

# Evidence Summary



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# Clinical relevancy

*Biatain® Silicone with 3DFit® Technology offers unique clinical benefits by conforming into the wound bed to match the shape of the wound*

All wounds are different. They vary in shape, size and depth, as well as underlying causes and risk factors. But there are some similarities as well. Many chronic wounds face challenges around effective exudate management. From a 2017 digital survey among 2000 healthcare professionals we found that:

- **42% of chronic wounds are macerated**  
Maceration can delay wound healing and could be caused by dressings spreading fluid across onto healthy skin.
- **24% of chronic wounds have exudate pooling**  
Small pools or pockets of exudate could lead to bacteria growth and possibly infection.

## **2017 Braunwarth<sup>1</sup>**

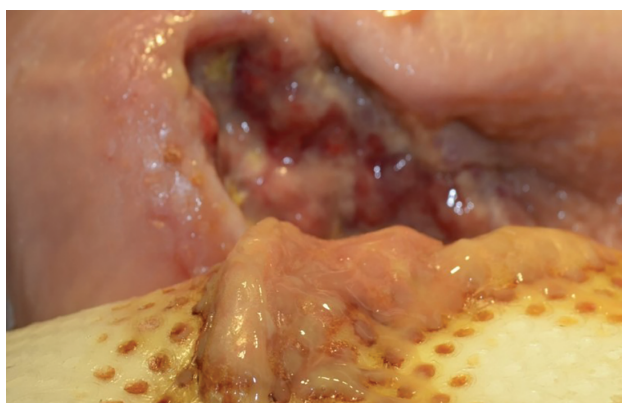
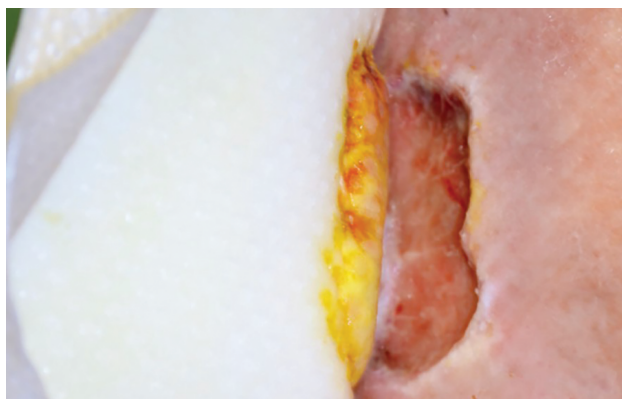
We looked at 104 wounds, and they were all different. But we treated them all with the same product. Biatain® Silicone does not spread fluid across onto the surrounding skin, and it conforms into the wound bed for up to 2 cm to create an intimate fit and reduce pockets of exudate.

The 104 wounds included all types of chronic wounds with different levels of depth and fluid levels, but only Biatain Silicone was used and we found comparable outcomes. In 100% of cases, the dressing had conformed exactly to the shape and depth of the wound, and in 0% of cases did we observe any gaps or any maceration.

## **Conforms into the wound bed**

Biatain® Silicone conforms into the wound bed up to a depth of 2 cm to match the shape of the wound and create an intimate fit.

*In 104 case studies where Biatain Silicone was used, 0% of wounds had any gaps or pooling.*

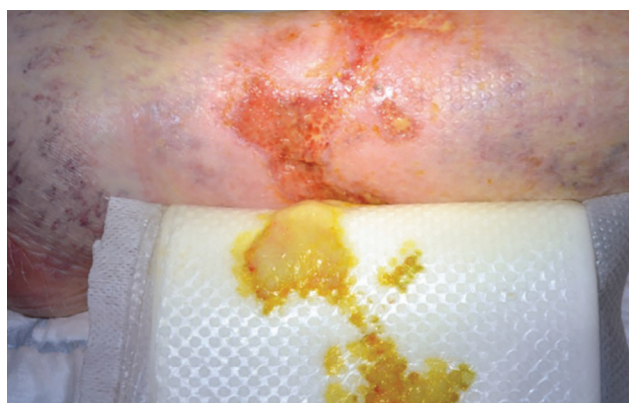




### Vertical absorption

Biatain Silicone absorbs wound fluid vertically, and not across, keeping it away from the surrounding skin.

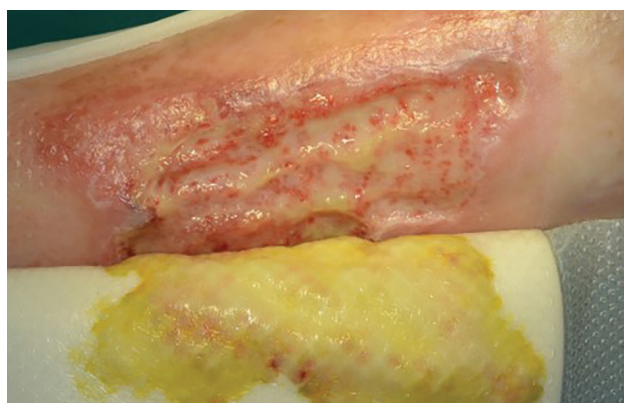
*In 104 case studies where Biatain Silicone was used, 0% of wounds had surrounding skin that was macerated.*



### Retains exudate

Biatain Silicone locks-in and retains exudate, including thicker, more viscous exudate, even under compression.

*Bacteria are trapped and retained within the dressing*, reducing the risk of an infection developing.



# User feedback

*Biatain® Silicone has been rated as 'better' or 'much better' by more than 80% of clinicians*

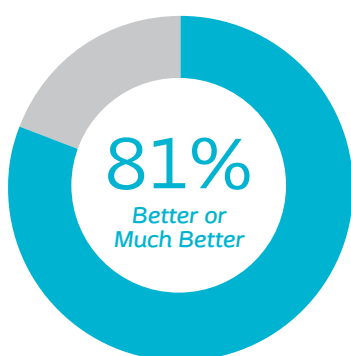
Having a chronic wound can have a huge impact on the person with that wound. This includes pain and distress, but also many physiological factors such as embarrassment, frustration, or even social isolation. Having a wound could also cause loss of employment or the ability to work.

One patient, called Norma, stated that having a chronic wound was worse than her cancer treatment. Her leg ulcer was very painful and took away her ability to drive, severely impacting her quality of life.

She found that the type of treatment made a significant difference, helping her sleep and drive and getting back to her normal life.

To get feedback on living and working with our dressing, we conducted several large multi-centered product evaluations. Across 3 studies, Biatain® Silicone was used on a total of 1,906 patients. In each study, more than 80% of clinicians rated Biatain Silicone as 'better' or 'much better' compared to a previously used foam dressing.

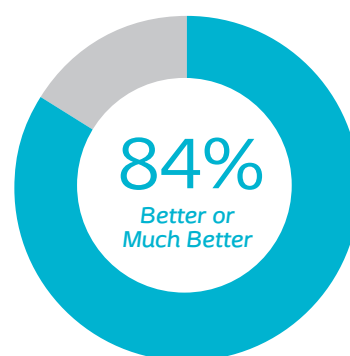
## Overall rating compared to previously used foam dressing



2014 Cartier<sup>1</sup>  
958 patients

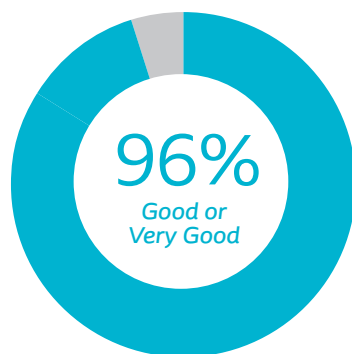


2015 Stadelman<sup>2</sup>  
512 patients

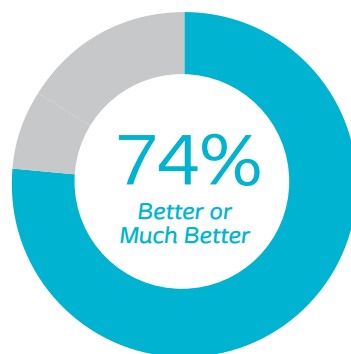


2017 Toxværd<sup>3</sup>  
436 patients

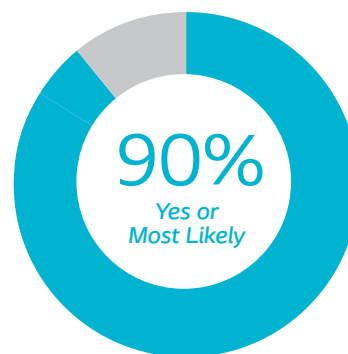
### Product performance<sup>1</sup>



Ability to manage exudate



Absorption compared to previously used foam dressing



Likely to use again

### Patient comfort<sup>1</sup>



Ease of application



Ease of removal



Conformability and flexibility

1. Cartier et al., Wound management with the Biatain Silicone foam dressing: A multicentre product evaluation, Wounds International, 2014.  
2. Stadelman et al., Product Evaluation: New Silicone Foam Dressing for the management of Exuding Wounds, ASWC, 2015.  
3. Toxvaerd et al., Product evaluation of new sizes and shapes of silicone dressing with the treatment of exuding wound, Wounds UK, 2017.

# Comparative data

*Biatain® Silicone has been rated by an independent review as the highest performing dressing in multiple categories*

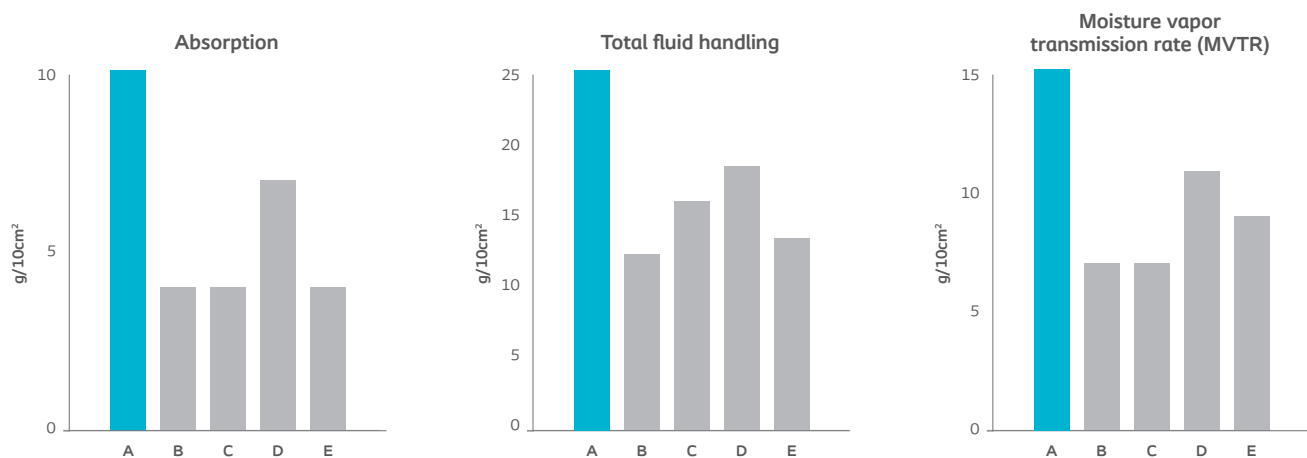
The amount of wound fluid that a foam dressing can absorb can vary between brands. Some brands can absorb more fluid, which means there is less risk of pooling or leakage. Higher absorption could also help to increase the wear time of dressings which in turn could reduce the number of nurse visits and the number of dressings needed. Dressings that absorb less fluid need to be changed more often, and more dressings may end up being used.

- **Absorption:** How much fluid a dressing can absorb over a given time period.
- **Moisture Vapor Transmission Rate (MVTR):** How much fluid can evaporate over a given time period. Higher MVTR typically means that more fluid can then be absorbed.
- **Total fluid handling:** The combination of all properties relating to managing wound fluid.

## 2018 NHS foam review<sup>1</sup>

The National Health Service (NHS) provides most of the healthcare in England (population 66 million), with a budget of approximately \$140 billion per year. The Clinical Evaluation Team (CET) is an independent, clinically driven review group for the NHS, tasked with providing guidance for clinicians and procurement specialists to secure the best quality product at the best price.

In their 2018 independent review of foam dressings, Biatain® Silicone has been rated by the CET as the highest performing dressing in multiple categories, including Absorption, MVTR, and Total Fluid Handling. The comparison was made between 20 brands of silicone foam dressings, including Allevyn Gentle Border, Allevyn Life, Mepilex Border, and Aquacel Foam.



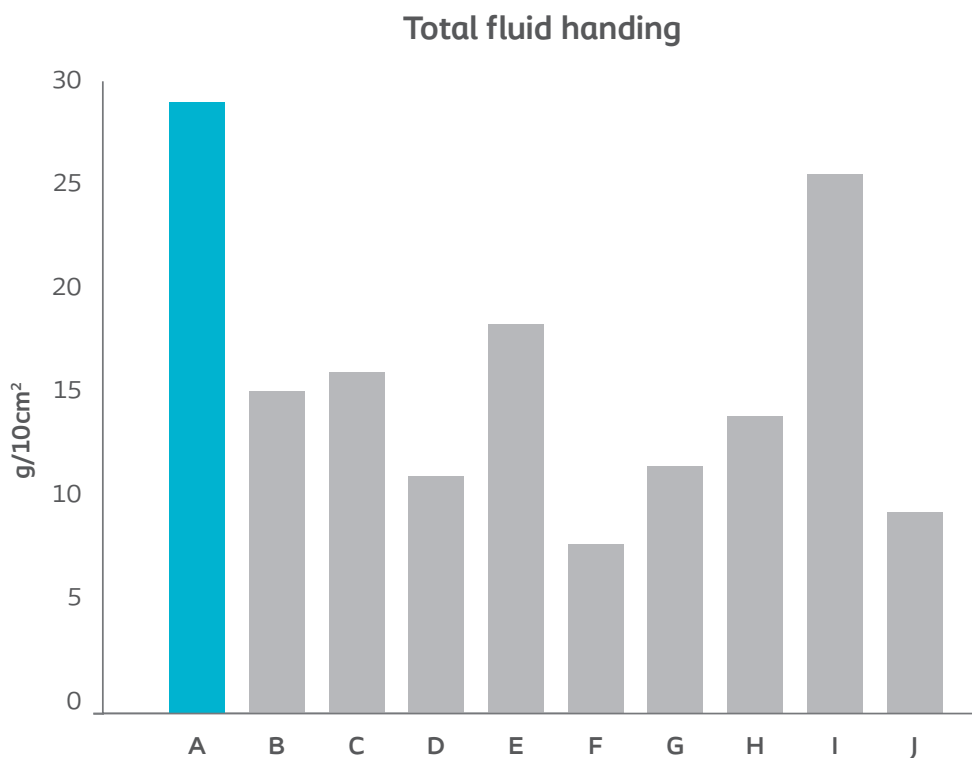
(A) Biatain Silicone (Coloplast), (B) Allevyn Gentle Border (Smith & Nephew), (C) Allevyn Life (Smith & Nephew), (D) Mepilex Border (Mölnlycke), (E) Aquacel Foam (ConvaTec)

## 2019 Nielson<sup>2</sup>

Coloplast sought to understand the true performance of Biatain® Silicone fluid handling capacity compared to other foam dressings available in the market. To get a fair and accurate reading, we used the same lab and the same test method as the market leader.

A statistical comparison was made of Biatain Silicone against 9 competitor products regarding absorption, moisture vapor transmission rate (MVTR) and total fluid handling capacity.

The mean total fluid handling capacity of Biatain Silicone is significantly higher compared to all competitor products (p-value<0.0001). Compared to the market leader, Biatain Silicone offers 77% higher fluid handling.



(A) Biatain Silicone (Coloplast), (B) Mepilex Border (Mölnlycke), (C) Mepilex Border Flex (Mölnlycke), (D) UrgoTul Border (URGO Medical), (E) Cutimed Siltec B, (F) Aquacel Foam Adhesive (Convatec), (G) Allevyn Gentle Border (Smith & Nephew), (H) Allevyn Life (Smith & Nephew), (I) Sorbact Foam Gentle Border (Abigo Medical) and (J) DragoFoam haft sensitive (Dr Ausbittel and Co).

# Cost effectiveness

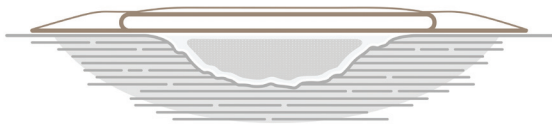
## *Biatain® Silicone can be used on its own instead of multiple dressings*

The treatment of chronic wounds comes with a high cost for both the patient's well-being and the healthcare facility's budget. Dressing costs play a role in managing limited budgets, and finding a balance with clinical outcomes can be difficult.

At dressing changes, using a single dressing instead of multiple dressings could reduce material costs, increase patient comfort, and improve the efficient use of nursing time.

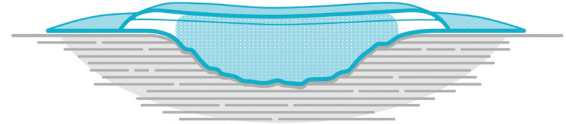
Using dressings that reduce risk factors that could delay healing, could further help the budget by reducing complications and setting chronic wounds onto the right path towards healing. This can make a difference in the short term, and in the continuity of care for these patients.

**80% of chronic wounds** are less than 2 cm deep. In many cases these wounds are treated with both a primary 'filler' dressing and a secondary 'cover' dressing, whereas they could be treated by just one dressing instead of multiple dressings.



### **Average depth of chronic wounds**

0.46 cm Venous leg ulcer  
1.06 cm Pressure ulcer  
0.74 cm Diabetic foot ulcer



### **Biatain® Silicone conforms up to 2 cm**

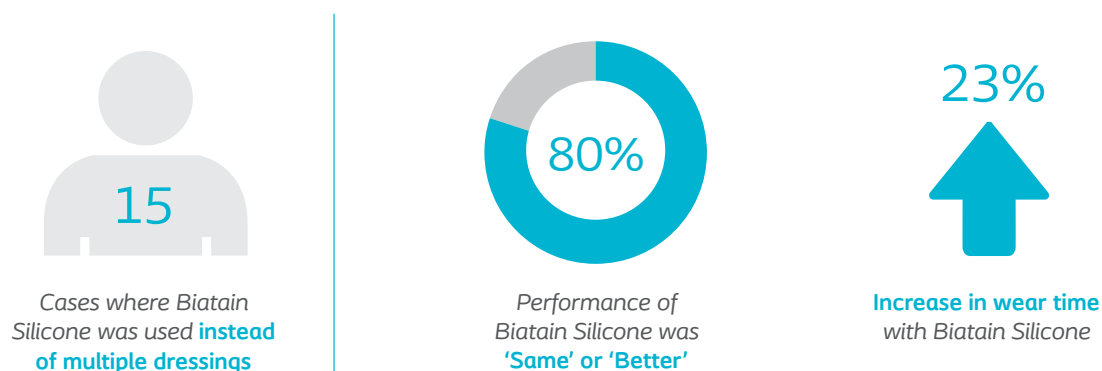
*Biatain Silicone conforms into the wound bed up to a depth of 2 cm to match the shape of the wound and create an intimate fit*

## **Biatain Silicone can be used on its own instead of multiple dressings**

Using Biatain® Silicone could eliminate the need for a primary 'filler' dressing. The two studies on the next page compare the use of just Biatain Silicone to a combination of multiple dressings, looking at clinical performance, wear time, and cost savings.

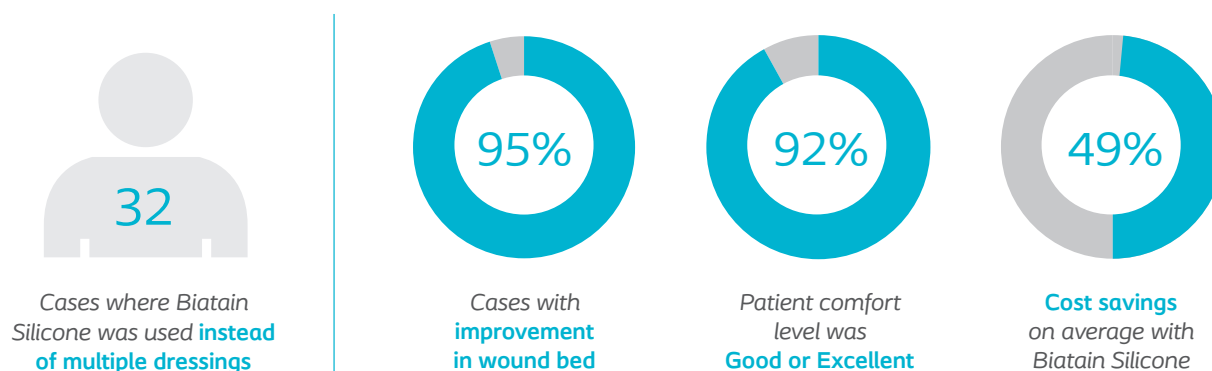
### 2018 Young<sup>1</sup>

In a 15-patient trial on wounds with depth, the performance of Biatain® Silicone (on its own) was measured against previous treatment of multiple dressings. In all cases, a dressing regime of multiple dressings was replaced by just using Biatain Silicone. In addition to cost savings from using fewer dressings, in **80%** of cases the performance of Biatain Silicone was rated as same or better. At the same time, the dressing wear time had **increased by 23%**.



### 2019 Wilson<sup>2</sup>

In 32 cases, Biatain® Silicone was used instead of treatment with multiple dressings. Improvement in wound bed was recorded in **95%** of cases, improvement in wound edge in 95% of cases, and improvement in periwound skin in 87% of cases. There was no change in the wear time. **92%** of patients reported that the dressing was very comfortable. For the cases where a filler was saved, the average cost saving was **49%**.



1. Young et al, Case study report of the effective use of a conforming foam dressing with 3DFit Technology® on wounds up to 2cms in depth, without the need of a filler dressing, Wounds UK, 2018.  
2. Wilson et al., A case series to consider the clinical effectiveness, patient satisfaction and potential health economic benefits of a silicone foam with 3DFit Technology® in the management of wounds, Wounds UK, 2019.



# Clinical outcomes

## Venous leg ulcer<sup>1</sup>

**Patient description:** This was a 76-year-old woman with a moderately exuding mixed venous/arterial leg ulcer.

**Symptoms:** The wound duration was 10 weeks and it measured 37 × 28 mm at baseline. The base of the ulcer showed the partial presence of fibrin and the periwound skin was normal.

**Protocol:** The patient received Biatain® Silicone and graduated, multilayer compression bandaging. All dressing changes during the study period were routine.

**Outcome:** After two weeks of treatment the wound showed good progress with a reduction in size to 34 × 25 mm and the wound bed was 100% granulating. At three weeks the wound had further reduced in size to 28 × 18 mm. The wound was completely healed at seven weeks. The dressing was very easy to apply and remove, had good absorption capacity and conformed very well to the wound bed. The patient found the dressing very comfortable.



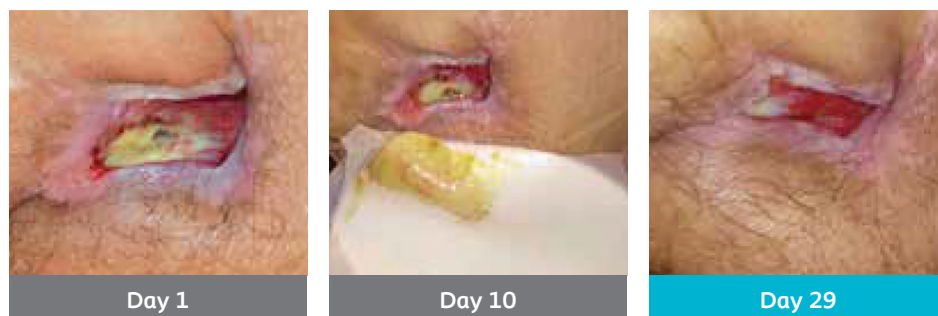
## Pressure ulcer<sup>2</sup>

**Patient description:** 52-year-old tetraplegic with multiple sclerosis.

**Symptoms:** Recurring pressure ulcer over the left ischium after flap surgery.

**Protocol:** Biatain Silicone Sacral was used for exudate management and was changed every two days.

**Outcome:** Within 29 days of treatment with Biatain Silicone, his wound size was reduced by nearly 50%.





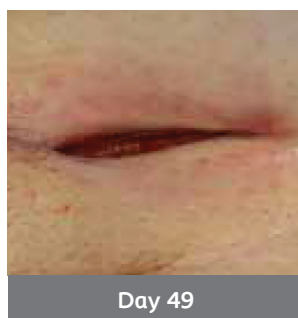
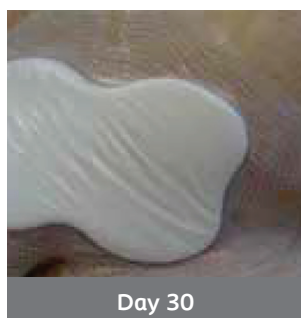
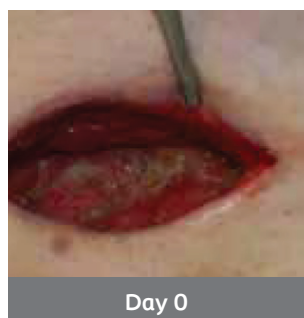
### Post-operative wound<sup>3</sup>

**Patient description:** 49-year-old underwent re-operation after a herniotomy. An abscess was found and the wound tissue was partially necrotic. The necrotic tissue was removed during surgery.

**Symptoms:** The wound was left open to heal by secondary intention.

**Protocol:** As the wound was deeper than 2 cm, Biatain<sup>®</sup> Silicone was initially combined with a wound filler. Upon signs of healing, Biatain Silicone was used on its own.

**Outcome:** The exudate was properly managed and no leakage was observed. The wound edge and periwound skin were protected and no maceration observed. After 97 days, the wound was healed.



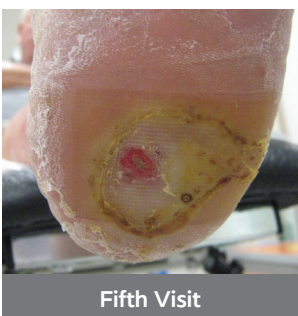
### Diabetic foot ulcer<sup>4</sup>

**Patient description:** 60-year-old male suffering with type 2 diabetes and peripheral vascular disease (PVD).

**Symptoms:** Presented with a heel ulcer from a blister on the left heel and a dehisced wound on the left leg.

**Protocol:** Biatain Silicone was changed every 5 days initially but after 3 weeks this was reduced to once a week. His foot was off-loaded with a removable cast/boot.

**Outcome:** The heel ulcer initially measured 6.2 cm x 3.3 cm and within 10 days it had reduced to 3.9 cm x 2.2 cm, a 42% reduction in area. The leg wound reduced from 1.9 cm x 0.7 cm to 0.9 cm x 0.5 cm, a 34% reduction in area.



3. Von Hallern, Biatain Silicone case study series, Coloplast, 2018.

4. Thomas et al., Smooth Sleek and Secure, Evaluating a Silicone Foam on Diabetic Feet, Wounds UK, 2013.





# Biatain® Silicone portfolio with 3DFit® Technology

💧—💧💧 Exudate Level

## Biatain Silicone



Item #	Size	Units
33434	3 x 3" (7.5 x 7.5 cm)	10
33435	4 x 4" (10 x 10 cm)	10
33436	5 x 5" (12.5 x 12.5 cm)	10
33437	6 x 6" (15 x 15 cm)	5
33438	7 x 7" (17.5 x 17.5 cm)	5
33400	4 x 8" (10 x 20 cm)	5
33401	4 x 12" (10 x 30 cm)	5

💧—💧 Exudate Level

## Biatain Silicone Lite



Item #	Size	Units
33452	2 x 2" (5 x 5 cm)	5
33453	2 x 5" (5 x 12.5 cm)	5
33444	3 x 3" (7.5 x 7.5 cm)	10
33445	4 x 4" (10 x 10 cm)	10
33445	5 x 5" (12.5 x 12.5 cm)	10

## Biatain Silicone Sacral



Item #	Size	Units
39000*	Sacral 9.8 x 9.8" (25 x 25 cm)	5
39001*	Sacral 6 x 7.5" (15 x 19 cm)	5

## Biatain Silicone Multishape



Item #	Size	Units
39010*	Multishape 5.5 x 7.6 (14 x 19.5 cm)	5

## Biatain Silicone Heel



Item #	Size	Units
33406	Heel 7 x 7" (18 x 18 cm)	5

For more information, visit [www.biatainsiliconeus.com](http://www.biatainsiliconeus.com)

\* To order in Canada use product codes 33405 (Sacral 25 x 25 cm), 33404 (Sacral 15 x 19 cm), and 33408 (Multishape 14 x 19.5 cm)  
All other product codes are the same.

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