HOW TO USE POSiFECT® BIO-ELECTRIC STIMULATION THERAPY IN CHRONIC WOUNDS

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The management of chronic wounds can pose several challenges to the clinician and patient alike; they drain healthcare resources, are a source of frustration and have a huge impact on quality of life. While major strides have been taken in developing products that manage issues such as exudate and maceration, until recently little has been available to directly influence static cellular activity, often the cause of non-healing. POSiFECT® is a new therapy that is specifically designed to change this.

For over 30 years, scientists have been aware that cells, the basic building blocks of all living things, communicate with each other and have their functions regulated by the transfer of electrochemical signals (Kloth, 2005). These signals are known as 'bio-currents', 'bio-electric currents' or 'ionic currents'. The discovery of these currents has had a significant impact on our understanding of disease processes and pharmaceutical interventions and resulted in the award of the Nobel Prize for Medicine in 1991.

Bio-currents are caused by the passage of different chemicals in and out of the cell wall. The currents not only help regulate how the cell works but also affect neighbouring cells; they enable the release of specific chemical messengers and promote the movement of some cells away or towards one another (galvanotaxis).

The role of bio-currents in wound healing

In wound healing, these bio-electric currents have a vital role. They promote the laying down of collagen and the formation of stronger scar tissue (Weiss et al, 1990; Sheridan et al, 1996; Tasgan et al, 1997), the formation of new blood vessels (angiogenesis) and the migration of white blood cells (Fukushima et al, 1953; Orida and Feldman, 1982). White blood cells are a key component of normal healing; they fight infection, breakdown dead and damaged tissues and release growth factors that stimulate fibroblast activity (Bourguignon and Bourguignon, 1987; Goldman and Pollack, 1996). It appears without doubt that bio-currents contribute to normal healing processes (Illingsworth and Barker, 1980; Vanable, 1989).

Bio-currents may also have a significant effect on bacterial colonisation in the wound. The effects of bio-currents on bacterial colonies have been known for many years (Wheeler et al, 1971; Rowley et al, 1974; Kincaid and Lavoie, 1989). It has also been found that the production of minute electrical fields affect the formation and stability of biofilms, causing them to break up (Moore, 2007).

Biofilms are formed by synergistic colonies of bacteria that attach to a surface, such as the wound bed, and produce a slimy protein covering (glycocalyx) to protect themselves from attack by the host's immune system. In chronic wounds it has been suggested that biofilms can be one of the causes of repeated infections, wound stagnation and tissue breakdown (Bowler et al, 2001).

Although bio-currents are normal and essential to wound healing, it has been found that in some chronic wounds these normal

electric currents are either absent or very weak (Jaffe and Vanable, 1984). It has been suggested that this is one of the reasons why these wounds fail to heal (Cutting, 2006).

Over the past few years, research in this area has focused upon exactly how much charge is needed to affect tissue repair. Findings indicate that the charge is very small; less than that needed to power a digital watch. By measuring these very small electric currents, it has been shown that if the right amount of electrical influence is delivered to the wound it is possible to 'kick start' the normal healing process (Cutting, 2006). This is known as electric stimulation.

Product description

POSiFECT® is a new therapeutic intervention that comes as an easy to apply, highly portable medical device. Studies have indicated that the product is capable of delivering bio-current to the wound bed and facilitates cost-effective healing outcomes (Hampton and King, 2005; Cutting, 2006; Clegg and Guest, 2007; Moore, 2007). The device is CE marked and produced in a single-use, disposable sterile format.

POSiFECT® is a one-piece construction made up of standard dressing materials. The bio-current therapy is integrated into the dressing matrix. The therapy is powered by the small electric module assembly (EMA) (*Figure 1*).

Adherent to the outer tan adhesive part of the dressing is a flexible metal ring (the anode).

Figure 1. The POSiFECT® medical device.

This is one of two contacts which are used to maintain and deliver the electric current to the wound. The second contact (the cathode) is on the end of a soft, insulated medical grade wire that is attached to the power unit under the dressing flap. This contact is placed on the wound bed during use. Both the anode and cathode are covered in a sodium-rich hydrogel to ensure good electrical contact.

The EMA attached to the dressing contains a low voltage battery supply and a tightly controlled micro-current delivery system. This system continuously and automatically adjusts the micro-current to levels clinically shown to initiate the wound healing process. Each dressing has enough battery life to continue working for at least 48 hours.

An adhesive-backed 'flap' is fitted to cover the wound and maintain a moist wound environment. It can also be used to secure additional absorbent dressing material if required, along with the cathode, on the wound surface.

When to use POSiFECT®

POSiFECT® has been developed for use in the treatment of chronic wounds that have failed to respond to conventional therapies. It can be used in conjunction with most other treatments (except metallic-based wound care products which would conduct the electric field causing the system to short-circuit). There are few contra-indications for the product, however, it should not be used to treat malignant wounds or wounds to the head and neck. In addition, due to its electrical component it should not be used on patients fitted with a demand-type cardiac pacemaker or while patients are monitored on an electrocardiogram (ECG).

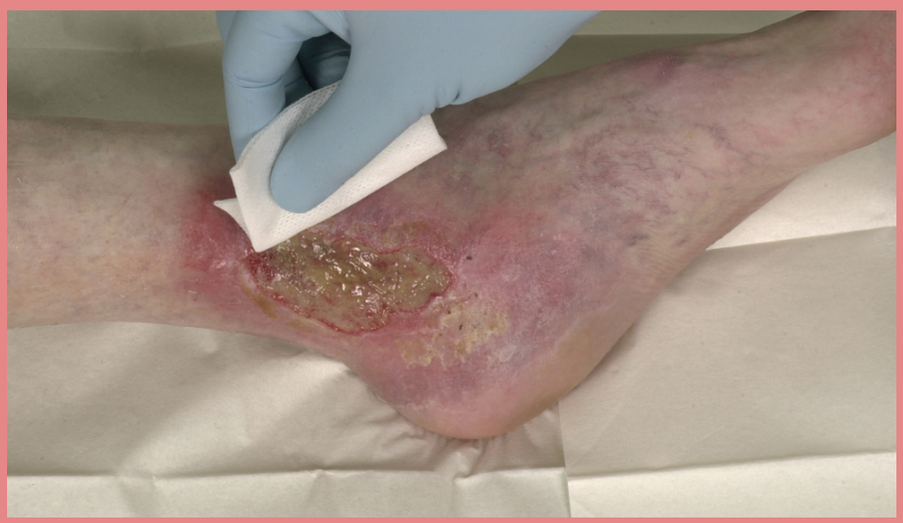


Figure 2.

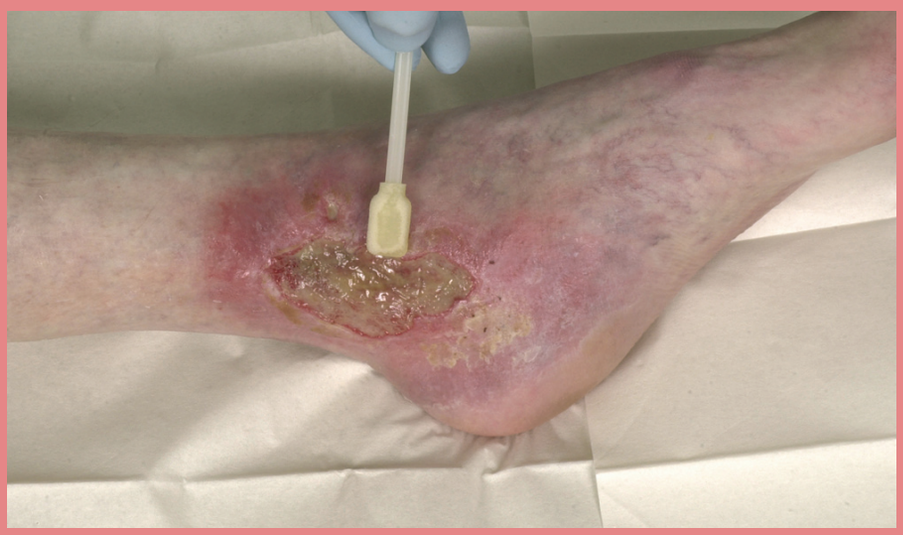


Figure 3.

Figure 4.

How to use POSiFECT®

1. Prepare the peri-wound area

The clinician first removes the previous dressing and cleanses the wound and the skin surrounding the wound (peri-wound skin) as normal (*Figure 2*). When used, POSiFECT® therapy may initiate a change in the inflammatory status of the wound. This could result in some temporary increase in wound exudation. On delicate skin it may be appropriate to protect the peri-wound area with a non-greasy barrier preparation such as Cavilon® No Sting Barrier Film (3M Healthcare, Loughborough)(*Figure 3*).

2. Open the POSiFECT® dressing

Once the wound and the surrounding skin are prepared as appropriate, the POSiFECT® dressing is removed from its foil outer wrapping and its inner pouch. Only the contents of the inner pouch are sterile (*Figure 4*).

3. Activate the dressing

The POSiFECT® dressing is activated by removing the black tab on the white EMA (*Figure 5*). A small red light then starts flashing.This indicates that the unit is ready to use.

4. Apply the anode ring

The backing can now be removed from the adhesive ring and the POSiFECT® dressing fixed over the wound. Folding back the flap enables the clinician to visualise the wound surface while manoeuvring the dressing making placement much easier (*Figure 6*). The dressing is positioned to ensure that the EMA does not increase

the risk of pressure damage from external sources, for instance compression bandages, or when load bearing (see 'Use with other treatment modalities').

Where the device is used to treat a large wound it should be positioned to ensure that at least 50% of the anode ring is on intact peri-wound skin. At each subsequent dressing change the position of the dressing is rotated to ensure the therapy is administered to the entire wound surface (*Figure 7*).

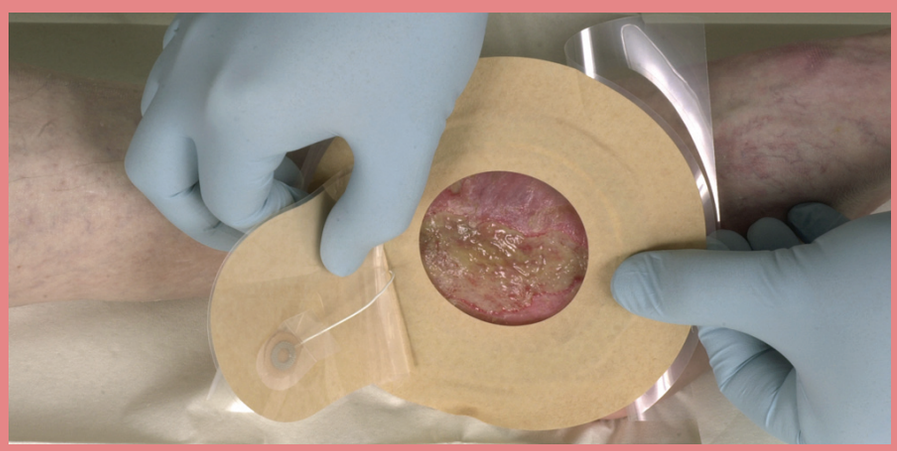
5. Position the cathode

Once the anode ring is fixed to the peri-wound skin, the backing should be removed from the centre cathode (*Figure 8*). The cathode paddle is placed at the base of the wound (*Figure 9*). Dampening the gloves with water or saline will help prevent the hydrogel component of the cathode sticking to the glove and so will aid handling. If POSiFECT® is being used to treat a sinus it should be placed over the exit wound. In deep wounds where it is impossible to attach the cathode to the wound bed, the cathode should be affixed to the side wall of the defect. Good contact with the wound bed is essential.

6. Ensuring therapy delivery

The light goes out when the system's electric current is successfully delivered into the wound. The light stays extinguished until either the contact is lost or the power-pack runs low. In the unlikely event of the light failing to extinguish, the clinician should check to ensure the cathode and anode are

Figure 5.



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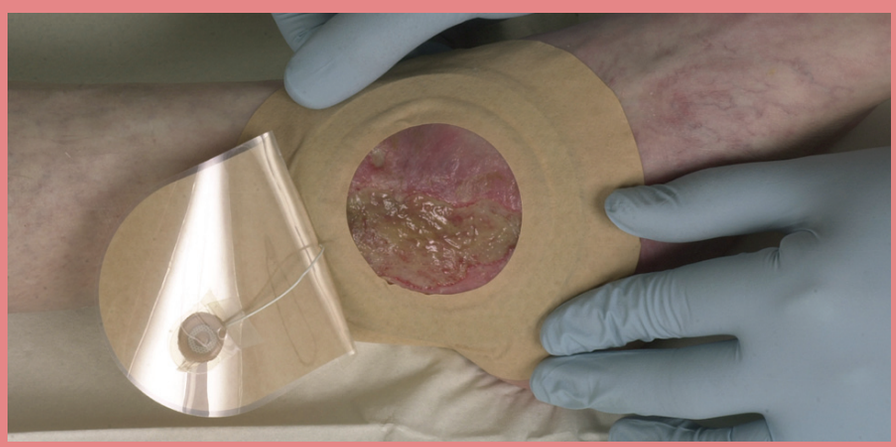
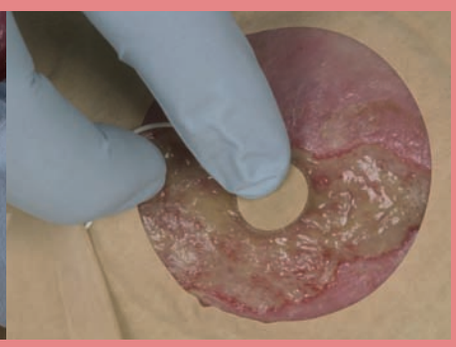


Figure 7.

Figure 8.



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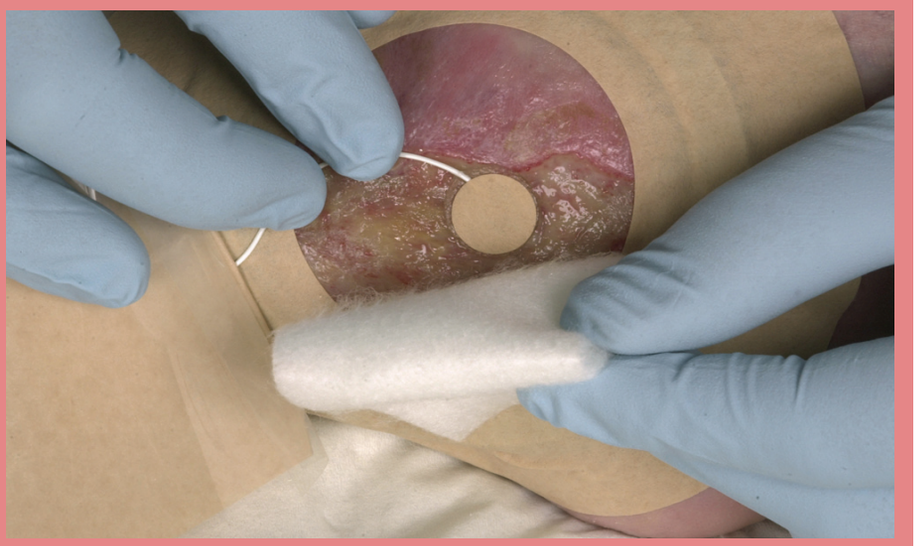

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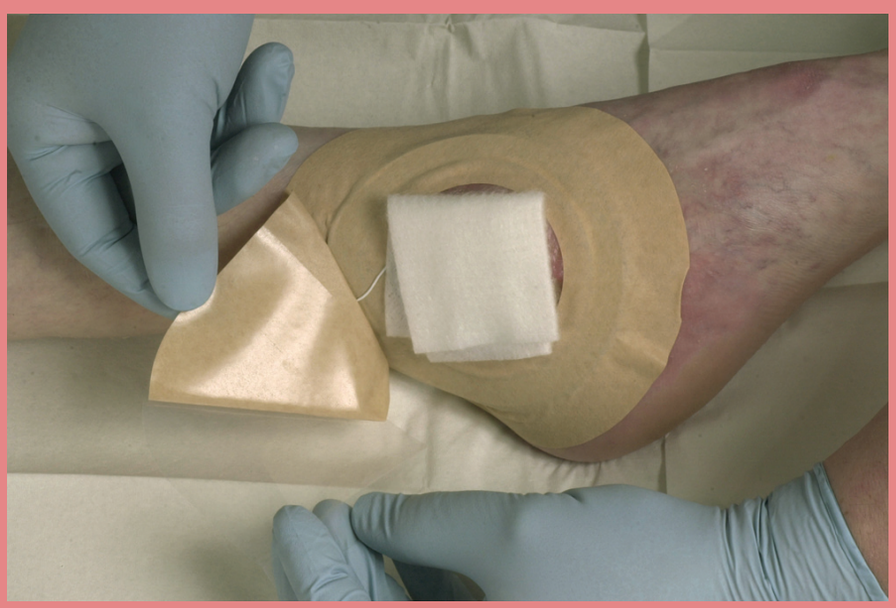

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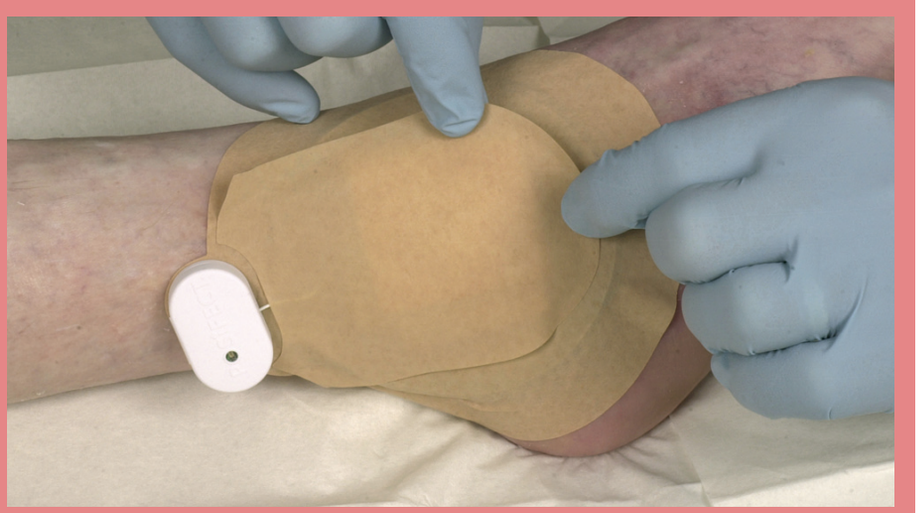


Figure 12.

properly positioned and making contact with the peri-wound and wound bed. If the light still does not go out, the dressing should be replaced.

7. The use of additional dressing material

Although called a dressing, POSiFECT® is a therapy. In most circumstances it will be used in conjunction with other dressing products. These are particularly important in the management of exudate and the prevention of maceration. Dressing materials such as alginates and hydrofibres can be placed over and around the cathode before closure of the adhesive flap to manage the local wound environment (*Figure 10 and 11*). If clinically indicated, antimicrobial dressings such as iodine or honey-based products may be used. Silver-based products must be avoided due to their conductive properties.

8. Close the flap

The flap should be secured over the cathode and to absorbent material if used. The flap can be later lifted to change any soiled or soaked secondary dressing material used, as required, without having to change the POSiFECT® dressing. Following repacking, the flap can be reapplied or replaced with a film dressing. In cases of very high exudate levels the flap may be removed and substituted by an absorbent pad or foam dressing.

9. Use with other treatment modalities

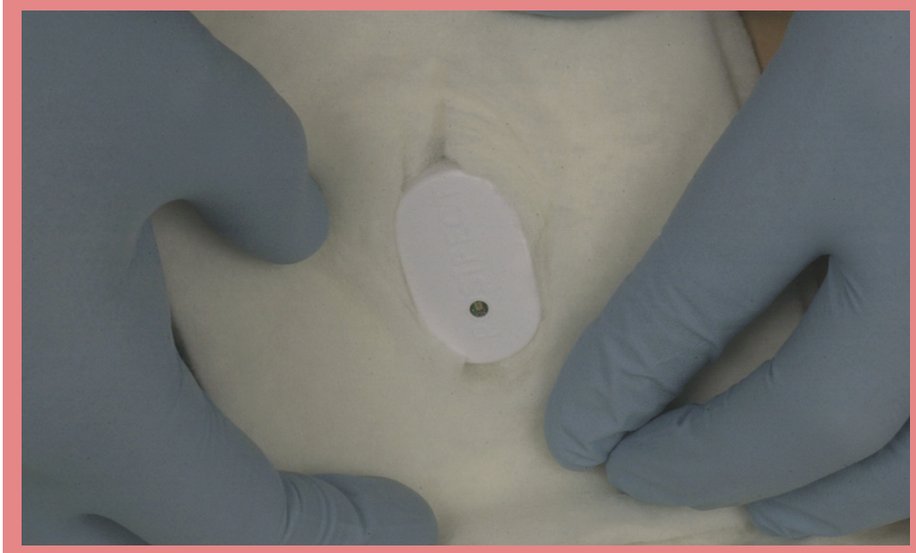
POSiFECT® may also be used in conjunction with other therapies such as sustained compression

bandaging, short-stretch bandaging and intermittent compression therapy. The clinician must ensure adequate measures are undertaken to prevent pressure damage to tissues. Wherever possible, the EMA should be positioned away from bony prominences, particularly the pre-tibial crest and ankle bones (*Figure 12*). Additionally, the position of the EMA should be rotated with each dressing change.

It is important to ensure adequate padding is used around the EMA to spread the load onto surrounding tissues. Using Laplace's equation, it is obvious that significant layers of padding over the EMA are not required as this will only increase the potential for pressure damage. Similarly, padding should not be placed under the unit. Instead, padding can be made from cut and shaped podiatry felt, foam or simply from orthopaedic wool bandage. It is important to ensure that any padding used is deep enough to prevent protrusion of the EMA above the level of padding (*Figure 13*). Reshaping of the limb with orthopaedic wool bandages may be subsequently required to ensure that the compression gradient is maintained (*Figure 14*).

10. Special instructions

The anode ring is made of soft malleable metal and can be folded to facilitate fitting to areas such as the heel. It is possible to cut the ring (make sure the EMA remains attached to the remains of the ring) but this is not necessary in most



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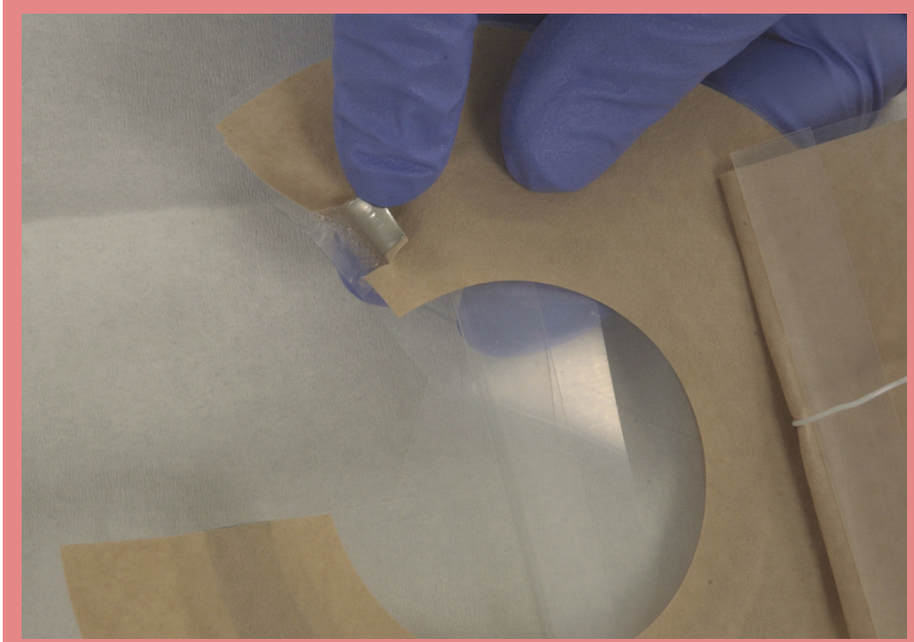

Figure 15.

Glossary

Collagen: fibres of glycoproteins manufactured by fibroblasts that hold tissues together.

Fibroblast: specialist cells that can convert ingested proteins into new tissues. They have an essential role in wound healing.

Synergistic: different organisms existing in a state of co-operation and mutual benefit.

Anode: a positively charged electrode.

Cathode: a negatively charged electrode.

Bioburden: the amount of bacteria within the wound.

cases. If this is undertaken the clinician must ensure that the cut edges of the anode are folded back to prevent patient injury from any sharp edges that may be produced (*Figure 15*).

Treatment regimens

The EMA in each POSiFECT® dressing contains sufficient power to last at least 48 hours. It is recommended that the dressing is changed every 2–4 days. The frequency of these dressing changes depends on the individual needs of each patient. For example, if a person has a high natural electric resistance the EMA will have to work harder and so the product will need more frequent attention.The presence of a flashing light when the unit is in place will indicate the battery is low, or that the circuit is open. When increasing the duration of dressing wear time the clinician should ensure that the light comes on when the circuit is broken (i.e. when it is removed).

POSiFECT® therapy is applied in two cycles of three weeks with a break of one week in between. During the break period and after completion of the second cycle of therapy the patient should return to their normal mode of treatment. Two treatment cycles are all that is normally required. Some patients respond so quickly that the full course of treatment is unnecessary; others may find their wound has not completely healed within this seven week period. It has been found that the benefits of POSiFECT® may continue after the active phase of therapy has been discontinued (Hampton and King, 2005; Moore, 2007). It has been speculated that this phenomenon is due to the correction in the naturally occurring bio-currents within the wound.

Other clinical findings

Some patients find that wounds treated with POSiFECT® develop a transient coating of slough (yellow semi-adherent debris) and may have an increase in wound odour. Slough is made up of a mixture of dead white cells, bacteria, rehydrated necrotic tissue and fibrous tissue. If changes are made to the wound bio-burden or to the white cell population within the wound it is expected that additional debris will be seen in the wound bed. Provided there is no extension of the wound margin, deepening of the ulcer/wound depth or no signs of clinical infection, the therapy should continue through this transitory phase.

To date very few patients have experienced any significant increase in pain when using POSiFECT®, in fact the reverse has been true in most cases. Some patients have reported mild burning, particularly over the cathode. This tends to be self-limiting, resolving after a few days and is manageable with mild analgesia.

Allergic reaction to topical products, known as allergic contact dermatitis, is caused by repeated exposure to an allergen. Patients with chronic wounds will have had multiple wound care therapies applied, often over many years, and many of the products used will contain known sensitising agents such as colophony and adhesives. As such there may be a small number of individuals who develop true contact sensitivity to POSiFECT®. This should, however, be distinguished from irritant dermatitis and maceration caused by unmanaged exudation. These conditions may be avoided by enhanced skin care regimes and the use of more absorbent secondary dressing products.

Conclusion

The challenge of chronic wound management is one that is faced by clinicians across the health care environment. Such wounds cost healthcare providers considerable amounts of money and resources. Until recently the focus of care has been on the control of wound care symptoms. However, renewed interest in understanding the underlying causes of wound chronicity has led to a new

imperative to seek innovative technological approaches to therapy. The challenges to clinicians are to extend their clinical knowledge, identify patient groups, implement appropriate evidence-based or evidence-linked therapies and measure outcomes.

The positive effects of bio-current on tissue repair and regeneration have been known for many years and yet until recently these have been largely ignored due to the technical problems of safely and effectively introducing electric currents in wound treatment situations. This has now been overcome by the development of the POSiFECT® bio-electric wound stimulation therapy dressing. This new tool to chronic wound treatment can offer significant cost effective care opportunities to patients and clinicians across the care community. **WE**

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The POSiFECT® bio-electric wound stimulation therapy dressing is a new tool to chronic wound treatment that can offer significant cost-effective care opportunities to patients and clinicians across the care community.

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Key Points

- **Bio-currents have a vital role in normal wound healing processes.**
- **In some chronic wounds, bio-currents are either absent or very weak, and this could be a reason why the wounds fail to heal.**
- **POSiFECT® is a new device capable of delivering bio-current to chronic wounds which 'kick starts' the normal healing process.**

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