

NEW CONFIDENCE® WOUND & FISTULA POUCH with FLEXIFIT®

USER ASSESSMENTS

Confidence®

Wound and Fistula Pouch with FLEXIFIT®
(non-sterile)



Recognising Salts research
into healthy stoma skin



DERMATOLOGICALLY
ACCREDITED

SALTS
HEALTHCARE
Excellence in stoma care

A UNIQUE WOUND MANAGEMENT PRODUCT

Confidence® Wound and Fistula Pouch with Flexifit® (non-sterile) comes with a range of features and benefits that make wound management easier for you and more comfortable for your patients. This is the first fistula pouch to include the unique Flexifit® shaped wafer, providing a much closer fit – even on awkward areas. Plus, you'll find innovative features such as a non-return valve, which helps to prevent backflow, and an easy-to-use outlet spout with wide bore. Available in a choice of sizes and orientations, including one that is long and narrow, meaning it is ideal for open (non-sterile) mid-line incisional wounds.



THE PERFECT FIT

This is the first fistula pouch to feature the unique Flexifit® shaped wafer:

- Six ingenious slits create flexible compression zones
- At just 1mm thick, the Flexifit® wafer is extremely flexible
- Flexes and moulds to the body better than a standard fistula pouch
- Perfect for patients with uneven skin or wounds in awkward areas



LONGER WEAR-TIME

- Specially formulated wound care adhesive
- Blend of elastomers, designed to resist breakdown for longer
- Provides improved wear-time
- Helps to reduce the frequency of changes

SUPERIOR SKIN-FRIENDLINESS

Salts Healthcare is the only ostomy manufacturer to have received recognition for its research into skin-friendly hydrocolloids, and is the first in the UK to be dermatologically accredited by the Skin Health Alliance. This ensures that the wafer is soft and gentle on your patient's skin.

NEW CONFIDENCE® WOUND & FISTULA POUCH WITH FLEXIFIT®

POUCH OPTIONS

CHOICE OF SIZES

Our small pouch comes with a choice of horizontal or vertical wafers, depending on the position of the wound or fistula; while our medium pouch features a long, narrow shaped adhesive which will fit perfectly between other pouches or dressings – ideal for open (non-sterile) mid-line incisional wounds.

RANGE OF CAPACITIES*

Our pouches can cater for low to medium exudate:

CWM01:.....	50ml
CWM02:.....	50ml
CWM03:.....	55ml

*Measurements taken from bottom of non-return valve

QUICK AND SIMPLE DRAINAGE

NON-RETURN VALVE

When pouch contents leak, they can cause contamination and skin erosion. Our special non-return valve ensures that harmful fluids are kept away from the wound and surrounding skin.

WIDE-BORE SPOUT OUTLET

The outlet features a wide-bore spout, through which thick exudate will still drain. The additional cap can be completely removed, should continuous drainage be required.



USING THE OUTLET SPOUT

Continuous drainage can be attached internally or externally to the outlet spout



PATIENT CASE STUDY No.1 (EIRE) PRODUCT USED: CWM01

PATIENT HISTORY

- 74-year-old female, widowed, who lived alone
- Had been unwell for several months, with reduced appetite and severe weight loss, but failed to seek medical help
- Eventually, neighbours persuaded her to see a local doctor, who admitted her immediately for review
- Subsequently diagnosed with an inoperable cholangioma following an exploratory laparotomy

MANAGEMENT CHALLENGES

- Wound, post laparotomy, failed to completely heal
- Small section of wound (10x10mm) continually drained serous fluid. A little red, inflamed and causing patient some degree of discomfort
- Output volumes ranged from just 30ml to 2400ml/24 hours
- Wound dressings were being changed sometimes 3–4 times an hour
- Sought advice from a Stoma Care Nurse



TREATMENT INTERVENTION

- Stoma Care Nurse suggested applying Confidence® Wound and Fistula Pouch CWM01, as numerous dressing changes were causing the patient some anxiety and stress
- Stoma Care Nurse was also concerned about surrounding skin and further deterioration of the wound and/or skin
- An additional seal and some paste were used. The CWM01 pouch was then just changed twice-weekly



COST BENEFIT

Prior to using the Confidence® Wound and Fistula Pouch, this patient was receiving 3–4 dressing changes every hour:

BEFORE – COST PER CHANGE:

3 x Release dressings	£0.42
	£10.08 per day
	£70.56 per week (168 changes)

Compared to CWM01 being changed just twice weekly:

AFTER – COST PER CHANGE:

1 x CWM01	£5.89
1 x Small Mouldable Seal	£1.88
Hydrocolloid paste (1/10 tube)	£0.75
Total per change	£8.52
Total per week	£17.04 (2 changes)

Saving £53.52 per week

OUTCOME

- Confidence® Wound and Fistula Pouch with Flexifit® has proven to be very highly effective in the management of a highly exuding wound, assessed to be non-sterile
- The CWM01 pouch provided comfort and security for the patient, eradicating the need for constant dressing changes, and removed the potential risk of damage to surrounding skin and wound integrity
- The wound healed and the output dried sufficiently after 2 weeks to recommence use of dry dressing
- The patient went home with additional support



PATIENT CASE STUDY No.2 (UK) PRODUCT USED: CWM02

PATIENT HISTORY

- A 51-year-old gentleman suffering with Crohn's disease
- Admitted for TPN (Total Parenteral Nutrition) therapy and management of small-bowel (SB) fistula

MANAGEMENT CHALLENGES

- To effectively manage and contain the SB fistula that was located in the centre of his laparotomy wound
- Surrounding the fistula were numerous creases, a complicated skin dip and some keloid scarring (Fig 1)
- SB fistula was 10x40mm and producing varying volumes of very watery/liquid faecal fluid, ranging from 100ml/24 hours when patient was Nil by Mouth to 1600ml/24 hours
- Skin surrounding the fistula on admission was red and broken due to excessive problems with poor adhesion of appliances and consequent leakage

TREATMENT INTERVENTION

- A barrier wipe (Salts Peri-Prep® Sensitive) was applied around the fistula to protect the skin
- A large Salts SecuPlast® Mouldable Seal was then applied underneath the fistula to protect the already excoriated skin, and in an attempt to achieve a flat surrounding skin surface onto which the CWM02 wound and fistula pouch could then be applied
- A few "sunshine nicks" were cut into the inside of the hydrocolloid after it had been cut to the correct size. This complements the Flexifit® technology on the outer part of the hydrocolloid wafer
- Both concepts allowed the hydrocolloid to flex and mould to uneven contours. A small amount of Hydrocolloid Paste was also used prior to adhering the Confidence® Wound and Fistula Pouch with Flexifit®
- Pouch was routinely changed every 2–3 days over the 2-week assessment period. However, on several occasions, it was left intact for up to 4 days

COST BENEFIT

Prior to using Confidence® Wound and Fistula Pouch with Flexifit®, the patient's previous appliance was being changed at least daily:

BEFORE – COST PER CHANGE:

1 x Large Vertical Oval Pouch.....	£3.25
1 x Peri-Prep® Sensitive barrier film wipe	£0.51
1 x SecuPlast® Mouldable Seal Large.....	£2.23
Hydrocolloid Paste (1/10 tube).....	£0.75
Total per change	£6.74
Total per week	£47.18 (7 changes)

AFTER – COST PER CHANGE:

1 x CWM02.....	£5.89
1 x Peri-Prep® Sensitive barrier film wipe	£0.51
1 x SecuPlast® Mouldable Seal Large.....	£2.23
Hydrocolloid Paste (1/10 tube).....	£0.75
Total per change	£9.38
Total per week	£28.14 (3 changes)
Saving	£19.04 per week

OUTCOME

- Confidence® Wound and Fistula Pouch with Flexifit® has proven to be highly effective in the management of SB fistula, providing comfort with security, and minimising the tremendous fear of leakage
- Patient found the hydrocolloid wafer was easily removed, leaving very little residue on the skin
- When Confidence® Wound and Fistula Pouch was applied, it adhered well, felt secure and very flexible, offering up to 4 days' wear-time
- After 12 weeks of TPN and proactive medical gastroenterology input, the patient was well enough to go home and returned a few weeks later for surgery



Easily removed
leaving very
little residue

Adhered well,
felt secure
and very flexible

PATIENT CASE STUDY No.3 (UK) PRODUCT USED: CWM02

PATIENT HISTORY

- 66-year-old lady, elective admission in July 2012 for a de-functioning loop colostomy for an obstructive sigmoid adenocarcinoma (Dukes' B stage)
- The patient went on to receive a short course of chemotherapy and radiotherapy
- Admitted in October 2012 for a low anterior resection, closure of loop colostomy and formation of a loop ileostomy, and experienced an uneventful recovery
- The patient was readmitted in early January 2013 for a reversal of the loop ileostomy
- However, a week post-op, she was taken back to theatre for an emergency laparotomy and repair of four enterostomies. Soon after, she developed two fistulae along her laparotomy wound (Fig 1)

MANAGEMENT CHALLENGES

- To effectively manage both fistulae and maintain the integrity of the surrounding skin, already traumatised as a result of two surgical procedures in under 7 days
- The fistulae were initially producing approximately 350ml/24 hours of faecal fluid, but the volume reduced steadily throughout the 2-week assessment period
- The patient had a poor physical status and was extremely oedematous.

TREATMENT INTERVENTION

- A barrier wipe (Salts Peri-Prep® Sensitive) was applied and a Salts Standard SecuPlast® Mouldable Seal, followed by a small amount of Hydrocolloid Paste (Fig 2)
- A Confidence® Wound and Fistula Pouch CWM02 was then applied (Fig 3)



OUTCOME

- The Confidence® Wound and Fistula Pouch has proven to be highly effective in the management of this faecal fistula
- Stoma Care Nurses reported that the wear-time was between 2–4 days
- It was highlighted that the shape of the wafer was ideally suited for small faecal fistulae and the Flexifit® provided the superb flexibility required when dealing with an abdomen with challenging contours
- Assessment was unfortunately discontinued due to the development of a further fistula, resulting in a larger capacity appliance and wafer being required
- The procedure took 1 nurse just 30 minutes to complete

PATIENT CASE STUDY No.4 (UK) PRODUCT USED: CWM03

PATIENT HISTORY

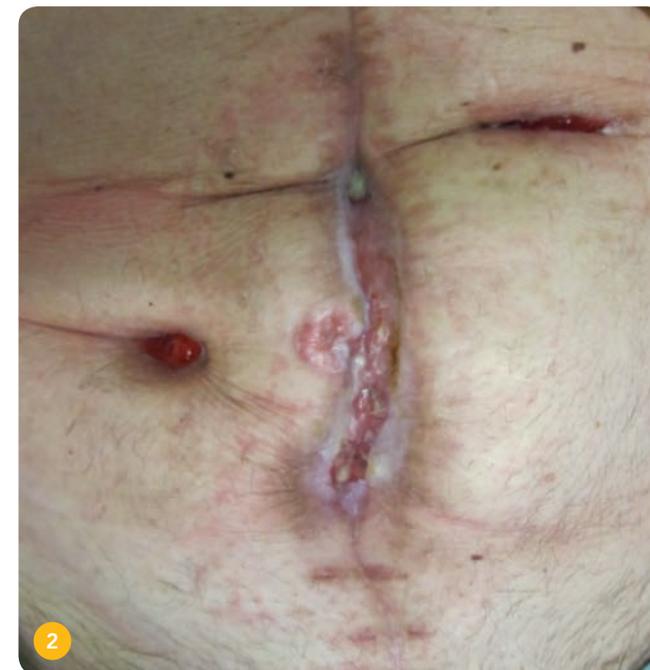
- 54-year-old gentleman diagnosed with an advanced colorectal cancer and subsequently given a palliative diagnosis
- The patient had required four laparotomies in 8 weeks, with the formation of a split ileostomy
- He had a poor nutritional status
- Bowel obstruction had recurred, requiring further surgical assessment and management. The patient subsequently underwent a further laparotomy in an attempt to relieve his symptoms, but with a high probability that the situation would recur
- A venting gastrostomy tube was inserted at surgery
- Unfortunately, following further palliative surgery to relieve symptoms, 10 days post-operatively after removal of clips, lower mid-line wound dehiscence occurred due to formation of a small bowel fistula
- He had an ileostomy in right iliac fossa abdominal region and an open wound from a previously closed colonic mucous fistula situated in his left iliac fossa

MANAGEMENT CHALLENGES

- Patient had up to 1000ml/24 hours of faecal fluid draining from a fistula within this mid-line laparotomy wound. As shown in Fig 1, there are still some clips *in situ*, but this was not the major challenge. Also present are two old drain sites, both on the left side, and his ileostomy on the right-hand side of his abdomen
- The gentleman had recently lost a lot of weight, so he also had numerous soft skin folds and creases
- The close proximity of the drain sites and stoma can often cause difficulties with fistula management. However, the unique shape of the new Confidence® Wound and Fistula Pouch CWM03 was found to be ideal

TREATMENT INTERVENTION

- A “wedge” of SecuPlast® Mouldable Seal and a small amount of Hydrocolloid Paste was applied to the lower end of the laparotomy wound to cover existing wound closure clips
- Then Confidence® Wound and Fistula Pouch CWM03 was placed *in situ*



OUTCOME

- The Confidence® Wound and Fistula Pouch was used for just 2 weeks and the fistula then began to dry up spontaneously (Fig 2)
- The patient evaluated the pouch as very comfortable to wear, finding that the adhesive was flexible, adhered well and was easily removed
- The CWM03 pouch proved highly effective in managing his fistula – so much so that it was possible to change twice weekly as a routine procedure
- This regime enabled the gentleman to plan his precious few weeks of life left with accuracy – ensuring valuable hours could be spent with loved ones while they visited, rather than them waiting in a dayroom while dressings were changed

PATIENT CASE STUDY No.5 (UK) PRODUCT USED: CWM03

PATIENT HISTORY

- 27-year-old lady diagnosed with Crohn's disease since the age of 9
- Countless surgical procedures eventually resulted in Pan-proctocolectomy at the age of 20
- The patient continued to be plagued by the formation of numerous complex fistulae and multiple chronic pelvic abscesses
- Unfortunately, the patient developed a spontaneous enterocutaneous fistula while at home
- She described a feeling prior to the development of the fistula of swelling along her previous midline incision and of redness, hot to touch, as well as experiencing severe abdominal pain

MANAGEMENT CHALLENGES

- As shown, there were now two fistulae producing extremely high volumes of small bowel fluid. The fistulae produced between 300 and 4000ml/24 hours
- Any fistula producing over 500ml/24 hours is viewed as a high output (Lloyd *et al*, 2006).
- With such high volumes of small bowel fluid, the fistula management was extremely challenging – firstly, for the Stoma Care Nurse; and secondly, for any fistula pouch
- It was vital for the product to adhere well, providing comfort and security for the patient, as well as an adequate wear-time
- The additional challenge in this situation was the close proximity of the left-sided ileostomy



TREATMENT INTERVENTION

- The fistulae were assessed and CWM03 was applied
- The unique shape of the hydrocolloid wafer was ideally suited as it provided adequate length to enable both fistulae situated within the old laparotomy incision to be incorporated into the same pouch
- Due to CWM03's slim width, it could be tailored into the small surface area present between the edge of fistula and start of left-sided ileostomy (Fig 2)

- The unique Flexifit® wafer was also extremely helpful in the management of these fistulae due to its ability to flex and bend with the numerous creases and scarring present on this young lady's undulating abdomen
- Salts standard SecuPlast® Mouldable Seals were applied around the top fistula
- A large SecuPlast® Mouldable Seal was broken in half and some was applied around each side of the lower fistula
- A small amount of Hydrocolloid Paste was then used to seal edges. After that, the assessment fistula pouch CWM03 was applied





COST BENEFIT

- Prior to using CWM03, the patient had tried numerous other fistula pouches, all with varying degrees of limited success
- The unique shape of the CWM03 and its erosion-resistant hydrocolloid was found to be hugely beneficial in terms of managing this complex fistula, by providing a greatly increased wear-time
- For example, over a 72-hour period, the assessment pouch CWM03 remained *in situ* and withstood 3780ml small bowel fluid
- The hydrocolloid remained intact and the skin surrounding the fistula on removal of the assessment pouch was evaluated as good, intact, and with no broken areas

EXAMPLE 1 BEFORE – PER CHANGE:

1 x XS Wound Manager	£11.48
1 x SecuPlast® Mouldable Seal Large.....	£2.23
2 x SecuPlast® Mouldable Seal Thin	£3.26
Hydrocolloid Paste (1/10 tube).....	£0.75
Total per change	£17.72
Total per week	£124.04 (7 changes)

EXAMPLE 2 BEFORE – PER CHANGE:

1 x Medium Wound Pouch	£6.81
1 x SecuPlast® Mouldable Seal Large.....	£2.23
2 x SecuPlast® Mouldable Seal Thin	£3.26
Hydrocolloid Paste (1/10 tube).....	£0.75
Total per change	£13.05
Total per week	£91.35 (7 changes)

EXAMPLE 3 BEFORE – PER CHANGE:

1 x Large Vertical Oval Pouch.....	£3.25
1 x SecuPlast® Mouldable Seal Large.....	£2.23
2 x SecuPlast® Mouldable Seal Thin	£3.26
Hydrocolloid Paste (1/10 tube).....	£0.75
Total per change	£9.49
Total per week	£66.43 (7 changes)

AFTER – PER CHANGE:

1 x CWM03.....	£7.80
1 x SecuPlast® Mouldable Seal Large.....	£2.23
2 x SecuPlast® Mouldable Seal Thin	£3.26
Hydrocolloid Paste (1/10 tube).....	£0.75
Total per change	£14.04
Total per week	£42.12 (3 changes)

Example 1saving of £81.92 per week
 Example 2saving of £49.23 per week
 Example 3 saving of £24.31 per week

OUTCOME

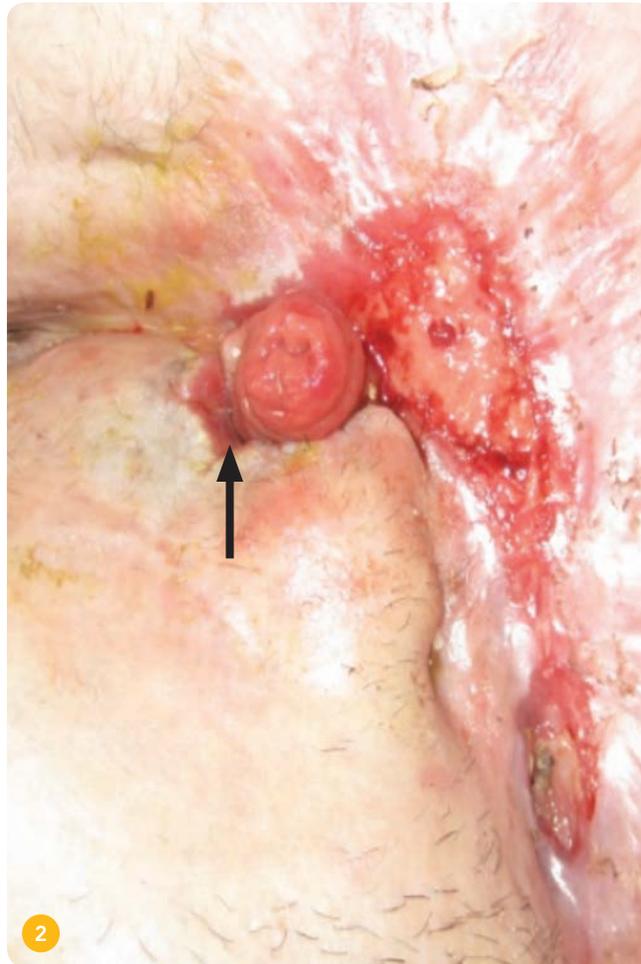
- The use of the Confidence® Wound and Fistula Pouch has proven to be highly effective in the management of small bowel (SB) fistulae
- The unique shape of CWM03 has proven to be extremely advantageous in the management of these fistulae that, all too often, unfortunately develop along a laparotomy wound
- The Flexifit® wafer provides additional comfort and security for the patient
- In this particular instance, the assessment period was extensive; the patient was shown how to apply the Confidence® Wound and Fistula Pouch, as well as the SecuPlast® Mouldable Seals, herself. She wore the CWM03 pouch for just over 6 months until further surgery was deemed safe and possible
- This patient had huge faith in the CWM03. It was the only pouch that remained *in situ* for any great period of time, the shape of the wafers was evaluated as very good, it was comfortable to wear and she trusted it not to leak
- The pouch helped this young lady regain control of her life by contributing to her ability to self-manage her complex fistulae with appropriate support
- Weekly contact from the local Stoma Care Nurse was arranged to ensure regular reviews were conducted



PATIENT CASE STUDY No.6 (UK) PRODUCT USED: CWM03

PATIENT HISTORY

- A 32-year-old gentleman diagnosed with Crohn's disease
- He had severe disease which was left untreated for many months. Admitted with multiple abdominal fistulae, and required Total Parental Nutrition for many months before having surgery to repair these multiple fistulae
- Fistulae were repaired but, unfortunately, the patient developed another high-volume small bowel fistula (Fig 1). The SB fistula was producing between 1500–3000ml watery faecal fluid in 24 hours



MANAGEMENT CHALLENGES

- The fistula was not only high output, but the apex was also positioned at the very base of the fistula. (See arrow – Fig 1)
- This was adjacent to an extremely deep crease, and surrounded by a lot of uneven skin, more creases and numerous deep skin folds (Fig 3)

TREATMENT INTERVENTION

- Procedure required two nurses
- Salts Thin SecuPlast® Mouldable Seals and Large Seals were applied into the creases, and a large SecuPlast® Mouldable Seal was 'rolled up' to fill the deep crease on the patient's right side, close to his hip (Fig 3)
- Hydrocolloid Paste was used to seal the edges and then additional retention strips were used
- The objective that the nurse was trying to achieve when using pastes and seals was that of a flat abdominal surface – this would enable successful application of the fistula appliance
- The paste and seals were being used as fillers. In this case, as you can observe from Fig 2 and Fig 3, it was hugely challenging. Figs 2 & 3 highlight the severity of the crease on the patient's right side
- The patient also had the presence of a left-sided ileostomy, which is not visible





Fig 4 illustrates the Confidence® Wound and Fistula Pouch (CWM03) *in situ*.

Much better
than anything
patient had tried
before

The size was
just right

The
wide-bore outlet
enabled better
free drainage

OUTCOME

- The Confidence® Wound and Fistula Pouch has proven to be the only product to have any form of success for this immensely challenging situation
- The CWM03 regularly remained *in situ* for 48–72 hours despite the SB fistula producing approximately 3000ml/24 hours. This proves that the newly formulated hydrocolloid is effective at managing high volumes of small bowel fluid that contains proteolytic enzymes that will often quickly break down some hydrocolloids
- The unique shape and the Flexifit® feature were invaluable when managing the challenging contours and deep creases
- The patient stated that the size was just right, flexibility was a lot better than anything he had previously tried and also that the wide-bore outlet enabled better free drainage, allowing him a certain amount of mobility
- This small, but precious, asset was vital for his mental wellbeing during his prolonged hospitalisation. It meant that he was able to walk for short distances with relatives and friends to the coffee shop, changing his immediate environment, which was irreplaceable



CONFIDENCE® WOUND AND FISTULA POUCH WITH FLEXIFIT® (NON-STERILE)

SIZE	ORDER CODES	PACK SIZE
SMALL Horizontal wounds up to 60mm wide x 40mm high	CWM01	10
SMALL Vertical wounds up to 40 mm wide and 60mm high	CWM02	10
MEDIUM Vertical wounds up to 53mm wide and 150mm high	CWM03	10

FISTULA AND WOUNDCARE ACCESSORIES

PRODUCT	ORDER CODES	PACK SIZE
SecuPaste®	NSP1	60g
SecuPlast® Hydro Tape (25mm wide)*	HT2	1.5m
SecuPlast® Hydro	SPH1	30
SecuPlast® Hydro Aloe	SPHA1	30

SECUPLAST® MOULDABLE SEALS

SIZE	DIAMETER	THICKNESS	ORDER CODES	PACK SIZE
THIN	50mm	3mm	SMST	30
STANDARD	50mm	4.2mm	SMSS	30
LARGE	100mm	3mm	SMSL	10

*Not available on Drug Tariff

Confidence®

Wound and Fistula Pouch with FLEXIFIT®
(non-sterile)

For more information and free samples, please call:
FREEPHONE 0800 626388 (UK), FREEPHONE 1-800 408508 (Ireland)
or visit www.salts.co.uk

Overseas customers can contact our International Customer Services Team:
Telephone: +44 (0) 121 333 2000 or email: international@salts.co.uk

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RM764539 10/13/3K