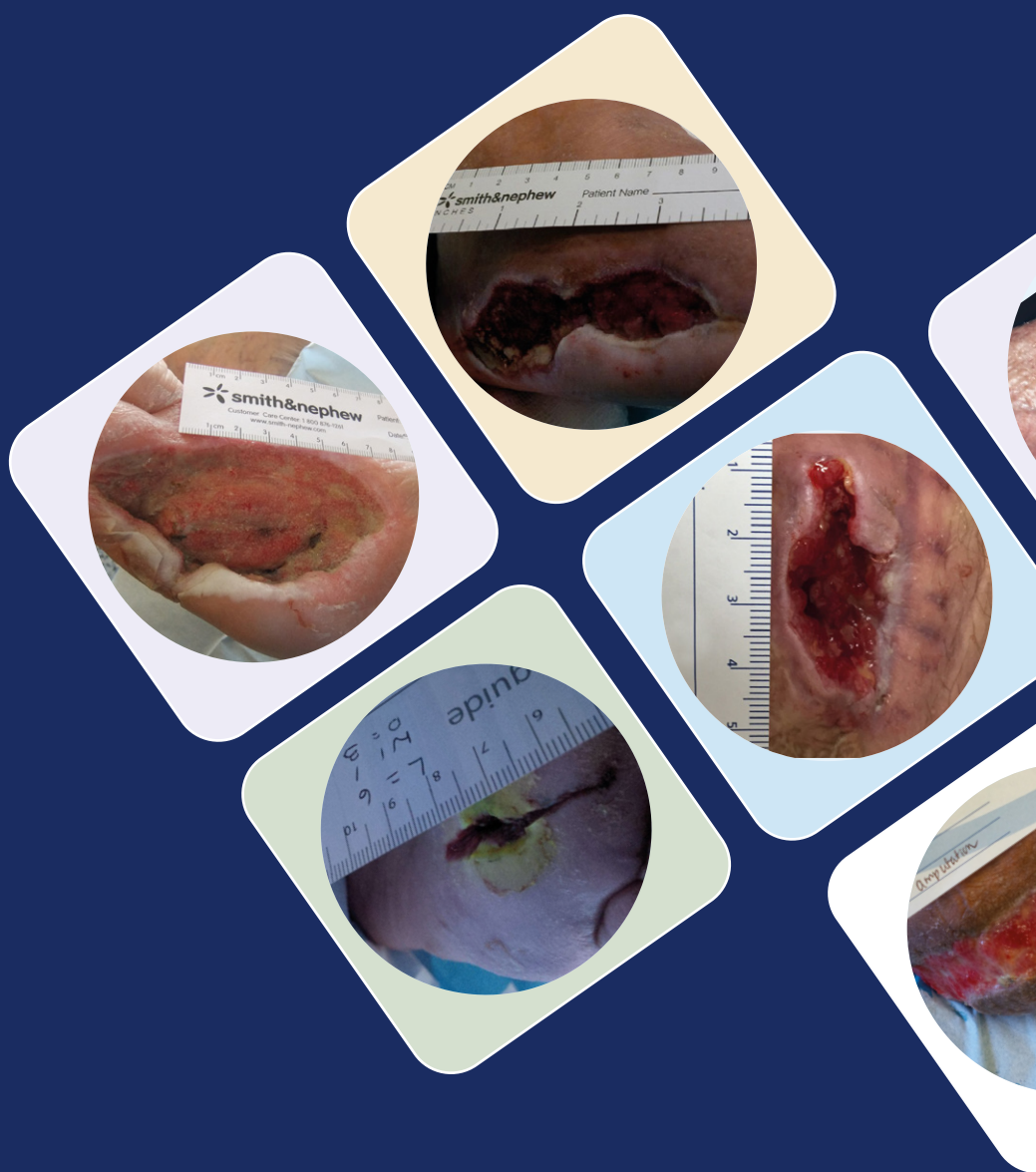


INTERNATIONAL  
**CASE STUDIES**

# Retrospective chronic and post-surgical wound case series: Understanding RENASYS™ TOUCH

CASE STUDIES SERIES 2020



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In these cases, RENASYS™ TOUCH was used with other wound care products. As with any case studies, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

## The latest advancement in NPWT device evolution

Negative pressure wound therapy (NPWT) in its modern form has been shown to be effective in the management of chronic and surgical wounds (Vig et al, 2011; Krug et al, 2011). The technology of NPWT devices has evolved continuously since its first inception. Early pumps were very basic in terms of their functionality and as time has progressed, the sophistication, capability and usability of the devices has continued to improve. Traditional NPWT is effective in treating acute, sub-acute and chronic wounds, and animal studies suggest intermittent therapy has potential for promoting faster growth of granulation tissue compared to continuous therapy (Morykwas et al, 1997).

RENASYS™ TOUCH Negative Pressure Wound Therapy System is the latest advance in the evolution of NPWT devices. This new NPWT device has enhanced usability, as exemplified by a touchscreen graphical user interface (GUI) and enhanced functionality, such as improved troubleshooting capability and an adjustable compression rate feature (Figure 1). The combination of RENASYS TOUCH and the range of RENASYS NPWT dressing kits has been shown to produce a mean wound area reduction of 55% and wound volume reduction of 80% versus baseline in 4 weeks (Forlee 2018). In addition, where wounds present with an infection management challenge, ACTICOAT™ FLEX 3 Antimicrobial Barrier Dressing can be used in conjunction with RENASYS TOUCH.

A recently completed clinical trial has further demonstrated the functionality, usability and efficacy of RENASYS TOUCH (Forlee et al, 2016; 2018). In addition, a series of case studies (beginning on page 4) covering a variety of wound types, show the range of uses for RENASYS TOUCH in combination with various dressing kits.



Figure 1: RENASYS™ TOUCH Negative Pressure Wound Therapy System graphical user interface

**Contributor:**  
**Martin Forlee,**  
 Kingsbury Hospital,  
 Cape Town, South Africa

## A CLINICAL TRIAL WITH RENASYS TOUCH

A prospective, randomised, open-label, multi-centre study was carried out to assess the clinical efficacy, safety, functionality and device performance of the RENASYS TOUCH portable NPWT system. Eighty-one patients were randomised to either variable intermittent or continuous therapy. Seventy-one patients were available for analysis: 35 intermittent, 36 continuous. Patient demographics were similar in both groups (mean age between 61.3 and 58.6 years, mean BMI between 30.2 and 31.7 kg/m<sup>2</sup> for the two study groups). Patients had a variety of wound types suitable for treatment with NPWT, mostly located on the foot or lower leg. A summary of the wound characteristics at baseline is presented in Table 1.

	<b>Variable Intermittent Therapy</b>	<b>Continuous Therapy</b>
Number of wounds	35	36
% of wounds in lower limbs	71.4%	63.9%
Chronic wounds	10	14
Subacute wounds	22	15
Acute wounds	3	7

Continuous NPWT setting was most frequently set at -120 mmHg (30% of users) or -80 mmHg (31% of users). In the adjustable intermittent pressure mode, the negative pressure most frequently oscillated between a high set point of -120/-80 mmHg for 10 minutes and a low set point of -25 mmHg for 2 minutes.

Patients were treated with NPWT for a maximum of 28 days. Clinicians could choose whether to apply foam or gauze wound fillers with or without a wound contact layer as deemed clinically necessary. Wound healing, device usability and functionality aspects were assessed at each dressing application and throughout the treatment period.

## WOUND HEALING

As a result of treatment with RENASYS TOUCH, there was a significant overall reduction in wound volume and area from baseline ( $p < 0.001$ ) (Table 2) with no difference between the groups. Wounds exhibited a significant increase in healthy tissue from baseline (20%,  $p < 0.001$ ), and 31/71 patients (43.7%) reached readiness for closure by the end of the 28-day study period. Wounds achieving readiness for closure were evenly distributed between the two groups: variable intermittent 15/35 (42.9%) and continuous 16/36 (44.4%).

## PATIENT COMFORT

Generally, reported pain levels were low. There was a significantly lower level of reported pain from patients using continuous therapy as opposed to intermittent therapy, both on initiation of treatment (no pain for 90.6% of the patients in the continuous therapy group and for 65.3% of the patients in the variable intermittent group) and removal (no pain in 83.3% and 62.7% of patients, respectively) of NPWT dressings. Both therapy modes were regarded as comfortable during wear at more than 99% of dressing changes.

Table 2. Wound healing	
	Overall (n=71)
Mean % reduction in wound area	54.8%
Mean % reduction in volume	80.3%
Mean % increase in healthy, viable tissue	20%

**ACCEPTABILITY OF DEVICE BY PHYSICIANS**

RENASYS TOUCH is the latest advancement in NPWT device evolution. This new NPWT device has enhanced usability, as exemplified by a touch screen graphical user interface (GUI; Figure 1). The therapy mode can be switched between continuous and variable intermittent mode using a therapy-mode toggle. General clinician acceptability of device functionality was >90% for all parameters assessed (Figure 2). Using the GUI, clinicians found the set-up of the device to be 'very easy' in 97.1% (variable intermittent group) and 100% (continuous group) of the cases. The level of portability of the device was rated as 'acceptable' by 97.1% (variable intermittent group) and 100% (continuous group) of the physicians. All physicians (100%) rated as 'acceptable' the management of exudate by the device canister (scale: acceptable/not acceptable).

Alarms are an important safeguard during use of NPWT. Where alarm conditions were observed, the alarm audibility was rated as 'acceptable' in most interventions.

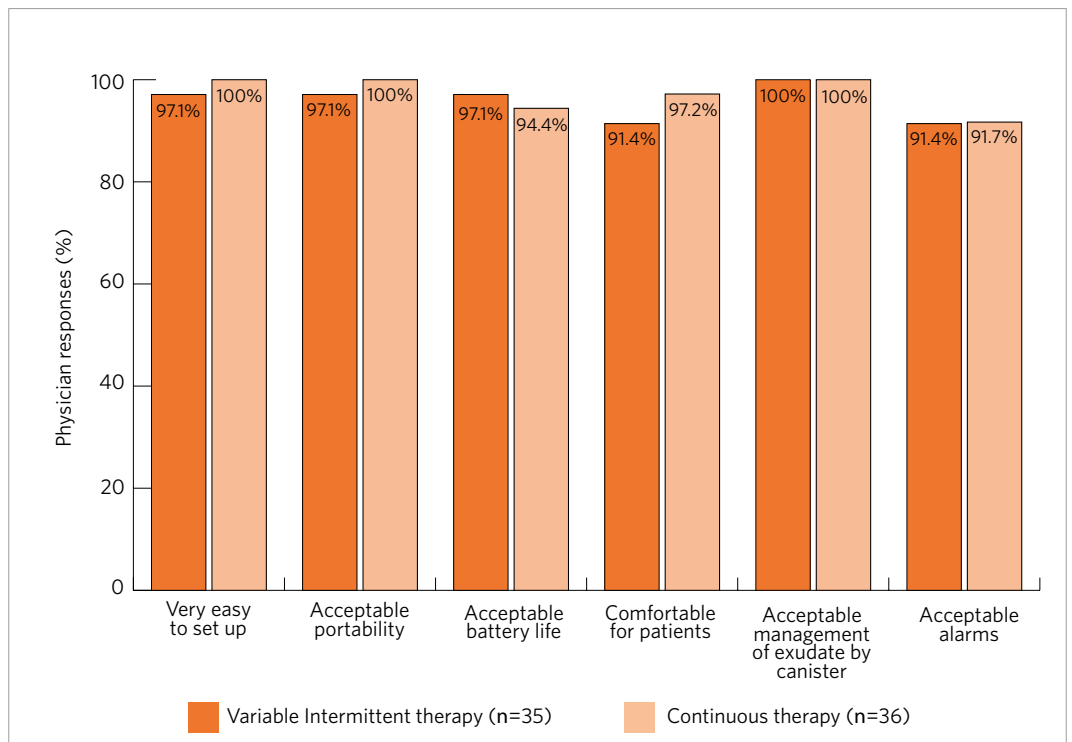


Figure 2: Clinician ratings of device functionality by treatment group

## CONCLUSION

The new portable RENASYS TOUCH device is effective in the treatment of all types of open wounds. RENASYS TOUCH is functional and easy to use for clinicians, and provides a variety of therapy settings, to allow for tailoring of wound management to individual patient needs and pain thresholds. New features of the device, such as the GUI, are user-friendly and easily understood by clinical staff. The ability to combine device settings and dressing options allows for patient- and wound-specific therapy which assists healing, even in complex wounds and patients.

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## CASE 1: CO-USE OF VERSAJET™, RENASYS™-F AND ACTICOAT™ FLEX 3 TO PROTECT AGAINST INFECTION

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

An 83-year-old male with a history of peripheral vascular disease, anaemia and steroid use as a result of osteoarthritis, presented with a 2-week-old post-surgical wound on the foot following a minor amputation. Systemic antibiotics being given at baseline were stopped, as there was no evidence of wound infection at that assessment. The wound had a sloughy and unevenly contoured wound bed at presentation and was debrided using VERSAJET™ Hydrosurgery System.

### MANAGEMENT AND OUTCOMES

Due to the debridement, wound depth was 20mm at the first wound assessment (day 3). Some signs of possible infection appeared following the cessation of antibiotics and, as a result, ACTICOAT™ FLEX 3 was applied as a wound contact layer with the aim of reducing bioburden\*. RENASYS™-F foam dressing was applied as the wound filler.

Pain was controlled with analgesic, but was grade 2 (out of 10, with 10 being highest imaginable pain), even in presence of analgesic. In order to manage patient pain on dressing application, the compression rate was adjusted to medium and the patient reported the dressing as comfortable.

At day 28, the wound was progressing normally to healing and had reduced in area by 53% and in depth by 60% since the initiation of therapy with VERSAJET, RENASYS-F and ACTICOAT FLEX 3. The signs of infection had resolved during this combined therapy without the need for further systemic antibiotics.

### CONCLUSIONS

The balance between negative pressure rate and patient comfort can be difficult for clinicians to navigate. In this case, adjusting the continuous pressure rate down helped the patient to feel the dressing was comfortable, and allowed the wound to significantly progress towards healing. In addition, signs of clinical infection resolved using the combination of wound care therapies.

\*ACTICOAT FLEX 3 can be used for a period of up to 3 days.

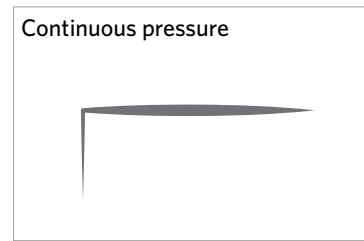
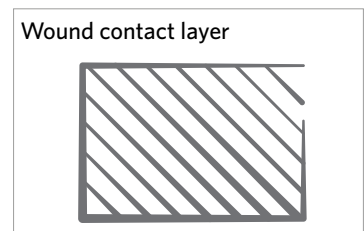
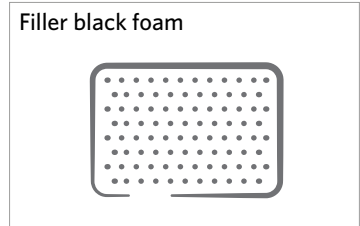


Figure 1: Day 3



Figure 2: Day 28

## CASE 2: USE OF RENASYS™-F FOR RAPID GRANULATION TISSUE FORMATION

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

A 77-year-old male with type 2 diabetes presented with a very deep post-surgical wound.

### MANAGEMENT AND OUTCOMES

RENASYS™-F foam was used as the wound filler material. Signs of possible infection were present at day 0 and as a result ACTICOAT™ FLEX 3 was applied as a wound contact layer.

At baseline, some contact dermatitis was observed as a result of previous bandaging. This rapidly resolved following the application of RENASYS TOUCH. The periwound skin was dry and flaky at the beginning of therapy, but this improved throughout the course of therapy and the surrounding skin was considered healthy at the end of the therapy.

At first dressing change, the visible signs of infection had resolved. No clinical infection developed through the course of therapy. ACTICOAT FLEX 3 use was continued throughout therapy, as the patient was at elevated risk for infection\*.

Although the patient was experiencing pain with his wound, he reported the RENASYS device as comfortable throughout therapy. At the end of therapy, the wound had reduced in area and depth by 83.2% and 92%, respectively, and was making good progress.

### CONCLUSIONS

Despite an elevated risk of infection, the use of ACTICOAT FLEX 3 resolved signs of infection, which did not reappear throughout the treatment period. In addition, RENASYS was judged by the patient to be comfortable, and the device was gentle on the fragile and previously damaged periwound skin.

\*ACTICOAT FLEX 3 can be used for a period of up to 3 days.

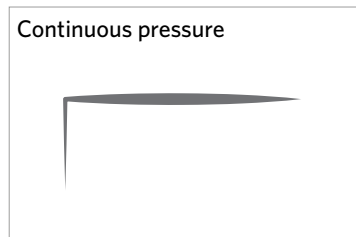
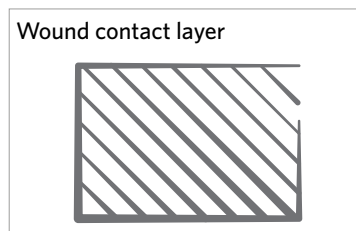
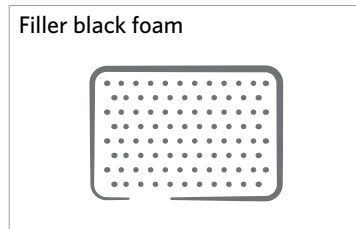


Figure 1: Day 0

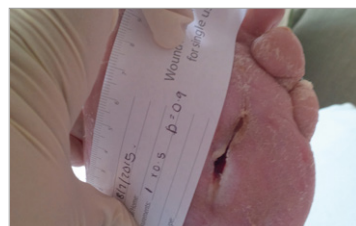


Figure 2: Day 26



## CASE 3: USING NPWT VARIABLES TO RESPOND TO CHANGES IN PATIENT PAIN

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

A 49-year-old male with type 1 diabetes presented with a lower extremity, sub-acute wound originally arising from a postsurgical wound, that had failed to heal. The wound had been present for over 9 weeks.

### MANAGEMENT AND OUTCOMES

Before application of RENASYS™ TOUCH, the wound had been very painful, scoring 8 out of 10 on the visual analogue scale (VAS) for pain (with 10 being the 'worst imaginable' pain). After application of RENASYS TOUCH, pain levels were typically lower at around 3 or 4 out of 10 on the VAS.

NPWT was applied in adjustable intermittent mode for the first 14 days of therapy and was well tolerated, with good wound progression. At around 14 days, an increase in wound pain was reported. To minimise wound pain, intermittent therapy was changed to continuous therapy for the remainder of the treatment duration. Wound pain thereafter returned to the lower levels. The patient reported the RENASYS system to be comfortable throughout therapy.

At day 0 the wound displayed signs of infection and, as a result, ACTICOAT™ FLEX 3 was applied as a wound contact layer, with the goal of helping to reduce bioburden\*. At the end of therapy the wound was progressing normally to healing, with a 100% reduction in wound depth and a 58.5% reduction in wound area.

### CONCLUSIONS

The ability to adapt therapy gives the clinician options with regard to patient tolerability of NPWT. As a result, the patient reported comfort with having RENASYS in place. In addition, using the continuous option allowed the system to stay in place, which resulted in resolution of wound depth and significant progress towards closure.

\*ACTICOAT FLEX 3 can be used for a period of up to 3 days.

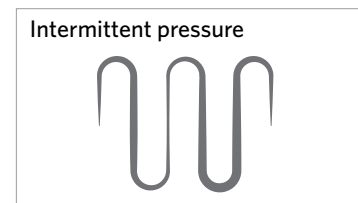
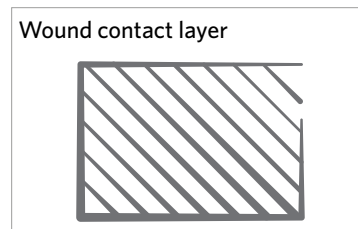
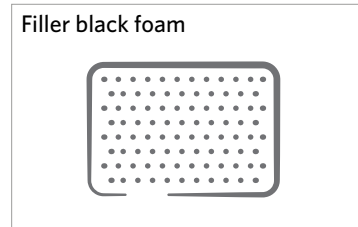


Figure 1: Day 0



Figure 2: Day 28

## CASE 4: USE OF ACTICOAT™ FLEX 3 TO COMBAT SIGNS OF INFECTION

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

A 79-year-old male with peripheral vascular disease, type 2 diabetes and immunosuppression presented with a post-surgical wound on the heel that had been present for 4 weeks.

### MANAGEMENT AND OUTCOMES

The wound had undergone a partial dehiscence and exhibited signs of clinical infection, including necrosis and inflammation of the periwound skin. Sharp debridement was carried out. To combat the signs of infection and to reduce bioburden, ACTICOAT™ FLEX 3 was applied beneath the RENASYS™-F foam wound filler. Adjustable intermittent pressure was applied at -120 mmHg for 10 minutes, followed by -25 mmHg for 2 minutes.

All signs of clinical infection had resolved by day 16. Throughout therapy, the inflammation in the periwound skin resolved and was no longer apparent at the final assessment (day 28). ACTICOAT FLEX 3 was applied throughout the 28 days of therapy\*.

At day 28, the wound was progressing towards healing and had reduced in area and volume by 88.5% and 40%, respectively.

### CONCLUSIONS

In a high-risk patient with a complex wound, the use of ACTICOAT FLEX 3 successfully resolved signs of infection and inflammation in the periwound skin. The use of RENASYS TOUCH helped a partially dehisced wound progress towards healing, and achieve the treatment goals.

\*ACTICOAT FLEX 3 can be used for a period of up to 3 days.

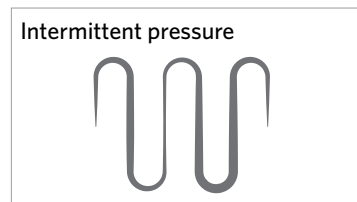
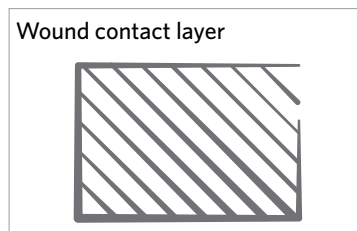
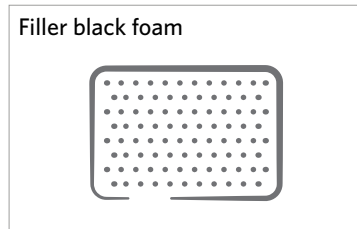


Figure 1: The wound at presentation



Figure 2: The wound following treatment

## CASE 5: KICK-START PROGRESSION OF A STALLED POST-SURGICAL WOUND

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

A 57-year-old male with impaired renal function, anaemia, controlled type 2 diabetes and a history of peripheral vascular disease presented with a partially dehisced post-surgical wound on the heel that had been present for 44 days.

### MANAGEMENT AND OUTCOMES

Oedema and inflammation in the peri-wound skin were present at baseline. The wound was considered at risk of infection and, as a result, ACTICOAT™ FLEX 3 was applied as a wound contact layer\*.

The wound was treated with RENASYS™-F wound filler. Continuous NPWT was applied at -100 mmHg.

After the 29-day treatment period, the inflammation and oedema had resolved, and the periwound skin was considered healthy.

### CONCLUSIONS

In a patient with a stalled, partially dehisced wound at high risk for infection, the therapy combination demonstrated to be effective and allowed for healing of the periwound skin. The use of ACTICOAT Flex 3 helped to resolve the visible signs of infection.

\*ACTICOAT FLEX 3 can be used for a period of up to 3 days.

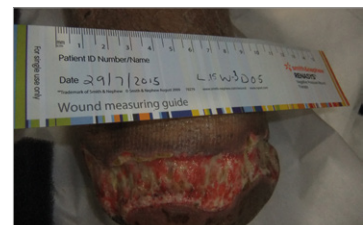
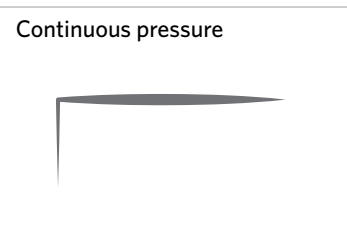
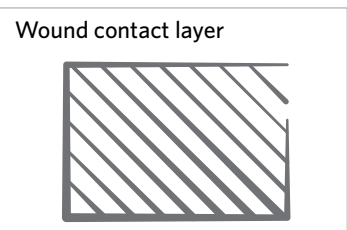
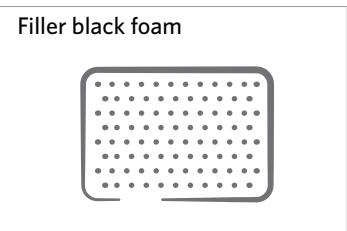


Figure 1: Day 0



Figure 2: Day 29

## CASE 6: USE OF RENASYS-F TO ENCOURAGE RAPID IN-FILL OF A SUB-ACUTE WOUND

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

A 24-year-old patient with no significant medical history presented with a sub-acute wound of 2 weeks' duration on the lower leg.

### MANAGEMENT AND OUTCOMES

The wound was treated with RENASYS™-F foam, and NPWT was applied using continuous -120 mmHg pressure. The patient was experiencing very little pain with the wound, allowing use of the high negative pressure.

The moderately contoured wound progressed to being flat during therapy. There were no signs of infection at any point during therapy.

Over 16 days of treatment, wound area decreased by 81.9% (39% per week) and volume resolved entirely. At this point, the wound had made sufficient progress such that it no longer required treatment with NPWT.

### CONCLUSIONS

The use of high negative pressure allowed a deep wound not complicated by comorbid factors to progress towards healing such that NPWT could be discontinued after just 16 days, and the wound could be allowed to heal by secondary intention.

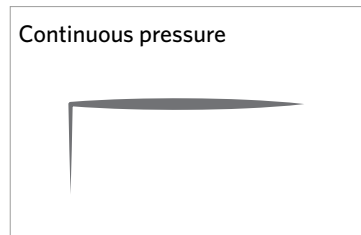
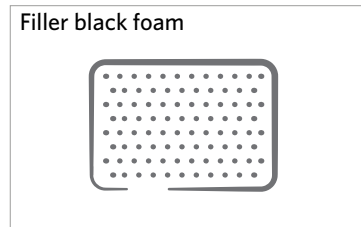


Figure 1: Day 0



Figure 2: Day 16

## CASE 7: CHANGING VARIABLES TO HELP MANAGE A PAINFUL WOUND

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

A 77-year-old female presented with a venous leg ulcer (VLU) of 4 weeks' duration. The patient was experiencing severe wound pain with a score of 8 out of 10 on the visual analogue scale (VAS), with 10 being the 'worst imaginable' pain.

### MANAGEMENT AND OUTCOMES

RENASYS-F was initially applied using the adjustable intermittent therapy mode with set points of -120 mmHg (10 minutes) to -25 mmHg (2 minutes). At the first wound assessment, the patient was continuing to experience high levels of pain (VAS 8) and, as a result, the set points were reduced to -80 mmHg and -25 mmHg, at the same intervals previously used. The pain experienced between dressing changes reduced to a VAS score of 5.

However, high levels of pain were experienced throughout therapy. To respond to wound pain, foam was initially substituted with gauze, and the therapy mode was changed to continuous mode, with a set point of -80 mmHg. The compression rate was also reduced to low.

At day 9, the patient developed signs of infection (erythema, friable granulation tissue). Signs of infection resolved by the following dressing change at day 11, and therapy was continued. On day 13, the wound was not deemed to be clinically infected. The patient made the decision to stop therapy. At the final assessment the wound area had reduced by 55.6%, and depth had reduced to 0 mm.

### CONCLUSIONS

Despite the high levels of pain and the patient decision to discontinue therapy after just 16 days, the wound had healed well, with a 55.6% reduction in wound area, and reduction was seen in wound volume.

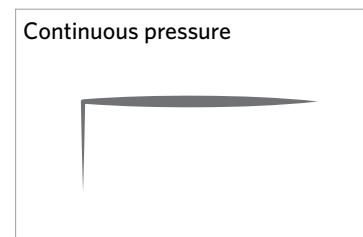
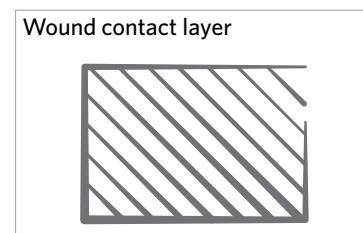
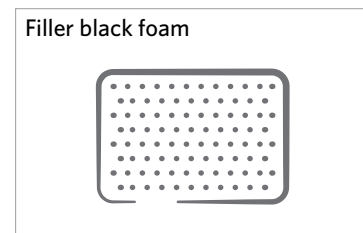
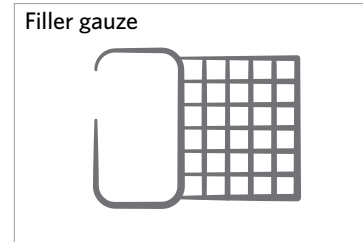


Figure 1: Day 0



Figure 2: Day 13

## CASE 8: RAPID GRANULATION TISSUE FORMATION AFTER SHARP DEBRIDEMENT

Author: **Martin Forlee**, Kingsbury Hospital, Cape Town, South Africa

### PRESENTATION

A 70-year-old male presented with a grade 2 diabetic foot ulcer of nearly 5 weeks' duration. No tunnelling or undermining were present.

### MANAGEMENT AND OUTCOMES

The wound was managed with RENASYS™-F foam dressing. ACTICOAT™ FLEX 3 was applied throughout therapy in an attempt to reduce bioburden\*.

Signs of clinical infection were present from day 6 of therapy, with development of purulent drainage, tissue necrosis and an increase in malodour. Sharp debridement was performed at days 12 and 14, resulting in a significant increase in the depth of the wound – from 2 mm to 13 mm. Systemic antibiotics were also prescribed at day 14, and the clinical infection resolved.

Following the debridement, despite some lingering signs of clinical infection (including erythema and inflammation), no further clinical infection developed. A rapid in-fill of granulation tissue reduced the wound depth from 13 mm immediately following sharp debridement to 3 mm 14 days later.

### CONCLUSIONS

After sharp debridement, the use of RENASYS™ TOUCH encouraged rapid in-growth of healthy tissue, nearly resolving depth in the wound bed over just 14 days, despite the presence of underlying risk factors and the presence of clinical signs of infection.

\*ACTICOAT FLEX 3 can be used for a period of up to 3 days.

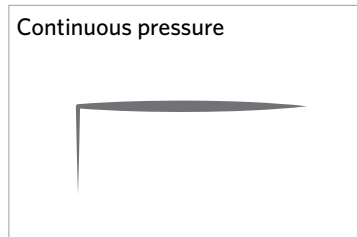
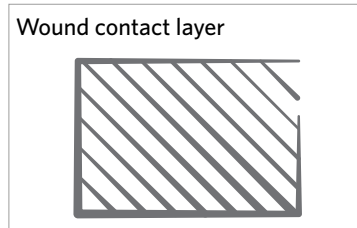
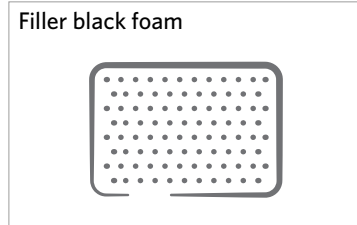


Figure 1: Day 0



Figure 2: Day 13

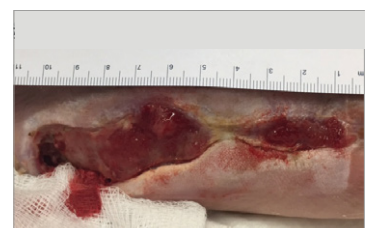


Figure 3: Day 28





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