formation in the synthetic soft tissue.

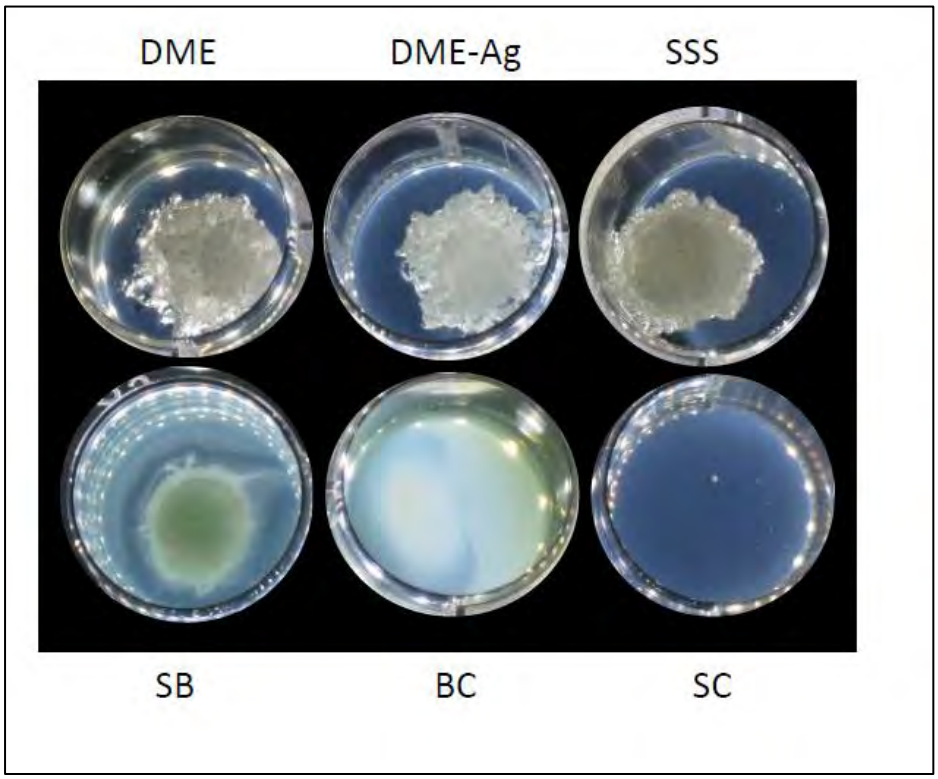

Figure 8. Zone of Inhibition. *DME = DryMax®Extra, DME-Ag = DryMax Extra with silver net, SSS= Sorbion Sachet S, SB= Sorbact®, BC = bacterial control, SC = sterility control

Test results – Inhibition of Biofilm Formation

The degree of inhibition of biofilm formation was determined by the different intensities of opacity and green colour. The green colour is due to the expression of pyocyanin secreted by *Pseudomonas aeruginosa*. It is a toxin that causes cellular damage and in vitro studies have shown it inhibits cell respiration. It has shown to be important in biofilm formation and hence Pseudomonas infection (Lau, G.W. 2004). In Figure 8 above, the lack of green colour can be seen in the soft tissue with the superabsorbent dressings (DME, DME-Ag, SSS).

The authors of this investigation postulated that the lack of pyocyanin in the soft tissue for the superabsorbent dressings including DryMax, indicates that the virulence factor was not produced. It suggests that biofilm formation was inhibited by the superabsorbent dressings possibly by making *Pseudomonas* less virulent even though the sequestered bacteria in the dressing were still active.

MMP

Non-healing wounds are often characterised by high levels of MMPs which can destroy tissues and inhibit growth factors (Eming S. 2008) making healing more difficult (Chen SM, 1997). Superabsorbent dressings including DryMax Super, can absorb and temporarily sequester bacteria and other detrimental substances into the dressing. The inner core will absorb metalloproteinases (MMPs) owing to its hydroactive properties (Wiegand. C, 2013).

DryMax – Clinical performance

DryMax Super is an ideal primary or secondary dressing for a wide range of exuding wounds to support healing.

Examples of wounds:

- Leg ulcers
- Pressure Ulcers
- Lymphoedema
- Diabetic Foot Ulcers
- Burns

Leg Ulcers

Leg ulcers of venous origin are frequently managed by compression bandages, wraps and hosiery. Mainly the former if exudate levels are high. When optimum compression is applied i.e. 40mmHg at the ankle, progressively reducing the compression when wrapping to below the knee, it is important to use a dressing that can both absorb and retain excess exudate, like a superabsorbent. If a non-appropriate dressing is used, the squeeze on the ulcer dressing can result in firstly absorbed exudate leaking back onto the wound bed, or damage to wound edges as absorbed exudate is forced into the wound margins.

DryMax Super, DryMax Blue and DryMax Border are therefore ideal dressings for use on leg ulcers.

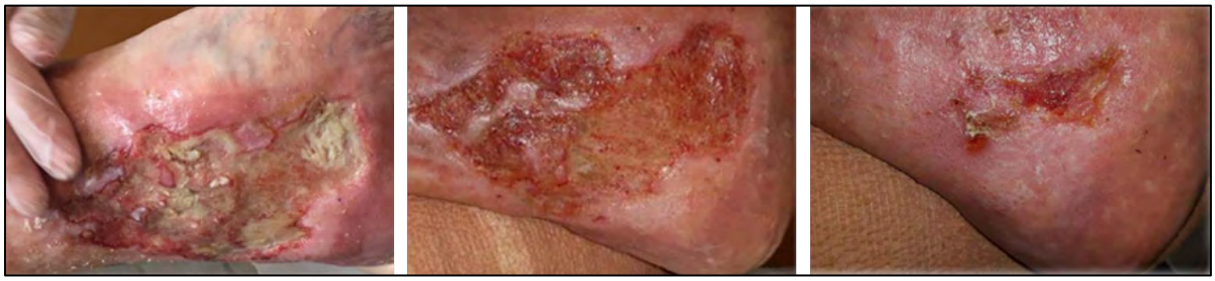

Figure 9. One patient's journey (Data on file, Absorbest).

The photos in figure 9 illustrates the venous leg ulcer of a 77-year-old man. The ulcer had been present for 8 years without healing. Treated with DryMax Super under compression. The wound healed after 170 days of treatment.

Conclusions:

DryMax Super is a suitable dressing to be used on leg ulcers even under compression since it will:

- absorb exudate even under high compression albeit reduced
- retain wound exudate under compression
- wick exudate using the optimum capacity of the dressing, reducing the risk of maceration of wound edges
- have the potential to reduce costs by increasing dressing change interval

Pressure ulcers

As part of a 30 patient case series on chronic wounds treated with DryMax* an 85-year-old woman with a pressure ulcer on her heel, which developed while in hospital for a hip fracture. The foam dressing originally used was oversaturated every day and wound culture showed resistant *Pseudomonas aeruginosa* (Figure 10a). After 8 weeks of treatment with the superabsorbent, the wound surface was much smaller (Hindhede A, 2011). The wound bed lay deeper than the wound edges, with the dressing no longer in direct contact with the wound bed. As there was still a large amount of exudate, an alginate dressing was used to fill the wound cavity and the superabsorbent dressing placed on top. To avoid pressure, the patient's heel was offloaded with a heel protector at night. Thin layers of fibrin were curetted during wound care and a PHMB solution was used to preserve the bacterial balance. After 6 months of treatment with no complications, reepithelialisation was almost complete (Figure 10b).

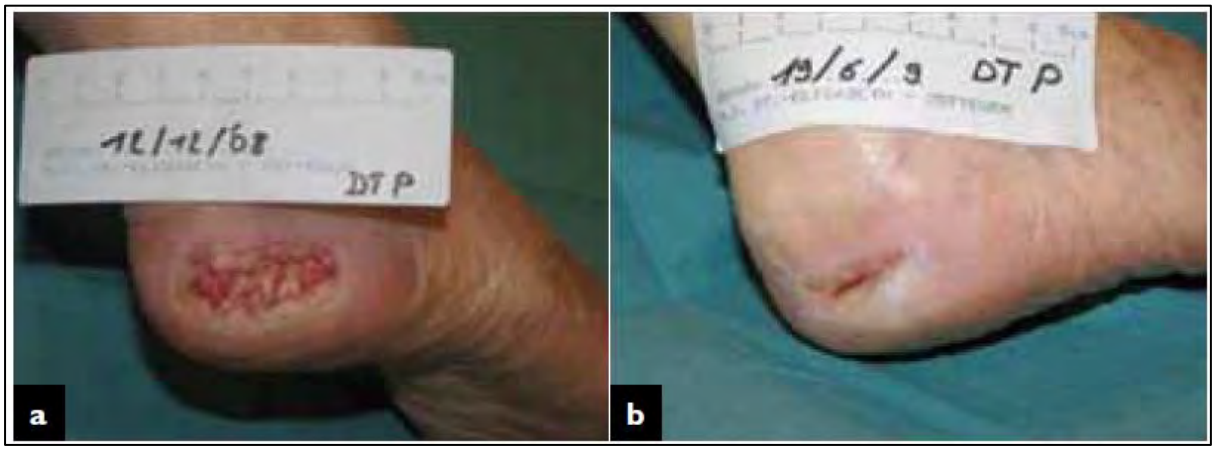

Figure 10. Hospital-acquired pressure ulcer on heel (a), and after 6 months of treatment with the superabsorbent dressing (b) * DryMax Extra. DryMax Super is the current formulation which is an improvement on DryMax Extra.

Lymphoedema

Lymphoedematous legs are commonly treated with compression wear. In the lower limb the ultimate goal of lymphoedema management is to stimulate lymphatic flow via alternative pathways so that lymph fluid is moved from the lymphoedematous regions, circumventing the damaged or obliterated normal pathways and draining excess lymph into the main leg veins.

The traditional treatment methods will vary depending on the patient's physical status and stage of condition. It is widely accepted that compression therapy is an effective component of lymphoedema treatment. The build-up of lymph is often accompanied by accumulation of proteins under the skin that can lead to skin breakdown and the formation of ulcers that produce large quantities of exudate.

DryMax Super can be used under compression bandages or garments to absorb excess exudate.

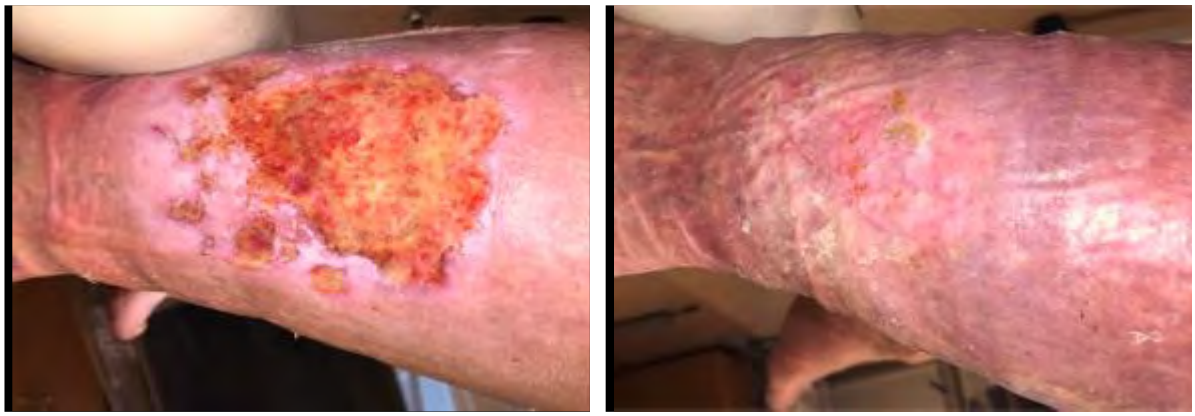

Figure 11. One man's journey with a lymphoedema and an ulcer.

Figure 11 shows a 54-year-old man's journey with a lymphoedema and an ulcer he had for one year before treated with DryMax Super.

Outcomes:

- Wound closure after 150 days with DryMax Super and compression therapy
- Patient could go back to full-time work
- Patient Increased quality of life

Burns

Burn wounds produce significant amounts of exudate in the first 72 hours, which can lead to dehydration and hypothermia, wound and skin maceration and increased risk of infection. Treatment strategies include using appropriate wound dressings. According to clinicians and patients, the ideal burn dressing should be non-adhering, absorbent and prevent infection.

Leaving dressed wounds undisturbed for longer periods of time minimises tissue disturbance and has been proved to help healing. Choosing super absorbent polymer (SAP) wound dressings which are both highly absorbent and retentive of exudate may not only lead to a reduced risk of infection and complications, but also diminish dressing wastage and costs.

Eight patients participated in this open case study. The patients were recruited and selected from a Swedish University hospital burn centre during a period of 20 months because of their exuding wounds, ranging from superficial dermal to full thickness burns.

Standard protocols were applied to patients included in the study. Normal procedure for this type of injury is to cover the wound with silver sulfadiazine cream to prevent infection, followed by a non-adherent wound contact layer covered by fluffy gauze and secured with roller and/or tubular bandages. During the study period, fluffy gauze was replaced with DryMax Super.
The time of participation in the study ranged between two and 12 days with an average length of seven days.

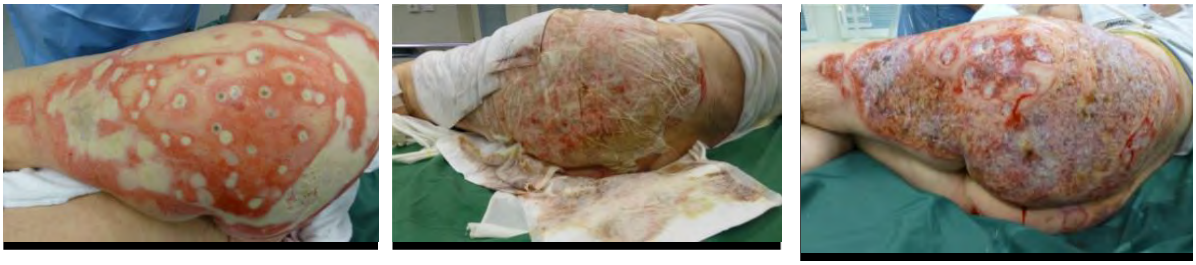

Figure 12. One patient's journey-A woman with contact burns on the left hip, buttock and leg1.5% superficial dermal, 2.5% deep dermal and 3% full thickness burns

The patient and bed in figure 12 remained dry. There was no decrease in skin temperature. The superabsorbent dressing did not stick to the wounds.

Conclusions were that DryMax Super meets the requirements of an ideal burn dressing since it has (Hindhede, A, 2019):

- excellent absorption and retention capacity
- ability to absorb thin watery as well as thicker wound exudate
- can absorb blood unlike other dressings
- can be left undisturbed longer aiding healing

DryMax – Patient satisfaction

In a UK study involving 16 patients with a variety of chronic wounds, patients reported on the following quality of life measures:

- Comfort of dressing
- Conformability of dressing
- Pain at dressing changes
- Dressing wear time
- Inconvenience of leaking or strike-through of wound fluid
- Malodour

10% of patients had necrosis and 90% of all wounds were reported as 'sloughy with areas of granulation tissue' at their first wound assessment on entering the study. All patients had wound exudate described as excessive or high. 42% of the wounds were documented as macerated at the start of the evaluation period and 98% of wound margins and wound beds were healthy or improving by week two (Allymamod A, 2011).

Results:

An example case at the end of the first week's evaluation, where there was a marked improvement in both the wound bed and periwound skin, as assessed using the evaluation sheet, which measured overall wound contraction or reduction of peri wound maceration (Fig 13 and 14)

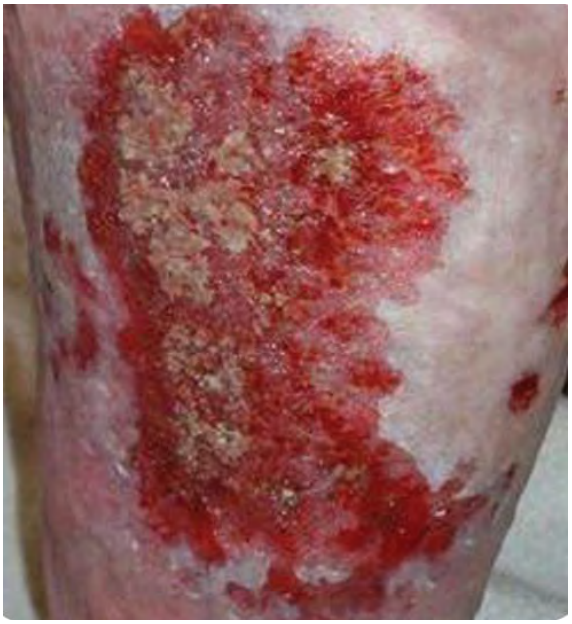

Figure 13. Wound on entry to the study

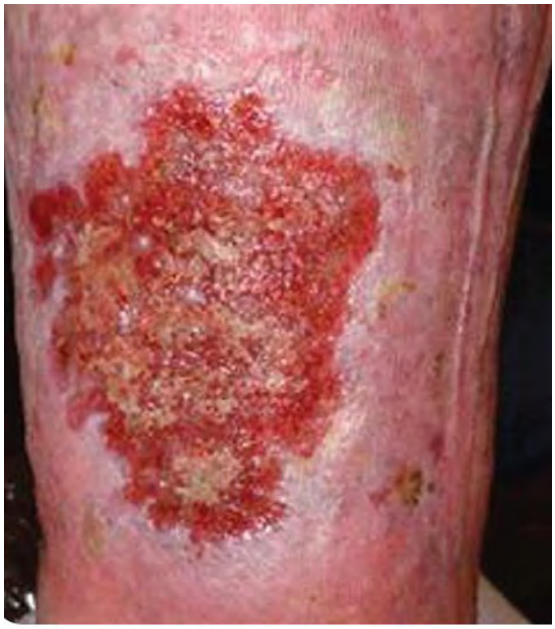

Figure 14. The same wound at week two. Note reduction in maceration and circumference.

All patients (100%) were satisfied or very satisfied with the dressing's conformability, comfort, and lack of leakage at week one. Pain was rated on a numeral rating scale of 1–5. The pain scores were recorded weekly and there was a beginning and end score throughout the evaluation. Three patients had no pain following the application of the dressing, 11 patients recorded mild pain and two patients had not documented a pain score (Figure 15). Only one patient recorded a pain score of 4, which was reduced to 2 at the end of the four-week period.

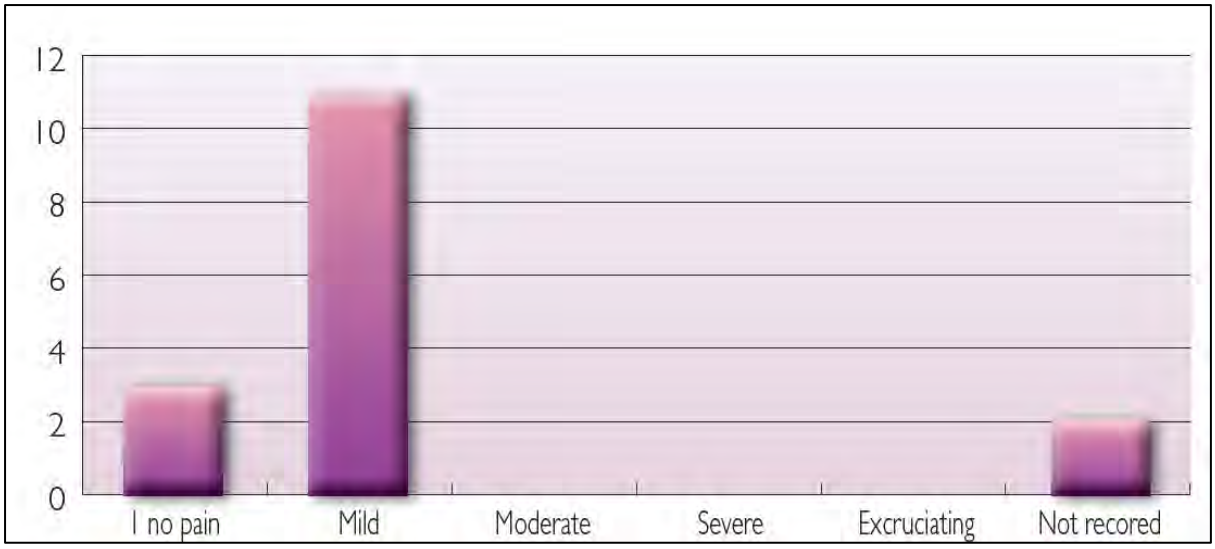

Figure 15. Quality of life pain scores at dressing changes weeks 1–4.

All patients were asked their opinion of the dressing's performance at the end of the study. 94% found the dressing comfortable and conformable. One patient reported leakage before seven days. This patient had lymphoedema and the dressing was managing the exudate with twice-weekly changes. No malodour was recorded after the dressings were applied by any of the patients enrolled in the study.