A new reinforced gelling fibre to reduce exudate pooling: Biatain® Fiber with HexaLock® Technology

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Exudate management remains a key challenge in clinical practice. The main goals of all exudate management interventions are to optimise the wound bed moisture level and to remove exudate that contains bacteria and other substances that can inhibit healing, in order to improve outcomes and patient quality of life. Gelling fibre dressings are a solution for moderate to highly exuding wounds (WUWHS, 2019), and are a well-accepted option in the management of exudate. Biatain® Fiber with HexaLock® Technology (Coloplast) is a soft and sterile gelling fibre dressing intended for use as a primary wound dressing. The dressing has been developed in consultation with clinicians to effectively absorb and retain exudate. The unique HexaLock Technology locks in exudate, minimises shrinkage and forms a cohesive gel that ensures an easy one-piece removal with minimal risk of leaving residue in the wound.

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While exudate plays a key role in the wound healing process, exudate — in the wrong amount, in the wrong place, or of the wrong composition — can cause complications, damage the wound and periwound skin and delay healing (WUWHS, 2019).

The main goals of all exudate management interventions are to optimise the wound bed moisture level as appropriate for the patient, protect the periwound skin, manage symptoms and improve patient quality of life (WUWHS, 2019). Appropriate dressing selection is the main option for exudate management at the wound level. Removal of exudate from the wound bed is a priority, with the aim of achieving a wound bed that is sufficiently moist for healing, but that does not cause problems such as maceration, while treating underlying contributory factors, enhancing patient quality of life, encouraging healing, addressing exudate-related problems and optimising healthcare resource use (Romanelli et al, 2014).

Biatain Fiber with HexaLock Technology is a soft and sterile gelling fibre dressing intended for use as a primary wound dressing. The dressing has been developed to effectively absorb and retain exudate to lock in exudate and bacteria, minimise the risk of gap creation and reduce exudate pooling.

Challenge in clinical practice: exudate pooling

Pooling of wound exudate can occur when exudate is not managed effectively or when the wound bed is not covered by an appropriate dressing. Wound exudate contains an excess level of proteases (e.g. matrix metalloproteinases [MMPs]) and other substances that can inhibit healing, as well as proteins that promote the growth of bacteria. Thus, pooling of exudate promotes bacterial growth, leading to increased risk of infection and subsequent development of biofilm (Young, 2012). Unmanaged exudate pooling within the wound can also cause maceration and damage to the periwound skin, increasing the wound surface area and prolonging healing time (Haryanto et al, 2016; WUWHS, 2019).

The risk of exudate pooling increases when dead space or a 'gap' forms as a result of the dressing not maintaining direct contact with the wound bed – allowing a literal gap where exudate can accumulate. A high amount of exudate increases the risk of leakage, primarily through the lower part of the dressing due to gravity. When applied on a leg, it is the distal part of the ulcer and the periwound skin that are in danger. Highly exuding wounds, cavity wounds and wounds with undermining and a steep angle between the wound edge and wound bed are at a higher risk of dead space

and exudate pooling (Dowsett et al, 2019). Exudate pooling can pose a particular challenge in deeper, undermined, highly exuding and sloughy wounds, such as cavity wounds and fistulas (von Hallern et al, 2020).

The wound gap presents a clinical challenge as there is:

- An increased risk of exudate pooling, which can increase the risk of leakage, maceration and infection (Cutting et al 2009; Young, 2012)
- The potential for inappropriate dressing use; some dressings may not conform fully to the wound bed, leading to exudate pooling or leakage (Dowsett et al, 2019).

Therefore, an optimal wound dressing should conform to the wound bed to manage the gap and reduce exudate pooling, creating a less favourable environment for bacteria (Dowsett et al, 2019).

Gelling fibre dressings

Selection of a suitable product for the right patient, the right wound, at the right time can reduce the risk of infection from external factors, optimise wound healing through maintaining a moist environment, improve patient experiences, reduce frequency of dressing changes and associated pain on dressing change, and potentially reduce workloads for clinicians (NHS, 2018). Dressings can vary widely in their material types, compositions and properties, which can make dressing selection challenging. For highly exuding wounds, properties such as exudate handling, conformability of the dressing, appropriate wear time and patient comfort should be considered.

In wounds that require exudate management, gelling fibre dressings are considered a suitable choice for moderate to highly exuding wounds (WUWHS, 2019). Upon exudate absorption, the fibres form a stable gel, supporting autolytic debridement, tissue granulation and maintaining a moist wound environment (Dabiri et al, 2016).

Gelling fibre dressings are used routinely and are easily available in most health centres/treatment rooms, ward and clinic environments, as well as in operating rooms, along with community services and in patients' own homes (NHS, 2018).

It is important for the wound bed and the gelling fibre to be in direct contact, and additionally for contact to be maintained between the gelling fibre and the secondary dressing. If the gelling fibre dressing shrinks too much, it will lose direct contact, resulting in a gap where exudate pooling can occur (Snyder, 2005).

The development of Biatain Fiber with HexaLock Technology

Biatain Fiber with HexaLock Technology was developed through extensive user insight, research and co-development with over 200 clinicians across the world. Through consultation, the key clinical challenges of using gelling fibre dressings were identified:

1. Not all gelling fibres are good at absorbing and retaining large amounts of exudate, which can lead to maceration
2. Some gelling fibre dressings have a surface shrinkage of more than 36% upon wetting (NHS, 2018), which can lead to gap formation, exudate pooling and maceration
3. Clinicians often experience issues in removing gelling fibre dressings (i.e. there is a lack of wet strength, which leads to the dressing breaking on removal or leaving residue/debris in the wound); this also results in increased time being required to remove the dressing or deal with resultant issues.

Consequently, the ability of gelling fibres to absorb and lock exudate, to have only minimal shrinkage and to form a cohesive gel were rated as important features for these dressings *[Figure 1]*.

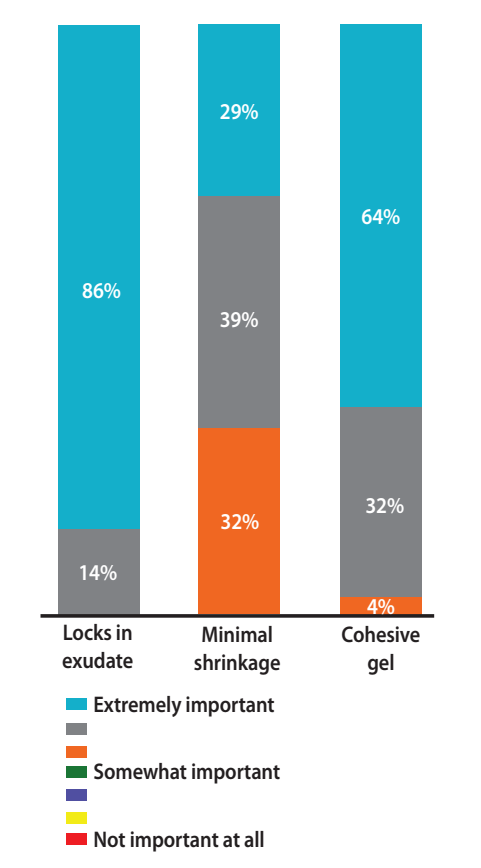
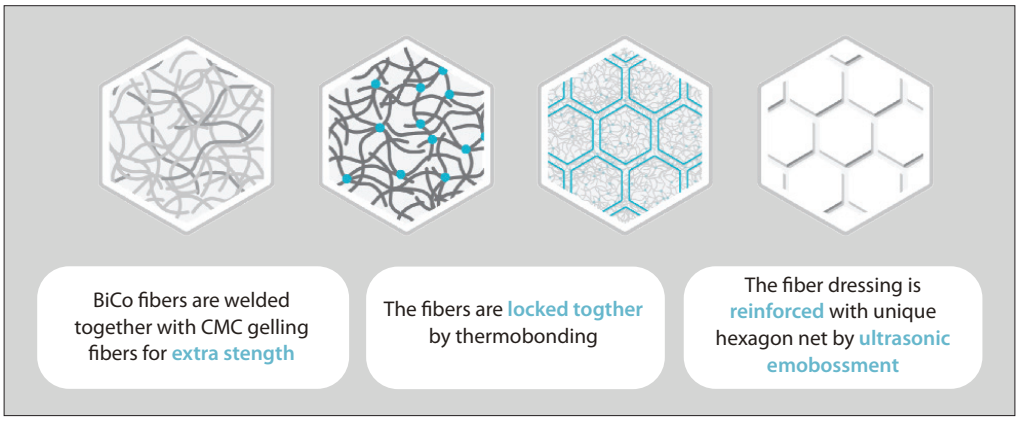


Figure 1. Importance of gelling fibre dressing features rated by clinicians.

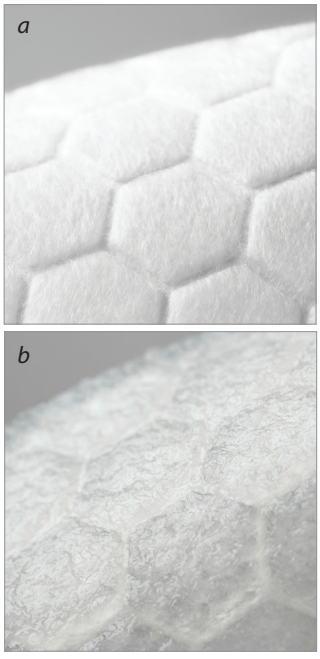
Figure 2. What is HexaLock Technology?



Biatain Fiber with HexaLock Technology was developed to address previously unmet needs in gelling fibre dressings, and perform highly on parameters such as absorption, minimal shrinkage and wet strength. The unique HexaLock Technology integrates the gelling fibres in a reinforced hexagon net, giving Biatain Fiber strength to lock in exudate and slough, in order to reduce exudate pooling and create optimal healing conditions. This also means that bacteria are locked in, reducing the risk of infection. The HexaLock Technology ensures that the dressing keeps its shape, minimises shrinkage (i.e. reducing the risk of a gap forming), and forms a cohesive gel for one-piece removal. See *Figure 2* for more detailed information about HexaLock Technology.

Biatain Fiber received recognition for its outstanding product design as the winner of the Red Dot 'Product Design 2020: Innovative Product' award, which acknowledges products that set new standards and lay the foundation for fundamental industry change (Red Dot, 2020).

Figure 3a & 3b. Biatain Fiber before and after addition of liquid.



Performance of Biatain Fiber on key dressing criteria

Recent in vitro testing (Larsen et al, 2019) assessed Biatain Fiber against the key dressing criteria:

Absorption capacity: tested on two performance parameters: free swell absorption and absorption under pressure, Biatain Fiber has a high absorption capacity and the dressing's capacity for vertical absorption was found to reduce lateral spread and thus reduce the risk of maceration.

Retention capacity: tested using a method quantifying the dressing's ability to retain fluid after being pressurised for one minute at 40mmHg (i.e. full compression) in fully wetted condition, the dressing is able to effectively 'lock in' exudate and associated bacteria.

Gelling characteristics: upon exudate absorption, the fibres form a gel, supporting autolytic debridement, tissue granulation and maintaining a moist wound environment.

Wet strength: important for removal of the dressing in one piece, minimising the risk of any fibres remaining in the wound — tested in the weakest direction using a Tensile Strength test method, with samples wetted in test fluid elongated at 100 mm/min until fracture.

Shrinkage: vital to ensuring the dressing makes direct contact with the wound bed — quantified using planimetry, with the dressing assessed for shrinkage in surface area upon wetting.

See *Table 1* for details about the dressing's performance in testing. In the gelling characteristics test, Biatain Fiber demonstrated fast gelling upon wetting; *Figure 3* shows the dressing before and after addition of liquid.

Table 1. The performance of Biatain Fiber on key testing parameters.

Parameter	Mean	Standard deviation
Free swell absorption	0.23g/cm^2	0.02g/cm^2
Absorption under pressure	0.17g/cm^2	0.01g/cm^2
Retention	0.20g/cm^2	0.01g/cm^2
Wet strength	7.1N/20mm	1.9N/20mm
Surface shrinkage	16%	1%

Overall, Biatain Fiber showed a solid performance on all the key gelling fibre dressing parameters, equal to or better than alternative gelling fibres on all important parameters. The dressing showed a strong ability to absorb and retain exudate, a high gelling performance and wet strength and resistance to shrinkage. The strong performance on these parameters demonstrates that the dressing can effectively

Box 1. Tips for use in practice.

- The packaging makes usage easier, with 1:1 product picture to assess the size required, and a QR code that links directly to an application video for guidance
- It would be worth considering applying the gelling fiber in combination with a foam dressing that conforms to the wound bed and absorbs exudate vertically (e.g. Biatain Silicone). In this way, less wound filler is required and secondly, the conformable foam 'seals' the wound area (von Hallern et al, 2020)
- Biatain Fiber can be cut in any direction to adjust for the individual wound shape

absorb and retain exudate and bacteria, thereby reducing exudate pooling and minimising the risk of infection and maceration. Furthermore, the stable shape minimises the risk of gap creation and exudate pooling and, finally, the cohesive gel ensures easy one-piece removal with minimal risk of leaving residue in the wound (Larsen et al, 2019).

Biatain Fiber in clinical practice

The first clinical evaluation in practice (von Hallern et al, 2020) found Biatain Fiber to be 'particularly excellent' for exudate management, with the ability to absorb and retain large quantities of exudate, with no signs of maceration. The dressing was found to form a cohesive gel and to be easy to remove without causing pain to the patient or leaving any fibre residue in the wound. The dressing performed well in areas of undermining, and the authors of the study suggested that clinicians consider using the dressing in these challenging wounds.

When to use

Biatain Fiber dressings have the capacity to manage large volumes of exudate. They also aid autolytic debridement of debris, necrotic tissue and slough; and they enhance the maintenance of a moist wound environment. They are conformable and can be used to fill wound cavities.

Biatain Fiber was designed and developed in collaboration with clinicians for use in highly exuding, sloughy and cavity wounds, including undermining wounds. To reduce exudate pooling in wounds with a depth of less than 2cm, a conforming silicone foam dressing can be used (e.g. Biatain® Silicone with 3DFit® Technology). Cases have shown that using an absorbent silicone foam dressing (Biatain Silicone), which conforms to the wound bed or to the primary dressing, further reduces the risk of exudate pooling and protects the wound edge and periwound skin from maceration (von Hallern, 2020).

Deeper, undermined, highly exuding and sloughy wounds tend to be more challenging wound types that require the additional reinforced gelling fibre (e.g. Biatain Fiber) to reduce pooling and ensure one-piece removal.

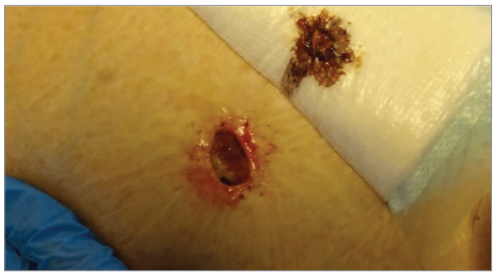
Case studies of Biatain Fiber in practice

Case 1: Post-operative abdomen wound (Bernd von Hallern, 2020)

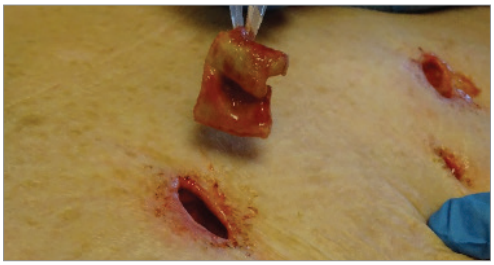
An 82-year-old, immobile patient with dementia resided in a nursing home after receiving a hemicolectomy and ostomy. One of the former drainage points was not healing. The wound diameter was 14mm, and the wound edges were partially undermined: 90°=10mm, 180°=6mm measured clockwise. The wound depth was a maximum of 38mm. The wound edges were thick and rolled with no epithelialisation. There were no signs of maceration at the wound edge or periwound skin. The wound presented medium levels of exudate, with exudate pooling in the base of the wound bed. The wound was rinsed and cleaned with a wound irrigation solution and gauze. Biatain Fiber was applied down to the wound bed, including the undermining areas, and the wound was covered with Biatain Silicone. The dressing was changed after two days. Exudate had been absorbed into the gelling fiber dressing and the dressing was easily removed in one piece.

Before application of Biatain Fiber.

After application of Biatain Fiber.

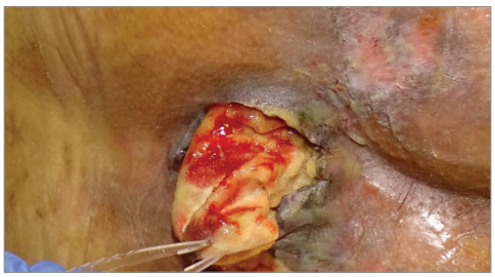


After removal of secondary dressing – Biatain Fiber in situ.



One-piece removal of Biatain Fiber.

After application of Biatain Fiber.



Removal of Biatain Fiber the next day.

Case 2. Sacral pressure ulcer (courtesy of Bernd von Hallern)

A 53-year-old patient with a condition following polytrauma 28 years previously, and a lumbar compression fracture with paraplegia and urinary and faecal incontinence. Recurrent sacral pressure ulcers had developed in the sacrum, coccyx, and ischial area. Various plastic surgeries had been carried out, with the aim of covering the ulcers but, unfortunately, a new pressure ulcer persistently developed.

The patient was in a special clinic for 8 months and underwent a total of 17 operations on the decubitus of the left ischium. During the further course of treatment in the home environment, there was a suture dehiscence with a deep opening of the wound. The wound showed no signs of infection and was necrosis-free upon first application of Biatain Fiber. The wound depth on presentation was 45mm. There was undermining at 12 o'clock of 65mm and 3 o'clock of 75mm. A total of 3 Biatain Fiber dressings (10 x 10cm) were placed into the wound cavity and areas of undermining. The dressings were changed after 24 hours, due to a strong exudate odour. The dressings absorbed all exudate, gelled, kept their shape and could be removed easily.

Case 3: Trans-metatarsal amputation wound (courtesy of Tonny Karlsmark)

A 29-year-old woman, with diabetes mellitus since she was 7 years old and no previous history of diabetic foot ulcers, developed an infection in the fifth toe of her right foot. A trans-metatarsal amputation of the fifth toe was required, and 2 days later, the fourth toe was also amputated. 5 days later, she had an infection in the foot (plantar abscess).

Wound size: 7 x 4.5 x 1.5cm (wound duration: 9 days).

Dressing removal of Biatain Fiber on Day 1.

After 5 days of management with Biatain Fiber, wound size had decreased 33%.

Treatment involved daily debridement, EMLA cream application and dressing change. The patient was prescribed oral antibiotics and advised to offload the foot.

The wound care specialist assessed the wound using the Triangle of Wound Assessment (Dowsett et al, 2015):

- Wound bed: 60% sloughy, 40% granulating tissue; medium level, clear exudate; no signs of infection
- Wound edge: Undermining 1cm at 4 o'clock
- Periwound skin: Normal.

Following assessment, the wound was filled with Biatain Fiber, and a secondary dressing (Biatain Silicone) was applied. After 5 days with Biatain Fiber, sloughy tissue had decreased while granulation tissue had increased. The wound area had decreased from 31.5cm^2 to 21cm^2. Biatain Fiber absorbed the exudate vertically and was easy to apply and remove.

Case 4: Post-traumatic lower extremity wound (courtesy of Deborah Granara)

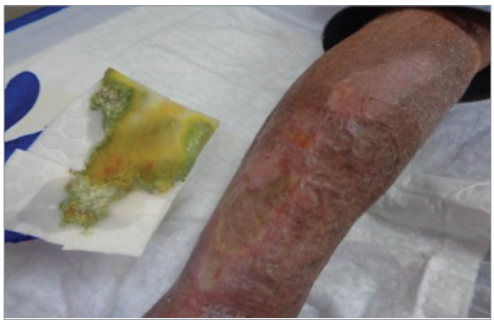
An 86-year-old male patient had a post-traumatic lower extremity wound that was necrotic and highly exuding. He lived with his wife, and had an active lifestyle caring for animals and working the fields in the countryside. He had a complex medical history of peripheral obstructive arterial disease, subjected to revascularisation with moderate hemodynamic compensation (APBI 0.7), atrial fibrillation during new oral anticoagulants therapy and hypertension. The wound had previously been treated with daily collagenase by a GP.

The wound measured 52.5cm^2, and the wound edge was macerated with rolled edges. The management goals were to remove non-viable tissue, manage exudate and protect newly formed granulation and epithelial tissue and the periwound tissue.

Treatment with Biatain Fiber with HexaLock Technology, and a secondary polyurethane foam dressing (Biatain® Non-Adhesive with 3DFit® Technology) was commenced with weekly dressing changes. The first change occurred after 6 days.

Biatain Fiber conformed to the wound bed, absorbed the exudate and limited maceration of the wound edges and periwound skin. The gelling of the dressing helped promote autolytic debridement of the devitalised tissue. The vertical absorption with retention of exudate helped to heal the wound after 2 months of treatment.

Initial wound assessment.



First dressing change (6 days of treatment).

Final review (52 days of treatment).

Case 5: Highly exuding venous leg ulcer (courtesy of Laurent Vierset)

A 64-year-old female patient, who was overweight and a non-smoker, with suspected alcohol consumption, presented with a very highly exuding venous leg ulcer that had been

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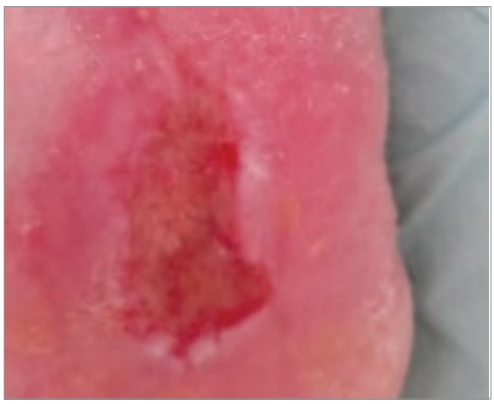
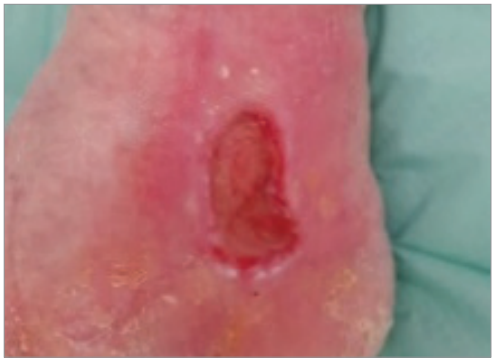


The wound at presentation.

The wound after 12 days.



The wound after 1 month.

present for over 5 months. The wound had previously been treated with 8 layers of gelling fibre, superabsorber, tubular stretch bandage and compression bandaging, with dressing changes twice daily. All layers were stained by exudate, but no further layers were added, as this was the maximum amount that enabled a shoe to be worn. Xylocaine was applied 1 hour before every dressing change, because the patient was anxious about pain.

At presentation, the wound bed was 90% sloughy, with a very high volume of thin exudate. The wound edges were normal, but periwound skin was dry. The wound measured 6.5cm x 3cm (19.5cm^2), with a depth of 1cm. The wound was not painful, but static and failing to progress towards healing.

Five layers of Biatain Fiber were applied, plus a superabsorber, tubular stretch bandage and compression bandage.

After 12 days, the wound area had decreased to 5.5cm x 2.5cm (13.75cm^2), with a depth of 1cm. The wound bed was 80% sloughy and there was still a high level of thin exudate.

After one month, the wound area had decreased to 4cm x 2cm (8cm^2) with a depth of 0.8cm. The wound bed was 70% sloughy with 10% epithelialisation and a high level of thin exudate.

At all dressing changes, there was no maceration of the wound edges or periwound skin. After Xylocaine application, some maceration was seen after 1 hour when the photos were taken; however, when the dressings were removed, there was no maceration (i.e. this was not due to Biatain Fiber).

In conclusion, good progress was made, for a wound that was static on presentation. Over 1 month of dressing use, the wound area reduced by 59%. The dressing showed very good absorption and retention for a patient with a very highly exuding wound. No shrinkage was observed, with very good ability to conform to the wound and to reduce exudate pooling. The dressing was comfortable for the patient to wear and did not leave residue in the wound upon removal.

Summary

Biatain Fiber with HexaLock Technology is a new gelling fibre dressing, developed in consultation with clinicians, designed to effectively absorb and retain exudate and bacteria, minimise the risk of gap creation and reduce exudate pooling. The dressing performs highly on key in vitro dressing criteria, with a strong ability to absorb and retain exudate, a high gelling performance and wet strength, and resistance to shrinkage. In the clinical cases, the dressing showed very good absorption and retention capacity, thereby protecting the wound edges and periwound skin from maceration. The dressing did not shrink in the wounds and stayed in place during wear, ensuring close contact with the wound bed to reduce exudate pooling. Finally, Biatain Fiber created a strong cohesive gel, was easily removed in one piece and did not leave residue in the wounds. WINT