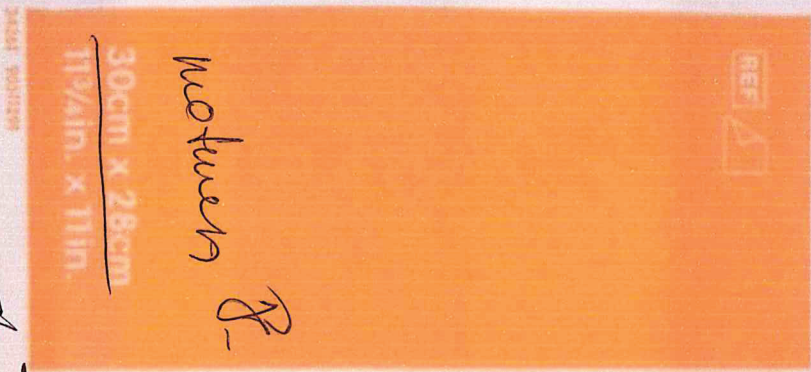


smith&nephew

chidango
+
niefer



2797
CE
MD
www.smith-nephew.com/patients
Smith & Nephew Operations B.V. Bloemlaan 2, 2132 NP Hockelshoop, Netherlands



notuena
R

stealkt

OPPOSITE

smith&nephew

- | | |
|-------------------------------------|-------------------------------------|
| (19) Transparent adhesive film | (27) Proluctra lipet kila |
| (20) Film adhesive transparent | (28) Proluctra lipetina kila |
| (21) Transparente Heftfolie | (29) Liliqulavet kila |
| (22) Proluctra adhesive transparent | (30) Anopox; curvoblym jupjopon |
| (23) Proluctra adhesive transparent | (31) Aditico ortopado film |
| (24) Proluctra adhesive transparent | (32) Curvoblym lipetiva |
| (25) Transparente zulkewende film | (33) Sualit lipet pihvle |
| (26) Curvoblym lipetiva | (34) Protopocryla kila samogrykypna |
| (27) Transparent guarent film | (35) Fole adhesive transparent |
| (28) Lipetiva kila | (36) Proluctra adhesive kila |
| (29) Curvoblym lipetiva | (37) Protopocryla lipet film |
| (30) Proluctra adhesive kila | (38) Protopocryla kila |
| (31) Protopocryla lipet film | (39) Sualit jupjopon film |

Smith & Nephew Medical Limited, 105 Havelock Road, Hill 1423 2804 England
Trade Mark of / Marque de commerce de Smith & Nephew
This product may be covered by one or more US Patents. www.smith-nephew.com/patents
www.smith-nephew.com
© Smith & Nephew Operations B.V. Bloemlaan 2, 2132 NP Hockelshoop, Netherlands
2797
CE
MD
www.smith-nephew.com/patients
Smith & Nephew Operations B.V. Bloemlaan 2, 2132 NP Hockelshoop, Netherlands



ahclonyw
niefer

21

RENASYS[®]-F Foam Dressing Kit with Soft Port application

Smith & Nephew

RENASYS[®]-F
Foam Dressing Kit with Soft Port

Use clean or aseptic techniques for application, according to your institutional protocol. Thorough wound cleansing should occur with each dressing change.

Clean and debride



1. Debride any devitalized or necrotic eschar tissue. Cleanse the wound and pat dry.

applied directly



2. If desired, protect the periwound skin from exposure to moisture and adhesive through the use of skin sealant. Allow the skin sealant to dry fully prior to placement of the transparent film.

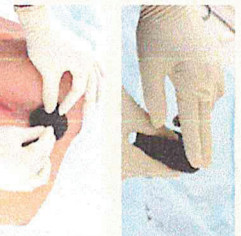


3. If desired, a non-adherent wound contact layer may be applied. Trim a single layer of non-adherent gauze and lay across the wound bed.

galenic plaster paper cover



4. Cut foam dressing to fit the size and shape of the wound and place cut foam into the wound. Avoid over packing. Foam should completely fill the wound cavity. It may be necessary to stack pieces of foam in deep wounds.



Precaution: If multiple pieces of wound filler are needed to fill the wound profile, count and record how many pieces are present to ensure all pieces are removed at a dressing change to minimise the risk of retention and possible infection. Foam should be cut to fit loosely into wound bed. Do not force or tightly pack foam into any areas of the wound to avoid damaging underlying tissue. Do not place foam into blind or unexplored tunnels. If a tunnel of known depth presents, cut foam longer than the tunnel, to ensure direct contact is made with the foam in the primary wound cavity. Do not cut foam directly over the wound cavity to avoid foam fragments from falling into the wound. Rub edges of the foam away from the open wound to remove loose fragments after cutting.



5. While holding the transparent film, expose one side of the adhesive backing by removing a single panel, and apply over the wound. Cover wound filler with transparent film, removing remaining adhesive panels to seal, then the top stabilisation panel.

Note: Avoid stretching or pulling the transparent film to minimise tension or trauma to the periwound skin. Overlap the edges of the transparent film by a minimum of 7.5cm/3in when using multiple pieces of transparent film.

Apply RENASYS Soft Port



6. Cut a circular opening (no less than 2cm/3/4in in diameter) in the centre of the film, over the wound filler. Remove any loose transparent film and dispose of away from the wound.



7. Remove the adhesive backing panel from the RENASYS Soft Port dressing, and align directly over the hole in the transparent film. Use gentle pressure to anchor the Soft Port to the transparent film.



8. Smooth the dressing down while removing the RENASYS Soft Port stabilisation frame.



9. Secure the RENASYS Soft Port to the patient according to your institutional protocol. Ensure the aeration disc, located near the orange quick click connector, is not covered or otherwise occluded by the method used to secure the Soft Port.



10. Connect the RENASYS Soft Port to the canister tubing by pushing the orange quick click connectors together. An audible click indicates connection is secure. Activate the RENASYS pump ensuring that it is operating at the prescribed therapy level. Please refer to your RENASYS pump manual for full operating instructions. The finished dressing should be fully compressed, firm to the touch and leak-free.

For detailed product information, including indications for use, contraindications, effects, precautions, warnings and important safety information, please consult product's instructions for use (IFU) prior to use.

Smith & Nephew Pty Ltd | Smith & Nephew Ltd
Australia | New Zealand
T +61 2 9857 2999 | F +64 9 820 2840
F +61 2 9857 3900 | F +64 9 820 2841
www.smith-nephew.com/australia
www.smith-nephew.com/new-zealand
Trademark of Smith & Nephew All trademarks acknowledged 21547-anz V1 SNJ 4870 REV0 04/20

Handwritten signature

Advanced Wound Management

Smith+Nephew

Tender toolkit

RENASYS[®] TOUCH Negative Pressure

Wound Therapy System 66802134

*neigiamo slėgio žaizdų gydymo
aparatas*



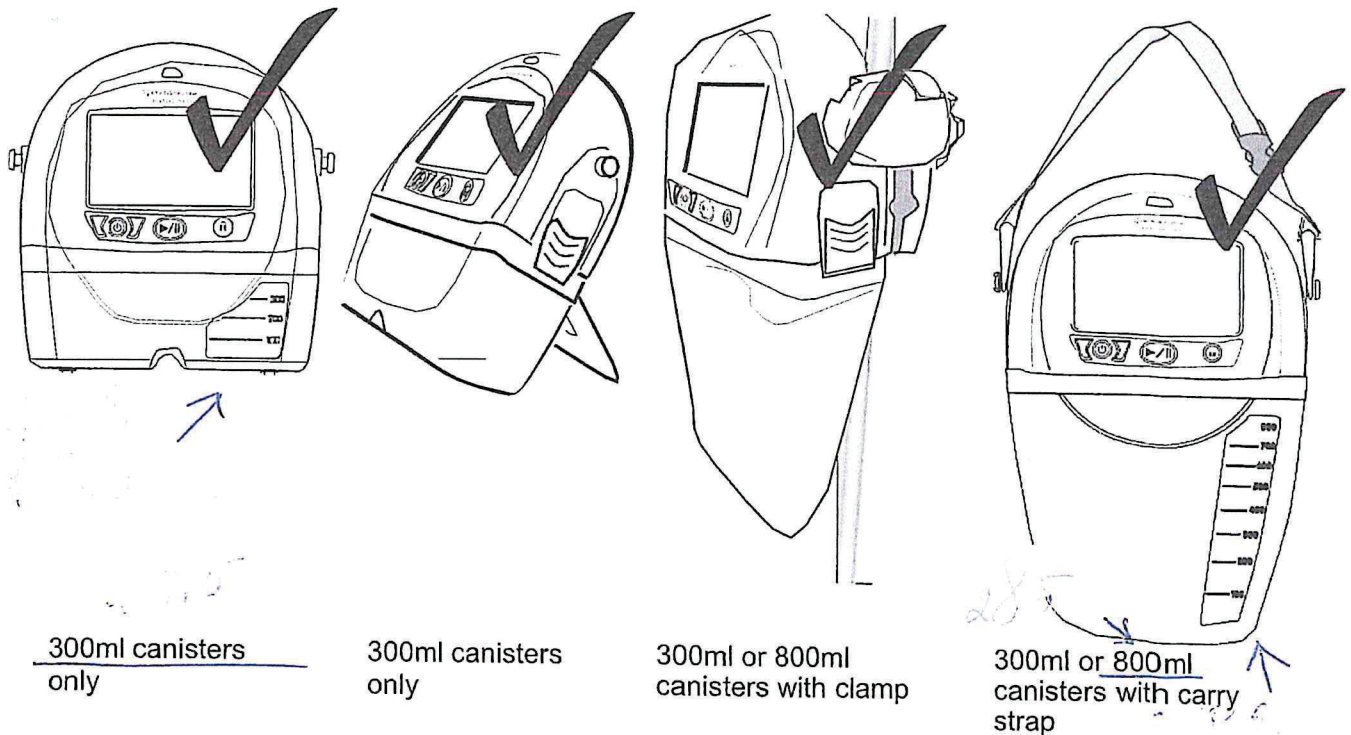
Device orientation during use

The device is designed to operate the upright position. Device orientation, rate at which fluid enters the canister and how exudate solidifies can impact filter occlusion. Operation in the upright position optimizes canister volume and alarm functionality. The device should be orientated to face the user's position when in stationary use.

Proper use/correct orientation

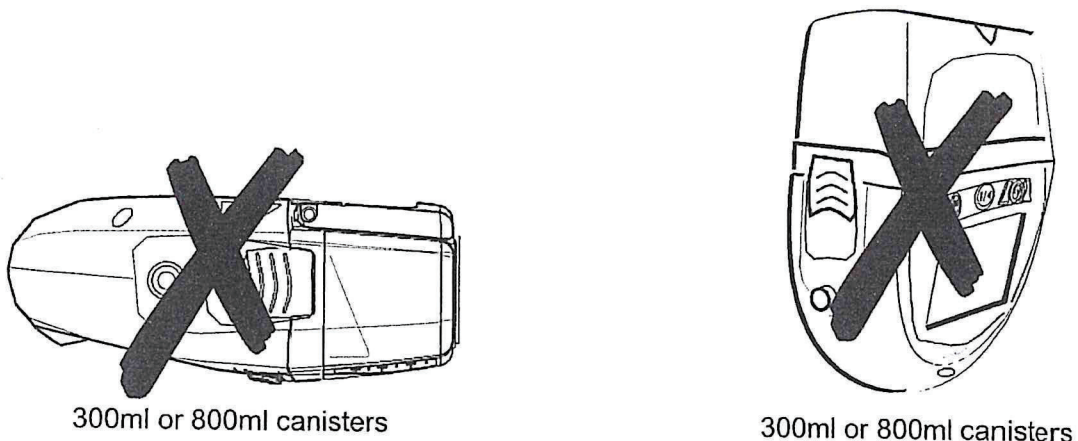
The 300ml canister has a kickstand and rubber feet. The device can stand in the upright position with the 300ml canister attached. Open the kickstand for additional stability and to change the viewing angle.

The 800ml canister does not include a kickstand or rubber feet. The IV pole/bed clamp or carry strap accessories can be used to mount the device in the upright position.



Incorrect orientation

Caution: Operating the device in a face-down position could result in damage to the device and inadvertent changes to therapy settings. Operating the device in an inverted position could impact filter occlusion resulting in a blockage alarm and requiring a change of canister.



RENASYS[®] Soft Port

A closer look at the RENASYS[®] Soft Port

The RENASYS[®] Soft Port replaces traditional plastic tubing with a soft, conformable, compression resistance alternative.^{2,3}

The system:

- Replacing hard plastic tubing with a soft, cushioned channel which may ease patient discomfort and may reduce the risk of pressure-related injuries.²
- Ensuring patient safety by sensing and alarming for blockages from the Soft Port opening all the way to the catheter.
- Allows the same application technique for a variety of wound types.



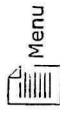
May help reduce the need for complex bridging²

Reduces patient discomfort and the risk of pressure injuries²

Delivers negative pressure even when kinked²

²Based on lab testing of pressure transfer. Fig. 2B

S4N



Abli'kotowai galad

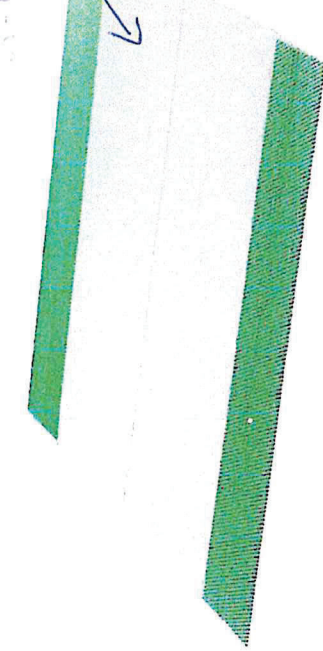
Dawo lipun aut-palis

pepildara Arsuaga

OPSITE INCISE

Adhesive Incision Drapes

OPSITE INCISE Drapes are a versatile range of breathable^{1,2} drapes with a low allergy adhesive.^{1,2}



Features and benefits

- Permeable to moisture vapour and oxygen^{1,2}
- High moisture vapour permeability (MVP)¹
- Breathable^{1,2}
- Helps to minimise risk of maceration^{3,4}
- Conformable and elastic⁵ - has been designed to be adaptable for the use on different areas of the body
- Highly extensible⁶
- Waterproof and showerproof⁵
- Film is a bacterial barrier which may help to minimise the risk of surgical site infection and to help maintain a sterile working field for surgical incisions^{3,7,8}
- Can be worn for up to 7 days dependent upon the nature of the wound and levels of exudate present^{9,11}
- Low allergy adhesive¹²
- Easy to apply^{8,13,14}
- Has been shown to secure drapes in place during surgery^{8,15}
- Remains in place during surgery^{15,16}
- Has been shown to provide secure catheter fixation¹³

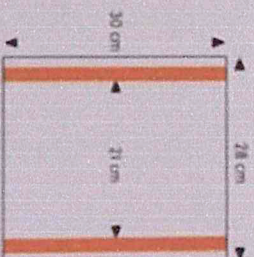
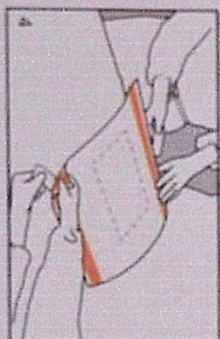
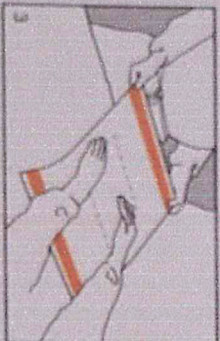
*n=16

| S+N Code | Description | Quantity |
|----------|---------------------------------|--------------|
| 4975 | OPSITE INCISE Drape 10cm x 14cm | Carton of 50 |
| 4986 | OPSITE INCISE Drape 15cm x 28cm | Carton of 10 |
| 4987 | OPSITE INCISE Drape 30cm x 28cm | Carton of 10 |
| 4995 | OPSITE INCISE Drape 40cm x 42cm | Carton of 10 |
| 4988 | OPSITE INCISE Drape 45cm x 28cm | Carton of 10 |
| 4989 | OPSITE INCISE Drape 45cm x 55cm | Carton of 10 |
| 4994 | OPSITE INCISE Drape 56cm x 84cm | Carton of 10 |

26

TE

- | | |
|------------------------------------|---------------------------------------|
| (1) Lipoalkylne lepliwisko | (1) Składki lipni pławek |
| (2) Gromadzony szklany siatek film | (2) Przezroczysta folia samoprzylepna |
| (3) Typowa adhezywna folia | (3) Folia adhezywna transparentna |
| (4) Przechłonna lepka folia | (4) Przechłonna adhezywna folia |
| (5) Przezroczysta lepka folia | (5) Przezroczysta lepka folia |
| (6) Lipoalkylne klepek | (6) Typowa adhezywna lepka folia |
| (7) Adhezywna lepka folia | (7) Siatka lepka folia |
| (8) Adhezywna lepka folia | |
| (9) Adhezywna lepka folia | |
| (10) Adhezywna lepka folia | |



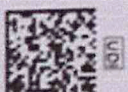
Smith & Nephew
www.smith-nephew.com
2024-02-01

STERILE



smith&nephew

REF 4987



GTIN 0500022304874
LOT 202409
WO 51208556

10
30cm x 28
113/4in. x 11

100% polystyren

27

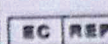
Smith+Nephew

RENASYS[®]-F

Foam Dressing Kit with Soft Port Large Kit (25 x 15 x 3cm / 9.8 x 5.9 x 1.2in)

- | | |
|--|--|
| <p>FR Kit de pansements de mousse avec Soft Port Grand kit</p> <p>DE Schaumverbandeset mit Soft Port Set Groß</p> <p>ES Kit de apósitos de espuma con puerto suave Kit grande</p> <p>PT Kit de pensois de espuma com porta suave Kit grande</p> <p>IT Kit per medicazione in schiuma con Soft Port Kit grande</p> <p>NL Schuimverbandeset met Soft Port Large</p> <p>SK Škumbandageset med Soft Port Stort set</p> <p>NO Skumbandagesett med Soft Port Stort sett</p> <p>FI Pehmeällä portilla varustettu vaihtolidossarja Suuri sarja</p> <p>SE Skumförbandekt med softport Stort kit</p> <p>RU Комплект повязки пены с Soft Port L комплект</p> <p>CZ Sada pěnového krytí s prostředkem Soft Port Veliká sada</p> <p>KR Veliki komplet za oblaganje s penom sa Soft Portom</p> <p>EE Pehme pordiga vahtplaastrikkomplekt suur komplekt</p> <p>GR Kit απόφους εμβύσματος με μαλακή θύρα μεγάλη kit</p> <p>HU Nagy méretű habkötszerkészlet Soft Porttal</p> <p>LV Putu pārsēja komplekts ar Soft Port Liels komplekts</p> | <p>LT Didelis porolionio tvaras su minkštuju prievadu</p> <p>PL Piankowy zestaw opatrunkowy z miękkim portem Zestaw duży</p> <p>RO Trusă pansament din spumă cu Soft Port Trusă mare</p> <p>BK Súpava penových krytí a měkkým portem Velká súpava</p> <p>SI Veliki komplet penastih oblog s kanalom Soft Port</p> <p>TR Soft Portlu Köpük Yara Örtüsü Kit Büyük Kit</p> <p>AR مجموعة ضمادة رغوية مع قنطرة قطنية Soft Port ملابس كبن</p> <p>CN 具備大型軟敷口套組的泡棉敷料套組</p> <p>KO 소프트 포트를 갖춘 폼 드레싱 키트 대형 키트</p> <p>MY Kit Dressing Busa dengan Port Lembut Kit Besar</p> <p>RU Комплект губчатых повязок большого размера с мягким портом</p> <p>TH ชุดผ้าปิดแผลฟองนุ่มมีช่องใส่สำลีขนาดใหญ่</p> <p>VN Bộ băng dán liên vết thương có bọt xốp với cổng mềm Bộ băng cỡ lớn</p> |
|--|--|

Smith & Nephew Medical Limited,
101 Hessle Road, Hull HU3 2BN England.
Trademark of / Marque de commerce de
Smith+Nephew, www.smith-nephew.com



Smith & Nephew
Operations B.V.,
Bloemlaan 2, 2132 NP
Hoofddorp, Netherlands

Country of Origin: Ireland
Kit packed in Ireland
with components originating in:
x1 RENASYS Soft Port - Ireland,
x3 RENASYS Transparent Film Dressing - Ireland,
x1 Foam Wound Dressing Large - USA

GTIN (01)30040565125931

REF 66800796

2024-06-28

(17) 2026-06-01

LOT (10) 78248

1x5



Rx only

STERILE EO



MD



UDI



(01)30040565125931(17)260601(10)78248

33159

2824

- The primary role of the first filter (the one facing towards the liquid in the canister) is to prevent liquid leaving the canister in a direction towards the pump. The secondary purpose of the first filter is to prevent bacteria from the canister leaving the canister in a direction towards the pump.
- The second filter provides odour protection.
- The third filter is at the exit of the canister to the pump. The primary role of the third filter is to prevent any bacteria that have not been stopped by the first filter progressing any further. The secondary purpose of the second filter is to prevent any liquid that might have breached the first filter, (e.g. due to mechanical failure), from progressing any further.

The mechanism by which these filters function is a combination of size exclusion and surface energy.

What materials are the RENASYS TOUCH canisters constructed from?

Body and Lid: Styrolution clearblend

Filters: The bacterial is hydrophobic and ePTFE membrane Solidifier

Clips: Valox 310

Tubing: Polyvinyl chloride (PVC)

Connector plug: nylon; zytel 101 F

Caps for Connector: Santoprene 271- 87

styrene polystyrene polycarbonate

Are RENASYS TOUCH canisters sterile?

No these are not sterile

What is the maximum capacity of the RENASYS 300ml and 800ml canisters with and without solidifier?

The RENASYS canisters has a indication to measure its capacity. Within the design of the canister, there is also an additional space above this which is used to accommodate the impact of the gelling agent before the activation of the canister full alarm. Hence the solidifier does not affect the amount of fluid displaced in the canister. We do not specify the total capacity of the canister as this is dependent on the orientation of the canister/device when in use. The canister is designed to hold either 300ml or 800ml with or without gelling agent before the canister full alarm activation.

Battery life and Charging

*Minikortti talpa 300ml
800ml, ysa su osovujantia
pelin maku*

What are the battery's operating conditions when charging?

Operational temperature 5°C to 40°C

Relative humidity 15% to 93% RH

Atmospheric pressure 700mbar to 1060 mbar

2. *Renasys Touch negative legio fluid oxygen to*
putatively risk on Renasys' mechanical pneumatic E

7. In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue use of NPWT and immediately seek medical assistance.
8. When treating enteric fistulas, do not place NPWT dressing in direct contact with exposed bowel. Cover the wound bed, including fistula opening, with non-adherent gauze or with one layer of saline moistened gauze. During the course of treatment patient's fluid levels must be closely monitored.
9. Avoid use of circumferential dressings except in cases of oedema or heavily exuding extremities, where this technique may be necessary to maintain a seal. Consider using multiple drapes to minimize risk of decreased distal circulation. Regularly assess distal pulses, and discontinue therapy if changes in circulation are detected.
10. Monitor patient for any signs of local or systemic infection. Infected wounds may require more frequent dressing changes. As NPWT is not intended to directly treat infection, if there are any signs of systemic infection or advancing infection at wound area, contact treating clinician immediately.
11. If multiple pieces of foam or gauze are needed to fill the wound profile, count and record how many pieces are present to ensure all pieces are removed at a dressing change to minimize the risk of retention and possible infection.
12. NPWT should remain on for duration of treatment. The length of time a patient may be disconnected from device is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage, integrity of dressing seal, assessment of bacterial burden and patient's risk of infection.
13. Do not use a dressing kit with breached or damaged packaging.
14. Use of NPWT presents a risk of tissue in-growth. Tissue in-growth may be reduced by reducing therapy pressure, using a wound contact layer or increasing the frequency of dressing changes.
- 15.
- NPWT should not be painful. If patient reports discomfort, consider reducing pressure setting and use of a wound contact layer. Pressure setting is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage and integrity of dressing seal.
16. Maintain regular monitoring of device and wound site during therapy to ensure therapeutic treatment and patient comfort.
17. Device is only to be used with Smith & Nephew authorized components. Use of any other products has not been proven safe and effective with RENASYS™ TOUCH device.
18. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position device and tubing appropriately to avoid risk of a trip hazard. Place device and tubing level with or below the wound. This will ensure the prescribed level of therapy is delivered.
19. When bathing or showering patient must disconnect from device, protecting both ends of tubing using tethered caps. Ensure aeration disc located near quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.
20. If any liquids penetrate device, discontinue use and return to your Smith & Nephew authorized provider for service.
21. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move device out of x-ray or scanner range.
22. Do not use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
23. AC mains power can only be removed by disconnecting power cord or AC power supply. Take care in positioning the device to allow access to the power jack.