



RENASYS AB

Abdominal Dressing Kit with Soft Port

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RENASYS[◇] AB

Abdominal Dressing Kit
with Soft Port

Supporting healthcare professionals

The RENASYS[◇] AB Abdominal Dressing Kit with Soft Port includes all the essential components to achieve safe and effective Temporary Abdominal Closure¹

The organ protection layer (OPL) and pre-shaped perforated foam are designed to support quick and easy application in the operating room.

The RENASYS AB Abdominal Dressing Kit with Soft Port is designed to protect and control the abdominal contents². Through the removal of exudates and the reduction of oedema,³ it may help to support primary fascial closure of the open abdomen.^{1,3,4}

Indications

RENASYS AB Abdominal Dressing Kit with Soft Port is intended to be used in conjunction with RENASYS TOUCH, RENASYS EZ MAX and RENASYS EZ PLUS pumps and canisters as a complete Negative Pressure Wound Therapy (NPWT) System for managing open abdominal wounds with NPWT.

RENASYS AB Abdominal Dressing Kit with Soft Port is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary.

It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.

The use of RENASYS AB is intended for use in acute hospital care settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre

Contraindications

The use of RENASYS AB is contraindicated in the presence of:

- Vital organs and structures not covered with the Organ Protection Layer (OPL)
- Patients with on-going or high potential for haemorrhage and/ or enteric leak
- Untreated osteomyelitis
- Necrotic tissue with eschar present
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Non-enteric and unexplored fistulas

Foam should never be placed in contact with exposed bowel, arteries, veins, organs or nerves.

Utilise the OPL at all times when using the RENASYS AB with the RENASYS NPWT system.



Always consult the Instructions for Use for your RENASYS dressing kit and pump prior to application for the full list of warnings and precautions for the RENASYS NPWT System.

Application

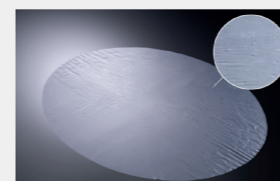
1. Preparation of Open Abdominal Wound

WARNING: Review all RENASYS NPWT system safety information prior to beginning wound preparation. Ensure that sufficient hemostasis has been achieved prior to applying the RENASYS AB dressing (refer to the Warnings section of the RENASYS AB Abdominal Dressing Kit Instructions for use (IFU)).



1. Eliminate any sharp edges or bone fragments from wound area.
2. Ensure any areas of necrosis are appropriately debrided.
3. Irrigate abdominal wound as needed.
4. Clean and dry the periwound area

2. Organ Protection Layer (OPL) Application



WARNING: Protect vital structures such as bowel and abdominal organs at all times with the Organ Protection Layer (OPL) during therapy. Foam should never be placed in contact with exposed bowel, arteries, veins, organs, or nerves (refer to CONTRAINDICATIONS SECTION in the RENASYS AB Abdominal Dressing Kit with Soft Port IFU).

NOTE: Either side of the OPL may be applied to exposed organs. The OPL may be cut or folded to accommodate the specific needs of the patient.

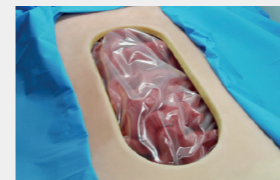


1. Remove kit contents from pouch and prepare the OPL on a sterile field. If cutting the OPL to a different size, ensure that each piece removed has been disposed of properly, away from the open wound.



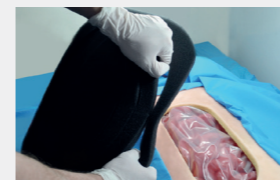
2. Gently position the OPL dressing evenly into the abdominal cavity, distributing the sides into both of the lateral paracolic gutters. Any excess material on the sides of the OPL may be folded back onto itself.

NOTE: Wet surgical gloves prior to applying the OPL to allow easier placement.

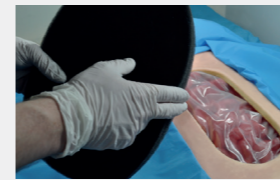


3. Ensure complete coverage of all exposed bowel in the abdominal cavity with the OPL, prior to filling the wound with foam.

3. Perforated Foam Application



1. Size the provided foam to the desired proportions along pre-scored perforations. Cutting the wound filler may be performed if desired. Do not cut the foam wound filler directly over the wound bed to avoid foam fragments from falling into the wound. Rub the edges of any cut foam, away from wound, to remove any loose fragments which may result. The foam should be placed directly over the OPL while maintaining contact with the margins of the wound.



2. Do not allow foam to contact intact skin without use of appropriate barrier, such as transparent film or a hydrocolloid.



3. Gently place perforated foam in the wound cavity over the OPL. Ensure that the foam is sized to fit loosely into the wound cavity and there is sufficient material up to the top surface of the abdominal wound. Do not under fill the wound. It may be necessary to stack pieces of foam in deep wounds depending on the wound profile. If multiple pieces of foam are needed, count and record the number of foam pieces used.

WARNING: Do not tightly pack or force foam into any areas of the wound.

4. Transparent film application



1. While holding the transparent film, expose one side of the adhesive backing by removing a single panel and apply over the foam.



2. Cover foam with transparent film, removing remaining adhesive panels to seal, as well as the remaining carrier panel. Film should extend at least 5cm beyond wound margin and be securely anchored to periwound area to maintain a good seal.

NOTE: Overlap the edges of the transparent film by a minimum of 7.5cm when using multiple pieces of transparent film.

NOTE: Avoid stretching or pulling the transparent film to minimize tension or trauma to the periwound skin.

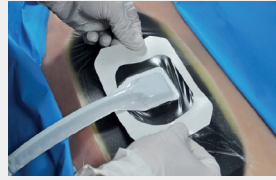
5. Soft Port Application



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



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

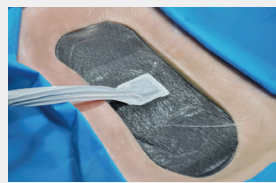


3. Smooth the dressing down while removing the RENASYS Soft Port's top stabilization frame.
4. Secure the RENASYS Soft Port to the patient according to your institutional protocol. Ensure the aeration disc, located near the orange quick click connector, is not covered or otherwise occluded by the method used to secure the Soft Port.

Initiation of therapy



1. Ensure canister is installed correctly. Connect the Soft Port to the canister tubing by pushing the orange quick click connectors together. An audible click indicates the connection is secure.
2. Activate the RENASYS EZ PLUS, RENASYS EZ MAX or RENASYS TOUCH pump on continuous mode, beginning at -80mmHg, checking that the dressing has a good seal. The recommended pressure range is -80 to -120mmHg.



3. The finished dressing should be fully compressed, firm to the touch and leak-free.
4. If required, adjust pressure setting to the desired level.
5. Pressure setting is a clinical decision based on individual characteristics of the patient and wound. Factors to consider include location of wound, volume of drainage and integrity of dressing seal.

Dressing changes

Precaution: When disconnecting the orange quick click connector, protect the tube ends by inserting the tethered caps of the quick click connector immediately before turning the pump off.

NOTE: When negative pressure is switched off, ensure the abdomen is adequately supported.

1. Remove and dispose of dressing per institutional protocol. Thoroughly inspect the wound to ensure all foam pieces have been removed.
2. Count and record number of foam pieces removed.
3. Dressings should be changed every 48 hours or more frequently based on continual monitoring of patient condition. In the event of heavy or viscous drainage, drainage with sediment, infection or when blood is present, more frequent dressing changes may be needed. Check dressings regularly and monitor the wound to check for signs of infection, bleeding or abdominal contamination. If there are any signs of systemic infection or advancing infection at the wound site, contact the treating clinician immediately.

Ordering

RENASYS® AB Abdominal Dressing Kit with Soft Port

S&N code	Contents
66800980	RENASYS AB Abdominal Dressing Kit with Soft Port

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Wound Management 101 Hessele Road T +44 (0) 1482 225181
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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.

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References: 1. Navsaria, P. *et al.* Negative pressure wound therapy management of the 'open abdomen' following trauma: a prospective study and systematic review. *World J Emerg Sur.* 2013 Jan 10;8 (1):4; 2. Barker, D. *et al.* Experience with Vacuum-pack Temporary Abdominal Closure in 258 Trauma and General and Vascular Surgical Patients. *Journal of the American College of Surgeons.* 2007. 204: 787-793; 3. Kubiak, B. *et al.* Peritoneal Negative Pressure Therapy prevents multiple organ injury in a chronic porcine sepsis and ischemia/ reperfusion model. *Shock.* 2010. 34(5):525-534; 4. Kaplan, M. *et al.* Guidelines for the management of the open abdomen. *Wounds* 2005 October 17: (suppl): S11-S24.