

# ABTHERA ADVANCE™

## OPEN ABDOMEN DRESSING



## INSTRUCTIONS FOR USE

Not for use with Instillation Therapy

**DE** - Nicht zur Verwendung mit Instillation Therapy **NL** - Niet te gebruiken bij instillatietherapie  
**FR** - Ne pas utiliser avec une thérapie d'instillation **IT** - Da non usare per la terapia a instillazione  
**ES** - No debe utilizarse con terapia de instilación **DA** - Må ikke anvendes sammen med instillationsterapi  
**SV** - Inte avsett för instillationsbehandling **PTBR** - Não deve ser usado com Terapia de Instilação  
**TR** - İnstilasyon Tedavisi ile kullanıma yönelik değildir **EL** - Δεν προορίζεται για χρήση με θεραπεία ενστάλαξης  
**FI** - Ei käytettäväksi huuhteluhoidossa **NO** - Skal ikke brukes med instilleringsbehandling

Only for use with Negative Pressure Therapy provided by INFOV.A.C.™ or V.A.C.ULTA™ Therapy Units

**DE** - ABTHERA ADVANCE™ Wundauflage für den Abdominalbereich. Nur zur Verwendung mit Unterdrucktherapie der Therapiesysteme INFOV.A.C.™ oder V.A.C.ULTA™  
**NL** - ABTHERA ADVANCE™-wondverband voor open buikwonden. Alleen voor gebruik met negatieve-druktherapie geleverd door INFOV.A.C.™ of V.A.C.ULTA™ behandelingsunits **FR**  
- Pansement pour abdomen ouvert ABTHERA ADVANCE™. À utiliser uniquement avec les unités de thérapie par pression négative INFOV.A.C.™ ou V.A.C.ULTA™  
**IT** - ABTHERA ADVANCE™ medicazione per addome aperto. Esclusivamente per l'uso con la terapia a pressione negativa erogata dalle unità terapeutiche INFOV.A.C.™ o V.A.C.ULTA™  
**ES** - Apósito para abdomen abierto ABTHERA ADVANCE™. Para uso exclusivo con terapia de presión negativa suministrada mediante unidades de terapia INFOV.A.C.™ o V.A.C.ULTA™ **DA** - ABTHERA ADVANCE™ Forbinding til det åbne abdomen. Kun til brug med undertryksterapi fra INFOV.A.C.™ eller V.A.C.ULTA™ Terapienheder  
**SV** - ABTHERA ADVANCE™-förband för öppen buk. Får endast användas till behandling med negativt tryck från INFOV.A.C.™- eller V.A.C.ULTA™-behandlingsenheter  
**PTBR** - Curativo para Abdome Aberto ABTHERA ADVANCE™. Somente para uso com Terapia com Pressão Negativa aplicadas pelas Unidades de Terapia INFOV.A.C.™ ou V.A.C.ULTA™  
**TR** - ABTHERA ADVANCE™ Açık Abdomen Pansumanı. Yalnızca INFOV.A.C.™ veya V.A.C.ULTA™ Terapi Üniteleri tarafından sağlanan Negatif Basıncılı Terapi ile kullanıma yöneliktir  
**EL** - Επιδεσμός ανοικτής κοιλιακής χώρας ABTHERA ADVANCE™. Μόνο για χρήση με τα συστήματα θεραπείας αρνητικής πίεσης INFOV.A.C.™ και V.A.C.ULTA™  
**FI** - Avoimen vatsaontelon ABTHERA ADVANCE™-sidos. Käytettäväksi vain INFOV.A.C.™- tai V.A.C.ULTA™-hoitoyksiköllä annettavan alipaineimuhoidon yhteydessä  
**NO** - ABTHERA ADVANCE™-forbindingen for åpent abdomen. Bare for bruk i behandling med undertrykk med behandlingsapparatene INFOV.A.C.™ eller V.A.C.ULTA™



# ABTHERA ADVANCE™ OPEN ABDOMEN DRESSING

## INSTRUCTIONS FOR USE

Only for use with Negative Pressure Therapy provided by INFOV.A.C.™ or V.A.C.ULTA™ Therapy Units

### PRODUCT DESCRIPTION

The ABTHERA ADVANCE™ Open Abdomen Dressing, when used with Negative Pressure Therapy provided by the INFOV.A.C.™ and V.A.C.ULTA™ Therapy Units provides an active temporary abdominal closure system, designed to remove fluids from the abdominal cavity and draw wound edges together, helping to achieve primary fascial closure while protecting abdominal contents from external contaminants.

### SAFETY INFORMATION

**IMPORTANT:** As with any prescription medical device, failure to consult a physician and carefully read and follow all therapy unit and dressing instructions and safety information prior to each use may lead to improper product performance and the potential for serious or fatal injury. Do not adjust therapy unit settings or perform therapy application without directions from / or supervision by the clinical caregiver.

All disposable components of the ABTHERA ADVANCE™ Open Abdomen Dressing are for single use only. Re-use of disposable components may result in wound contamination, infection and / or failure of the wound to heal.

### INDICATIONS FOR USE

The ABTHERA ADVANCE™ Open Abdomen Dressing is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and / or repeat abdominal entries are necessary. The intended use of this dressing is in open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.

### CONTRAINDICATIONS

- **Never** place exposed foam material directly in contact with exposed bowel, organs, blood vessels or nerves. Protect vital structures with the Visceral Protective Layer **at all times** during therapy.
- Patients with open abdominal wounds containing non-enteric unexplored fistulas should not be treated with the ABTHERA ADVANCE™ Open Abdomen Dressing.

Management of the open abdomen has been documented in case reports and consensus panel literature. Please refer to the **References List** section of this document.

### WARNINGS

**Not for use with Instillation Therapy:** Although it is accepted medical practice to flush a contaminated open abdominal cavity with saline or other medical solutions, the ABTHERA ADVANCE™ Open Abdomen Dressing was not designed for this purpose, and KCI has no studies to support its safe and effective use with instillation therapy. Potential risks of instillation into the open abdomen include:

- Instillation of fluid in the abdomen without sufficient fluid recovery may lead to abdominal compartment syndrome.
- Instillation of fluids in the abdomen that are untested for safety and efficacy with this application could lead to severe hollow viscus and solid organ damage.
- Instillation of unwarmed fluid in large quantities may lead to hypothermia.

**Only Use the SENSAT.R.A.C.™ Pad:** Substitution with any other tubing, alteration of the SENSAT.R.A.C.™ Pad or breach of the prescribed SENSAT.R.A.C.™ Pad application for the purpose of instilling fluids into the open abdomen is not recommended under any circumstance. This may lead to loss of system efficacy or harm to the patient.

**Bleeding:** Patients with abdominal wounds must be closely monitored for bleeding as these wounds may contain hidden blood vessels which may not be readily apparent. If sudden or increased bleeding is observed in the dressing, tubing or canister, immediately discontinue Negative Pressure Therapy, take appropriate measures to stop bleeding, and contact the physician. Negative Pressure Therapy is not designed to prevent, minimize or stop bleeding.

**Hemostasis must be achieved prior to dressing placement.**

The following conditions may increase the risk of potentially fatal bleeding.

- Suturing and / or anastomoses
- Trauma
- Radiation

- Inadequate wound hemostasis
- Non-sutured hemostatic agents (for example, bone wax, absorbable gelatin sponge or spray wound sealant) applied in the abdomen may, if disrupted, increase the risk of bleeding. Protect against dislodging such agents.
- Infection in the abdominal wound may weaken visceral organs and associated vasculature, which may increase susceptibility to bleeding.
- Use of anticoagulants or platelet aggregation inhibitors.
- Bone fragments or sharp edges could puncture vessels or abdominal organs. Beware of possible shifting in the relative position of tissues, vessels or organs within the abdominal wound that might increase the possibility of contact with sharp edges.

**Intra-abdominal Pressure Monitoring:** Laparotomy with the placement of any temporary abdominal closure **does not** eliminate the possibility of elevation in intra-abdominal pressure (IAP). When using Negative Pressure Therapy, IAP monitoring (for clinical or diagnostic signs and symptoms of elevated IAP) should continue as indicated by patient condition and in accordance with institutional clinical practice or guidelines. If intra-abdominal hypertension (IAH) or abdominal compartment syndrome (ACS) is observed or suspected, note intra-abdominal pressures and turn off power to the Negative Pressure Therapy Unit, discontinuing negative pressure. After full expansion of the perforated foam, obtain a new intra-abdominal pressure measurement. If IAH / ACS persists without negative pressure, discontinue the use of Negative Pressure Therapy and address the underlying condition as medically indicated.

**Use of Visceral Protective Layer:** When using Negative Pressure Therapy, ensure that the Visceral Protective Layer completely covers all exposed viscera and completely separates the viscera from contact with the abdominal wall. Place the Visceral Protective Layer over the omentum or exposed internal organs, and carefully tuck it between the abdominal wall and internal organs, making sure the Visceral Protective Layer completely separates the abdominal wall from the internal organs.

**Adhesions and Fistula Development:** Formation of adhesions of the viscera to the abdominal wall may reduce the likelihood of fascial reapproximation and increase the risk of fistula development which is a common complication in patients with exposed viscera.

**Infection:** Infected abdominal wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as patient condition, wound condition and treatment goals. Refer to dressing application instructions for details regarding dressing change frequency.

**Dressing Placement:** Always use a dressing from a sterile package that has not been opened or damaged. Do not force any dressing component into the wound, as this may damage underlying tissue.

**Dressing Removal:** The dressing components are not bioabsorbable. Always remove all dressing components from the abdomen at every dressing change.

**Keep Negative Pressure On:** Never leave the dressing in place without active negative pressure for more than two hours. If negative pressure is off for more than two hours, change dressing as shown in the dressing application instructions. Either apply a new dressing from an unopened sterile package and restart negative pressure, or apply an alternative dressing.

**Defibrillation:** Remove adhesive drape from area of defibrillation to prevent inhibition of electrical energy transmission.

**Acrylic Adhesive:** The drape has an acrylic adhesive coating, which may present a risk of adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives. If a patient has a known allergy or hypersensitivity to such adhesives, do not use the dressing. If any signs of allergic reaction or hypersensitivity develop, such as redness, swelling, rash, urticaria or significant pruritus, discontinue use and ensure appropriate emergency medical treatment. If bronchospasm or more serious signs of allergic reaction appear, remove dressing and ensure appropriate emergency medical intervention as indicated.

**Magnetic Resonance Imaging (MRI) – Therapy Unit:** The Negative Pressure Therapy Unit is MR unsafe. Do not take the device into the MR environment.

**Magnetic Resonance Imaging (MRI) – ABTHERA ADVANCE™ Open Abdomen Dressing:** The dressing can remain on the patient with minimal risk in an MR environment, assuming that use of Negative Pressure Therapy is not interrupted for more than two hours; please refer to **Keep Negative Pressure On** section.

**Hyperbaric Oxygen Therapy (HBO):** Do not take the negative pressure therapy unit into a hyperbaric oxygen chamber. The negative pressure therapy unit is not designed for this environment, and **should be considered a fire hazard**. After disconnecting the negative pressure therapy unit, either (i) replace the dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the SENSAT.R.A.C.™ Pad Tubing with dry gauze. For HBO therapy, the tubing must not be clamped. Never leave a dressing in place without active negative pressure for more than two hours (refer to **Keep Negative Pressure On** section).

**Application Setting:** Dressing applications and changes should be performed under strict sterile conditions in the operating theater. If dressing change is performed outside the operating theater, it must be performed in an environment equipped to address the onset of critical complications (refer to **WARNINGS** section) and where strict aseptic technique can be utilized.

### PRECAUTIONS

**Standard Precautions:** To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluids is likely.

**Intra-abdominal Packing:** When using intra-abdominal packing with Negative Pressure Therapy, packing material may be drier than anticipated. Evaluate packing material prior to removal and rehydrate if necessary to prevent adherence or damage to adjacent structures.

**Monitor Fluid Output:** The dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with Negative Pressure Therapy, the volume of exudate in the canister and tubing should be frequently examined.

**Patient Size and Weight:** The size and weight of the patient should be considered when prescribing Negative Pressure Therapy. Initial lower negative pressure should be considered for certain small or elderly patients who are at risk of fluid depletion or dehydration. Monitor fluid output including the volume of exudate in both the tubing and canister. This therapy has the potential to remove and collect large volumes of fluid. Tubing volume = approximately 25 mL from SENSAT.R.A.C.™ Pad to canister.

**Spinal Cord Injury:** In the event a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue Negative Pressure Therapy to help minimize sensory stimulation.

**Bradycardia:** To minimize the risk of bradycardia, the dressing must not be placed in proximity to the vagus nerve.

**Enteric Fistula or Leak:** When treating an open abdomen where enteric fistulas are present, clinicians should consider the potential for abdominal contamination if effluent is not appropriately isolated or managed.

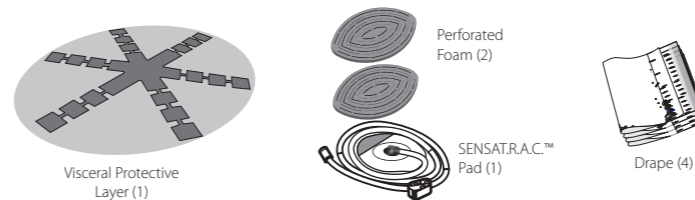
**Protect Periwound Skin:** Consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile / friable periwound skin with additional drape, hydrocolloid or other transparent film.

- Multiple layers of the drape may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the drape, foam or SENSAT.R.A.C.™ Pad tubing appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the drape over the foam dressing during drape application.

If there are any questions regarding the proper placement or usage of the ABTHERA ADVANCE™ Open Abdomen Dressing, please contact your local KCI clinical representative.

### DRESSING APPLICATION

#### ABTHERA ADVANCE™ OPEN ABDOMEN DRESSING COMPONENTS



### WOUND PREPARATION

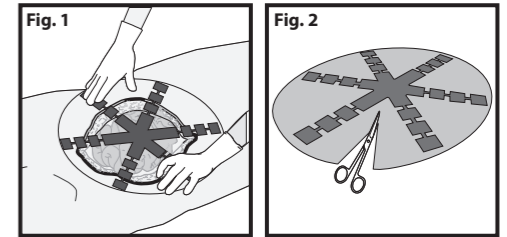
**WARNING: Review all ABTHERA ADVANCE™ Open Abdomen Dressing Safety Information before beginning wound preparation. Ensure adequate hemostasis has been achieved prior to dressing placement (refer to Bleeding section under WARNINGS).**

1. Sharp edges or bone fragments must be eliminated from wound area or covered (refer to **Bleeding** section under **WARNINGS**).
2. Irrigate abdominal wound and cleanse periwound skin as indicated.
3. Clean and dry periwound tissue; consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile / friable periwound skin with additional drape, hydrocolloid or other transparent film.

### VISCERAL PROTECTIVE LAYER APPLICATION

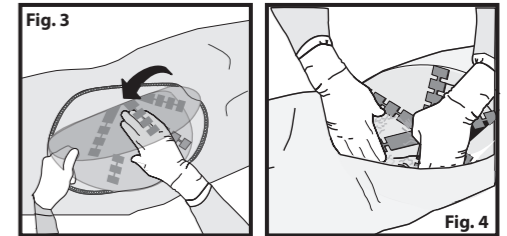
The Visceral Protective Layer is fenestrated to allow for active fluid removal when negative pressure is applied and is designed to allow application of this layer directly over omentum or exposed internal organs.

**WARNING: The foam in the Visceral Protective Layer is encapsulated for patient safety. Protect vital structures with Visceral Protective Layer at all times during therapy. Never place exposed foam material directly in contact with exposed bowel, organs, blood vessels or nerves.**



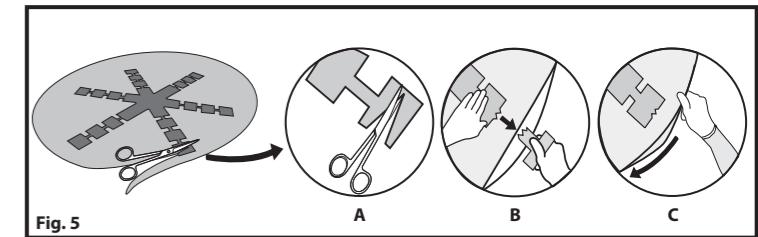
1. Remove contents from inner pouch and unfold the Visceral Protective Layer in a sterile field. Either side of the Visceral Protective Layer may be placed on the omentum or viscera.
2. Gently place Visceral Protective Layer over the open abdominal cavity (**Fig. 1**).
3. Determine the orientation of the dressing for the specific application. If Visceral Protective Layer will be placed around tubes, drains or the falciform ligament, cut only between the foam extensions (**Fig. 2**). Do not cut near or through foam extensions. Orient the Visceral Protective Layer accordingly before cutting.
4. Size the Visceral Protective Layer by folding or cutting as described in the following sections.

#### Folding Visceral Protective Layer to Size



1. Hold dressing by the edge and slightly lift. Slowly lower dressing into the paracolic gutter, using the other hand to gently and evenly work the dressing down (**Fig. 3**). Fold any excess Visceral Protective Layer up and over onto itself.
2. Continue placing Visceral Protective Layer between abdominal wall and internal organs (**Fig. 4**) throughout the abdominal compartment. The goal is to ensure full coverage of all viscera.

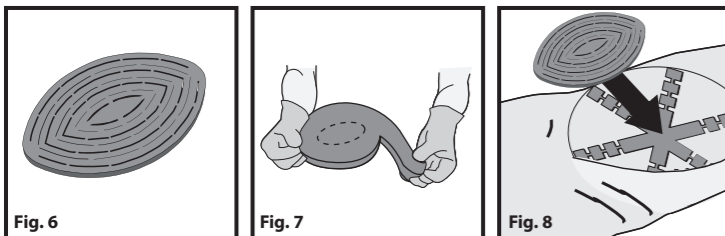
#### Cutting Visceral Protective Layer to Size



1. Cut Visceral Protective Layer away from wound, through center of large foam squares using sterile scissors (**Fig 5A**). Do not cut through narrow connecting tabs between the large foam squares.
2. Pinch the remaining half of the foam square and its connecting tab and pull. The foam and tab will separate at the next square (**Fig. 5B**). This will ensure that edges of Visceral Protective Layer cover exposed foam edge (**Fig. 5C**) and foam cannot contact organs (see **WARNING** above).
3. Document number of foam extensions removed and that each piece has been properly disposed of away from wound cavity.

**CAUTION:** Do not tear the foam over the wound, as fragments may fall into the wound. Rub or trim foam away from wound, removing any fragments to ensure loose particles will not fall into or be left in the wound upon dressing removal.

## PERFORATED FOAM APPLICATION



The perforated foam (Fig. 6) provided with the ABTHERA ADVANCE™ Open Abdomen Dressing is intended to:

- Transfer negative pressure from the Negative Pressure Therapy Unit to the Visceral Protective Layer to promote active fluid removal.
- Provide medial tension upon foam collapse to help maintain fascial domain.

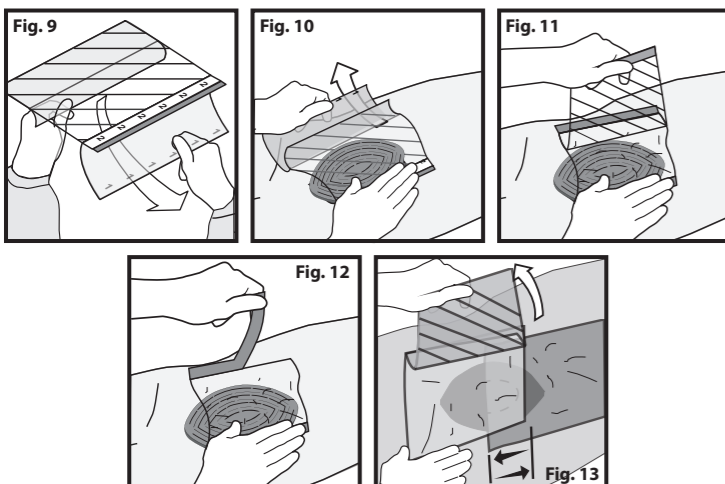
1. Tear or cut perforated foam to needed size as shown above (Fig. 7). The foam should fit directly over the Visceral Protective Layer and be in contact with wound edges. Do not allow foam to contact intact skin. One or both pieces of the provided perforated foam can be used, depending on the wound profile.

2. Gently place perforated foam into wound cavity over the Visceral Protective Layer (Fig. 8).

**NOTE:** Ensure foam-to-foam contact for even distribution of negative pressure.

**NOTE:** Always note the total number of pieces of foam used and document on the drape and in the patient's chart.

## DRAPE APPLICATION



1. Holding the drape, partially pull back one side of layer 1 to expose adhesive (Fig. 9). Be sure to hold layer 1 flap back, to prevent re-adherence to drape.

2. Place the drape adhesive-side down to cover foam and intact skin, ensuring drape covers at least an 8 - 10 cm border of intact periwound tissue (Fig. 10). Use any excess drape to seal difficult areas, if needed.

**NOTE:** To avoid trauma to the periwound skin, do not pull or stretch the drape over the foam dressing. Minimize wrinkles, as they may be a source of negative pressure leaks (refer to **PRECAUTIONS, Protect Periwound Skin** section).

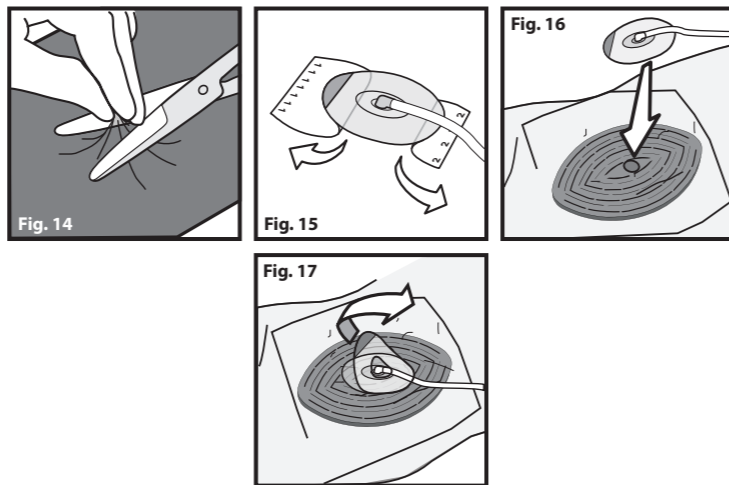
3. Remove remaining tab 1 backing material and pat around drape to ensure an occlusive seal.

4. Remove green-striped stabilization layer 2 (Fig. 11).

5. Remove perforated blue handling tabs from drape (Fig. 12).

**NOTE:** When using multiple pieces of drape, ensure that the edges of the drape overlap in order to achieve a seal (Fig. 13).

## SENSAT.R.A.C.™ PAD APPLICATION



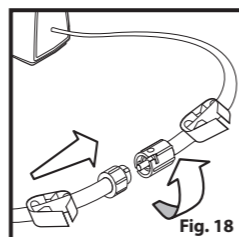
**NOTE:** Do not cut off the pad or insert the tubing into the foam dressing. This may occlude the tubing and cause the Negative Pressure Therapy Unit to alarm and could injure underlying viscera.

1. Choose pad application site. Give particular consideration to fluid flow and tubing position to allow for optimal flow and avoid placement over bony protuberances or within creases in the tissue.
2. Pinch drape and cut a 2.5 cm hole (not a slit) through the drape (Fig. 14). It is not necessary to cut into the foam.

**NOTE:** Cut a hole rather than a slit, as a slit may self-seal during therapy.

3. Apply pad, which has a central disc and a surrounding outer adhesive skirt.
  - Gently remove both backing layers 1 and 2 to expose adhesive (Fig. 15).
  - Place pad opening in central disc directly over hole in drape (Fig. 16).
  - Apply gentle pressure on the central disc and outer skirt to ensure complete adhesion of the pad.
4. Pull back on blue tab to remove pad stabilization layer (Fig. 17). Dressing application is complete.

## V.A.C.® NEGATIVE PRESSURE THERAPY APPLICATION



**NOTE:** Only for use with Negative Pressure Therapy provided by INFOV.A.C.™ and V.A.C.ULTA™ Negative Pressure Therapy Units. Refer to the therapy unit user manual for complete instructions for use.

**NOTE:** SENSAT.R.A.C.™ Pad tubing is not compatible with hospital vacuum systems.

**WARNING: Review all Negative Pressure Therapy System Safety Information before initiating therapy.**

1. Remove canister from packaging and insert into the therapy unit until it locks into place.

**NOTE:** Abdominal wounds often have copious drainage. Consider using the 1000 cc / mL canister. Ensure an adequate supply of canisters is readily available.

**CAUTION:** Consider the size and the weight of the patient, patient condition, wound type, monitoring capability and care setting when using the 1000 cc / mL canister.

**NOTE:** If the canister is not fully engaged, the therapy unit will alarm.

2. Connect SENSAT.R.A.C.™ Pad tubing to canister tubing and ensure clamp on each tube is open (Fig. 18). Position clamps away from patient.

3. Turn on power to the therapy unit and select 125 mmHg, continuous mode therapy setting for efficient fluid removal rates. Negative pressure therapy settings below 125 mmHg are not recommended.

**CAUTION:** Do not use intermittent therapy / DYNAMIC PRESSURE CONTROL™ Therapy with the ABTHERA ADVANCE™ Open Abdomen Dressing.

4. Initiate therapy. Assess dressing to ensure integrity of seal. The dressing should collapse and have a wrinkled appearance. There should be no hissing sounds. If there is any evidence of non-integrity, check drape and SENSAT.R.A.C.™ Pad seals, tubing connections, and canister insertion, and ensure clamps are open. Secure excess tubing to prevent inadvertent tension on tubing, which may disrupt the seal.

**Monitor Fluid Output** - The dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with the Negative Pressure Therapy Unit, the volume of exudate in the canister and tubing should be frequently examined

**Bleeding: Patients with abdominal wounds must be closely monitored for bleeding as these wounds may contain hidden blood vessels which may not be readily apparent. If sudden or increased bleeding is observed in the dressing, tubing or canister, immediately discontinue Negative Pressure Therapy, take appropriate measures to stop bleeding, and contact the physician. Negative Pressure Therapy is not designed to prevent, minimize or stop bleeding. (Refer to WARNINGS, Bleeding section).**

## ALARM RESOLUTIONS

All therapy unit alarms should be addressed in a timely manner. Refer to the therapy unit user manual for complete information on alarm resolutions.

In case of a leak alarm, patch leak source with additional drape to ensure integrity of seal.

**CAUTION:** Due to the highly exudative nature of abdominal wounds, Negative Pressure Therapy should be interrupted only for wound care and dressing change. Interruption of therapy can result in loss of seal integrity.

## DRESSING CHANGES

Dressing changes should occur every 24 to 72 hours, or more frequently based upon a continuing evaluation of wound condition and patient presentation. Consider more frequent dressing changes in the presence of infection or abdominal contamination.

Refer to **Application Setting** section under **WARNINGS**.

Whenever the dressing is changed, always replace all dressing components with components from an unopened sterile package.

## DRESSING REMOVAL

Remove and discard previous dressing per institution protocol. Completely inspect wound, including paracolic gutters, to ensure all pieces of dressing components have been removed. If intra-abdominal packing is present, packing material may be drier than anticipated. Evaluate packing material prior to removal and rehydrate if necessary to prevent adherence or damage to adjacent structures.

**WARNING: Refer to Dressing Removal section under WARNINGS.**

## EXPLANATION OF SYMBOLS USED

	Do not use if package is damaged or open		Manufacturer
	Single use only		Date of Manufacture
	Do not reutilize		Content information
	Consult instructions for use		
	Contains Phthalates		
	DEHP		
	Method of sterilization - Radiation		Catalog number
	Use by		Lot number
	Keep dry		

**Rx Only CAUTION:** Federal (US) law restricts this device to sale / rental by or on the order of a physician.



Always count and record number of foam pieces used in wound.

References available on request. Please contact KCI at 1-800-275-4524 (in the US).

Kaplan M. Managing the open abdomen. Ostomy Wound Management, 2004 Jan; 50(1A suppl); C2, 1-8

Kaplan M, Banwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S. Guidelines for the Management of the Open Abdomen. WOUNDS. 2005 Oct; 17(Suppl 1); S1S24

Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. The American Journal of Surgery, 2001 Dec; 182(6); 630-8

Barker DE, Kaufman HJ; Vacuum Pack Technique of Temporary Abdominal Closure; A 7-Year Experience with 112 Patients. Presented at the 59th Annual Meeting of the American Association for the Surgery of Trauma. September 16-18, 1999. Boston Mass.

Brock WB, Barker DE; Temporary Closure of Open Abdominal Wounds; The Vacuum Pack. Presented at the 66th Annual Scientific Meeting of the Southeastern Congress, Lake Buena Vista, Florida. February 6-10, 1994

Sherck J, Seiver A; Covering the "Open Abdomen"; A Better Technique. Presented as a Poster at the 66th Annual Scientific Meeting and the Postgraduate Course Program. Southeastern Surgical Congress. Atlanta, Georgia. January 31-February 4, 1998.

## CONTACT INFORMATION

For questions regarding this product, maintenance, or additional information about KCI products and services, please contact KCI or a KCI authorized representative, or:

In the US call 1-800-275-4524 or visit [www.aclecity.com](http://www.aclecity.com) or [www.openabdomen.com](http://www.openabdomen.com). KCI USA, Inc., 12930 IH 10 West, San Antonio, TX 78249

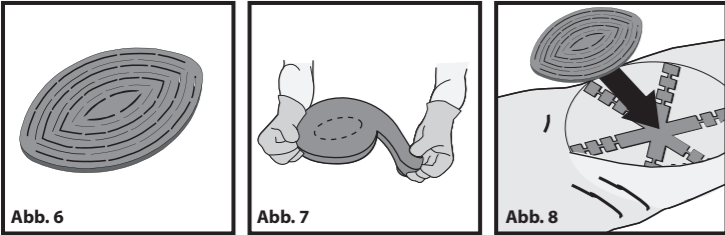
Outside the US visit [www.kci-medical.com](http://www.kci-medical.com).

## MANUFACTURER INFORMATION

**Manufactured For:**  
KCI USA, Inc.  
12930 IH 10 West  
San Antonio, TX 78249 USA  
1-800-275-4524  
[www.aclecity.com](http://www.aclecity.com)



## AUFBRINGEN DES PERFORIERTEN SCHAUMSTOFFS



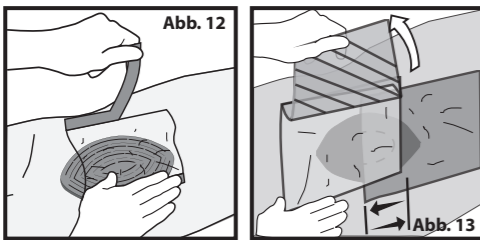
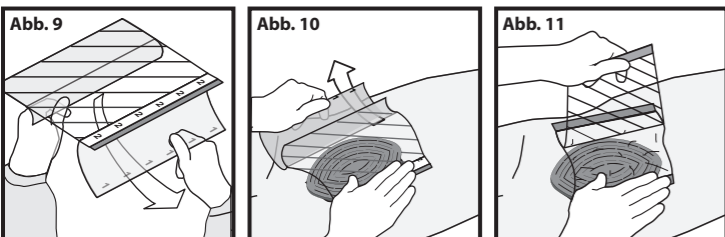
Der im Lieferumfang des ABTHERA ADVANCE™ Wundauflage für den Abdominalbereich enthaltene perforierte Schaumstoff (**Abb. 6**) ist vorgesehen, um:

- Unterdruck von der Unterdrucktherapieeinheit zur Viszeralenschutzschicht zu übertragen und damit die aktive Flüssigkeitsentfernung zu fördern.
  - mediale Tension beim Kollabieren des Schaumstoffs zu bieten, damit der Faszienbereich erhalten bleibt.
1. Den perforierten Schaumstoff wie oben dargestellt (**Abb. 7**) durch Abreißen oder Abschneiden auf die passende Größe bringen. Der Schaumstoff sollte genau auf die alle Wundränder abdeckende Viszeralenschutzschicht passen. Schaum nicht auf intakte Haut aufbringen. Je nach dem Profil der Wunde können ein oder beide Schaumstoffstücke verwendet werden.
  2. Den perforierten Schaumstoff vorsichtig in die Wundhöhle über den Viszeralerschutz (**Abb. 8**) legen.
 

**HINWEIS:** Auf direkten Kontakt zwischen den Schaumstoffstücken achten, um eine gleichmäßige Verteilung des Unterdrucks zu gewährleisten.

**HINWEIS:** Immer die Gesamtzahl der verwendeten Schaumstoffstücke notieren und auf der Folie sowie in den Patientenaufzeichnungen angeben.

## AUFBRINGEN DER FOLIE

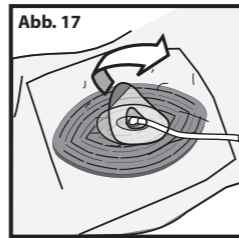
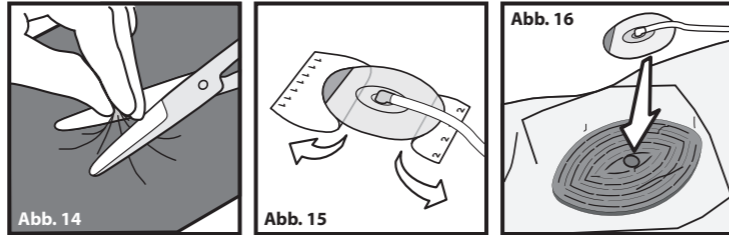


1. Die Folie festhalten und eine Seite der Lage 1 teilweise abziehen, um die Klebefläche freizulegen (**Abb. 9**). Die gelöste Lage 1 gut festhalten, um ein erneutes Ankleben an die Folie zu verhindern.
2. Die Folie mit der selbstklebenden Seite nach unten auflegen und Schaumstoff und intakte Haut damit abdecken. Dabei sicherstellen, dass die Folie mindestens einen 8–10 cm breiten Streifen an intaktem umliegendem Gewebe (**Abb. 10**) bedeckt. Bei Bedarf überschüssige Folie zur Abdichtung problematischer Bereiche verwenden.
 

**HINWEIS:** Zur Vermeidung eines Traumas in der Wundumgebung die Folie nicht über den Schaumverband ziehen oder dehnen. Das Entstehen von Falten vermeiden, da diese eine Ursache für Unterdruckleakagen sein können (siehe Abschnitt **Schutz der Wundumgebung** unter **VORSICHTSMASSNAHMEN**).
3. Verbleibendes Schutzpapier (Lage 1) entfernen und Folie für eine sichere Abdichtung andrücken.
4. Grün gestreifte Stabilisierungsschicht 2 entfernen (**Abb. 11**).
5. Perforierte blaue Griffflaschen von der Folie abtrennen (**Abb. 12**).
 

**HINWEIS:** Bei Verwendung mehrerer Folien sicherstellen, dass sich die Ränder der Folien überlappen, um eine gute Abdichtung zu erzielen (**Abb. 13**).

## ANWENDUNG DES SENSAT.R.A.C.™ PADS

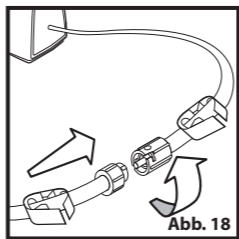


**HINWEIS:** Pad nicht abschneiden und Schlauch nicht in den Schaumverband einführen. Dadurch kann der Schlauch blockiert und der Alarm der Unterdrucktherapieeinheit ausgelöst sowie das darunter liegende Gewebe verletzt werden.

1. Anbringungsstelle für das Pad auswählen. Dabei vor allem Flüssigkeitsabfluss und Position des Schlauchs beachten: Es muss ein optimaler Fluss möglich sein und der Schlauch darf nicht über Knochenvorsprüngen oder in Gewebefalten platziert werden.
2. Folie anheben und ein Loch mit **2,5 cm** Durchmesser (keinen Schlitz) in die Folie schneiden (**Abb. 14**). Es ist nicht erforderlich, in den Schaumstoff zu schneiden.
 

**HINWEIS:** Die Öffnung sollte rund und nicht schlitzförmig sein, da sie sich sonst während der Therapie von selbst wieder schließen könnte.
3. Das Pad, das eine zentrale Scheibe und einen umlaufenden selbstklebenden Rand hat, anlegen.
  - Die beiden Schutzpapiere 1 und 2 vorsichtig entfernen und die Klebefläche freilegen (**Abb. 15**).
  - Die Öffnung des Pad-Schlauchanschlusses in der zentralen Scheibe direkt über dem Loch in der Folie platzieren (**Abb. 16**).
  - Vorsichtig auf die zentrale Scheibe und den äußeren Rand drücken, um sicherzustellen, dass das Pad vollständig haftet.
4. An der blauen Lasche nach hinten ziehen, um die Stabilisierungsschicht des Pads zu entfernen (**Abb. 17**). Damit ist das Anlegen der Wundauflage beendet.

## ANWENDUNG DER V.A.C.® UNTERDRUCKTHERAPIE



**HINWEIS:** Nur zur Verwendung mit dem Unterdrucktherapiesystem der Unterdrucktherapieeinheiten INFOV.A.C.™ und V.A.C.ULTA™. Eine ausführliche Gebrauchsanweisung finden Sie im Benutzerhandbuch der Therapieeinheit.

**HINWEIS:** Das SENSAT.R.A.C.™ Pad ist nicht kompatibel mit klinischen Vakuumsystemen.

**WARNUNG: Alle Sicherheitsinformationen für das Unterdrucktherapiesystem durchlesen, bevor eine Therapie begonnen wird.**

1. Den Kanister aus der Verpackung nehmen und in die Therapieeinheit einrasten lassen.
 

**HINWEIS:** Bauchwunden weisen häufig umfangreiche Drainagen auf. Gegebenenfalls den 1000-ml-Kanister verwenden. Sicherstellen, dass jederzeit ausreichend Ersatzkanister verfügbar sind.

**ACHTUNG:** Bei Verwendung des 1000-ml-Kanisters sind Größe, Gewicht und Zustand des Patienten, Wundart, Beobachtungsmöglichkeiten und Versorgungsumfeld zu berücksichtigen.

**HINWEIS:** Wenn der Kanister nicht vollständig einrastet, wird der Alarm der Therapieeinheit ausgelöst.
2. Den SENSAT.R.A.C.™ Pad-Schlauch mit der Kanisterleitung verbinden und sicherstellen, dass die Klemmen an beiden Schläuchen offen sind (**Abb. 18**). Die Klemmen vom Patienten abgewandt positionieren.
3. Die Therapieeinheit einschalten und kontinuierlichen Modus mit 125 mmHg für eine effiziente Flüssigkeitsentfernung auswählen. Einstellungen unter 125 mmHg werden für die Unterdrucktherapie nicht empfohlen.
 

**ACHTUNG:** Keine intermittierende Therapie/DYNAMIC PRESSURE CONTROL™ Therapie mit der ABTHERA ADVANCE™ Wundauflage für den Abdominalbereich anwenden.

4. Therapie starten. Die Wundauflage überprüfen, um die Abdichtung der Wundauflage sicherzustellen. Die Wundauflage sollte kollabieren und Falten aufweisen. Es dürfen keine Zischgeräusche zu hören sein. Wenn Anzeichen einer Undichtigkeit vorhanden sind, die Folien- und SENSAT.R.A.C.™ Padversiegelungen, die Schlauchanschlüsse sowie den Kanistersitz prüfen und sicherstellen, dass die Klemmen geöffnet sind. Überstehende Schläuche fixieren, um unbeabsichtigte Spannungen am Schlauch zu vermeiden, die möglicherweise die Versiegelung beschädigen.

**Beobachten der abgegebenen Flüssigkeitsmenge:** Mit der Wundauflage wird Flüssigkeit effizient aus dem abdominalen Kompartiment entfernt und der Unterdruck gleichmäßig verteilt. Bei der Behandlung mit der Unterdrucktherapieeinheit ist die Exsudatmenge im Kanister und Schlauch regelmäßig zu kontrollieren.

**Blutungen: Patienten mit Bauchwunden müssen sorgfältig auf Blutungen beobachtet werden, da diese Wunden verborgene und schwer erkennbare Blutgefäße enthalten können. Wenn sich in Wundauflage, Schlauch oder Kanister eine plötzliche oder verstärkte Blutung zeigt, ist die Unterdrucktherapie umgehend abzubrechen, und es sind entsprechende Maßnahmen zur Stillung der Blutung einzuleiten und ein Arzt hinzuzuziehen. Unterdrucktherapie ist nicht zum Verhindern, Reduzieren oder Stillen von Blutungen vorgesehen. (Siehe unter „WARNHINWEISE“ den Abschnitt „Blutungen“).**

## ALARMBEHEBUNG

Alle Alarme der Therapieeinheit müssen zeitnah behoben werden. Ausführliche Informationen zur Alarmbehebung finden Sie im Benutzerhandbuch der Therapieeinheit.

Bei einem Leckagealarm die undichte Stelle mit zusätzlicher Folie abdichten, um die Abdichtung sicherzustellen.

**ACHTUNG:** Da Bauchwunden von Natur aus viel Exsudat aufweisen, sollte die Unterdrucktherapie nur zur Wundversorgung und zum Wundauflagenwechsel unterbrochen werden. Eine Unterbrechung der Therapie kann zu einem Dichtigkeitsverlust führen.

## WUNDAUFLAGENWECHSEL

Die Wundauflage sollte alle 24 bis 72 Stunden gewechselt werden, oder häufiger, falls die kontinuierliche Beurteilung des Wundzustandes und das klinische Bild des Patienten dies erfordern. Wenn eine Infektion oder Kontamination des Abdominalbereichs vorliegt, sind u. U. häufigere Wundauflagenwechsel indiziert.

Siehe Abschnitt **Anwendungsumfeld** unter **WARNHINWEISE**.


Bei jedem Wechsel der Wundauflage sind stets alle Wundauflagekomponenten aus einer ungeöffneten sterilen Verpackung zu ersetzen.


## ENTFERNEN DER WUNDAUFLAGE


Die alte Wundauflage entfernen und gemäß den Krankenhausvorschriften entsorgen. Die Wunde vollständig untersuchen, einschließlich des Bereichs zwischen Colon und Bauchwand. So wird sichergestellt, dass alle Wundauflagekomponenten entfernt wurden. Bei einer abdominalen Tamponade können die Bauchtücher trockener als gewöhnlich sein. Vor dem Entfernen müssen die Bauchtücher überprüft und ggf. befeuchtet werden, damit sie nicht mit benachbarten Strukturen verkleben oder sie beschädigen.

**WARNUNG: Siehe Abschnitt Entfernen der Wundauflage unter WARNHINWEISE.**


## ERLÄUTERUNG DER VERWENDETEN SYMBOLE


 Nicht verwenden, wenn die Verpackung beschädigt ist oder bereits geöffnet wurde.

 Nur für den Einmalgebrauch

 Nicht wieder sterilisieren

 Gebrauchsanweisung beachten

 Enthält Phthalate

 Sterilisationsverfahren – Bestrahlung

 Verfallsdatum

 Trocken lagern

 vac therapy


 Hersteller

 Herstellungsdatum

 Informationen zum Inhalt

 Each

**Rx Only** **ACHTUNG:** Nach Maßgabe der Bundesgesetzgebung der USA darf dieses Gerät nur von zugelassenen Ärzten bzw. auf deren Anordnung verkauft bzw. vermietet werden.

 REF Katalognummer

 LOT Chargennummer

Stets die Gesamtzahl der in die Wunde eingebrachten Schaumstücke zählen und notieren.

Literaturhinweise sind auf Anfrage erhältlich. Rufen Sie KCI an unter +1-800-275-4524 (in den USA).

Kaplan M. Managing the open abdomen. Ostomy Wound Management, Jan. 2004; 50(1A suppl); C2, 1-8

Kaplan M, Banwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S, Guidelines for the Management of the Open Abdomen. WOUNDS. Okt. 2005; 17 (Suppl 1); S1S24

Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. The American Journal of Surgery, Dez. 2001; 182(6); 630-8

Barker DE, Kaufman HJ; Vacuum Pack Technique of Temporary Abdominal Closure; A 7-Year Experience with 112 Patients. Vorgestellt bei der Veranstaltung 59th Annual Meeting of the American Association for the Surgery of Trauma. 16.–18. September 1999. Boston Mass.

Brock WB, Barker DE; Temporary Closure of Open Abdominal Wounds; The Vacuum Pack. Vorgestellt bei der Veranstaltung 66th Annual Scientific Meeting of the Southeastern Congress, Lake Buena Vista, Florida. 6.–10. Februar, 1994

Sherck J, Seiver A; Covering the "Open Abdomen"; A Better Technique. Als Poster vorgestellt bei der Veranstaltung 66th Annual Scientific Meeting sowie dem Postgraduate Course Program. Southeastern Surgical Congress. Atlanta, Georgia. 31. Januar bis 4. Februar 1998.

## KONTAKTINFORMATIONEN

Bei Fragen zu diesem Produkt, zur Wartung oder zu anderen Produkten und Dienstleistungen von KCI wenden Sie sich bitte an KCI oder einen von KCI autorisierten Vertreter. Alternativ haben Sie folgende Möglichkeiten:

Innerhalb der USA erreichen Sie uns telefonisch unter 1-800-275-4524, oder Sie besuchen uns im Internet unter [www.acycity.com](http://www.acycity.com) oder [www.openabdomen.com](http://www.openabdomen.com). KCI USA, Inc. 12930 IH 10 West, San Antonio, TX 78249, USA

Außerhalb der USA besuchen Sie die Website [www.kci-medical.com](http://www.kci-medical.com).

## HERSTELLERINFORMATIONEN



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1-800-275-4524  
[www.acycity.com](http://www.acycity.com)

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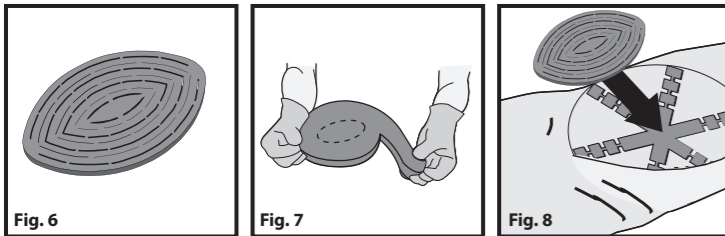








## APPLICATION DE LA MOUSSE PERFORÉE



La mousse perforée (Fig. 6) fournie avec le pansement ABTHERA ADVANCE™ pour abdomen ouvert est destinée à :

- transférer la pression négative de la thérapie par pression négative au film de protection du contenu abdominal pour favoriser l'élimination active des liquides ;
- assurer une tension médiane lorsque la mousse se rétracte, afin de maintenir le contenu abdominal dans son enceinte native.

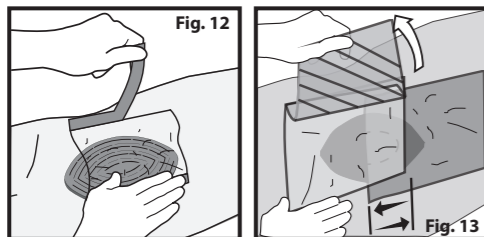
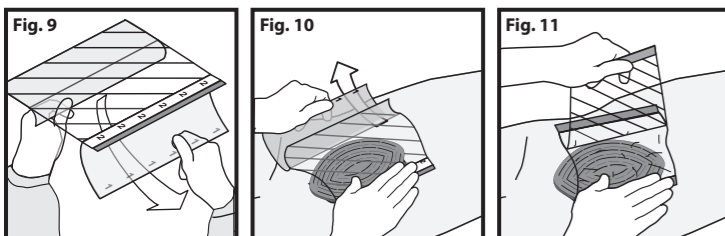
1. Découper ou déchirer la mousse perforée aux dimensions souhaitées comme illustré ci-dessus (Fig. 7). La mousse doit être posée juste au-dessus du film de protection du contenu abdominal tout en restant au contact des berges de la plaie. S'assurer que la mousse ne recouvre pas la peau intacte. Utiliser une ou deux pièces de mousse perforée selon la taille de la plaie.

2. Positionner délicatement la mousse perforée dans la cavité de la plaie sur le film de protection du contenu abdominal (Fig. 8).

**REMARQUE :** afin d'assurer une répartition uniforme de la pression négative, vérifier le contact mousse-mousse.

**REMARQUE :** toujours compter le nombre total de pièces de mousse utilisées ; le noter sur le champ adhésif et dans le dossier du patient.

## APPLICATION DU CHAMP ADHÉSIF



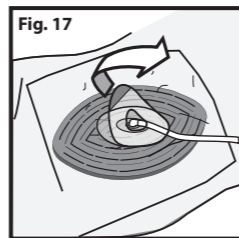
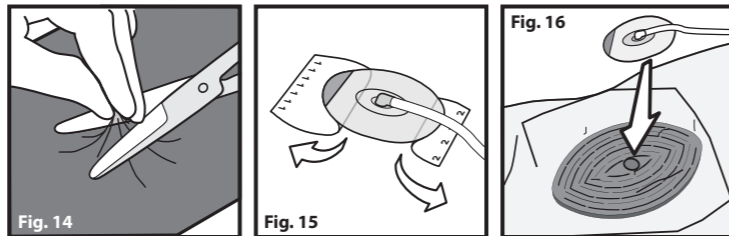
- En tenant le champ adhésif, tirer partiellement sur une extrémité de la couche 1 pour exposer l'adhésif (Fig. 9). Bien maintenir le rabat de la couche 1 en arrière pour éviter que le champ adhésif ne se recolle.
- Placer le côté adhésif de manière à recouvrir la mousse et la peau intacte, en veillant à ce que le champ recouvre une bordure supplémentaire d'au moins 8 à 10 cm de tissu périlésionnel intact (Fig. 10). Utiliser tout excès éventuel de champ adhésif pour réaliser l'étanchéité dans les zones difficiles, si nécessaire.

**REMARQUE :** pour éviter de traumatiser la peau périlésionnelle, ne pas tendre ou étirer le champ adhésif sur le pansement en mousse. Éviter la formation de plis qui risqueraient d'engendrer des prises d'air de pression négative (se reporter au paragraphe **Protection de la peau périlésionnelle** de la section **PRÉCAUTIONS D'EMPLOI**).

- Retirer le restant de la couche 1 et tapoter le champ adhésif afin d'assurer une étanchéité occlusive.
- Retirer la couche 2 de stabilisation qui est verte et rayée (Fig. 11).
- Retirer les languettes de manipulation perforées bleues du champ adhésif (Fig. 12).

**REMARQUE :** lorsque plusieurs pièces de champ adhésif sont utilisées, s'assurer que les bords du champ se chevauchent afin d'obtenir une bonne étanchéité (Fig. 13).

## APPLICATION DU TAMPON SENSAT.R.A.C.™



**REMARQUE :** ne pas découper le tampon ni insérer la tubulure dans le pansement en mousse. Cela pourrait boucher la tubulure, déclencher l'alarme de l'unité de thérapie par pression négative et blesser les viscères sous-jacents.

1. Choisir le site d'application du tampon. Porter une attention particulière quant au débit du liquide et au positionnement de la tubulure afin de permettre un débit optimal et d'éviter le positionnement sur des proéminences osseuses ou dans des plis du tissu.

2. Pincer le champ adhésif, puis découper un orifice de **2,5 cm** (et non une fente) dans le champ adhésif (Fig. 14). Il n'est pas nécessaire de découper dans la mousse.

**REMARQUE :** découper un orifice plutôt qu'une fente. En effet, une fente pourrait se refermer par elle-même au cours de la thérapie.

3. Appliquer le tampon, doté d'un disque central et d'un contour adhésif externe.

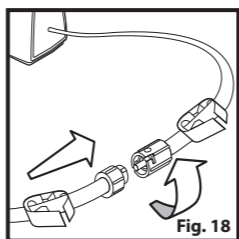
- Retirer doucement les couches 1 et 2 pour exposer l'adhésif (Fig. 15).

- Placer l'ouverture du tampon dans le disque central directement sur l'orifice du champ adhésif (Fig. 16).

- Appliquer une légère pression sur le disque central et le contour externe afin d'assurer une adhérence complète du tampon.

4. Tirer sur la languette bleue pour retirer la couche de stabilisation du tampon (Fig. 17). L'application du pansement est terminée.

## APPLICATION DE LA THÉRAPIE PAR PRESSION NÉGATIVE V.A.C.®



**REMARQUE :** à utiliser uniquement avec les unités de thérapie par pression négative INFOV.A.C.™ ou V.A.C.ULTA™. Pour connaître les instructions complètes d'utilisation, consulter le manuel d'utilisation de l'unité de thérapie.

**REMARQUE :** la tubulure du tampon SENSAT.R.A.C.™ n'est pas compatible avec les systèmes d'aspiration hospitaliers.

**MISE EN GARDE :** lire l'ensemble des consignes de sécurité relatives au système de thérapie par pression négative avant d'instaurer la thérapie.

1. Retirer le réservoir de son emballage et l'insérer dans l'unité de thérapie jusqu'à ce qu'il s'enclenche.

**REMARQUE :** les plaies abdominales sont souvent associées à un drainage important. Envisager l'utilisation du réservoir de 1 000 cc/ml. S'assurer qu'une quantité suffisante de réservoirs est disponible.

**AVERTISSEMENT :** tenir compte de la taille et du poids du patient, de son état, du type de plaie, des capacités de surveillance et de l'environnement de soins au moment d'utiliser le réservoir de 1 000 cc/ml.

**REMARQUE :** si le réservoir n'est pas enclenché à fond, l'alarme de l'unité de thérapie se déclenche.

2. Relier la tubulure du tampon SENSAT.R.A.C.™ à la tubulure du réservoir et vérifier que le clamp de chaque tube est ouvert (Fig. 18). Positionner les clamps à distance du patient.

3. Mettre l'unité de thérapie sous tension et sélectionner 125 mmHg et le mode de thérapie continu pour obtenir des taux corrects d'élimination des liquides. Il n'est pas recommandé de paramétrer la thérapie par pression négative à une valeur inférieure à 125 mmHg.

**AVERTISSEMENT :** Ne pas utiliser de thérapie intermittente / de thérapie DYNAMIC PRESSURE CONTROL™ avec le pansement ABTHERA ADVANCE™ pour abdomen ouvert.

4. Démarrer la thérapie. S'assurer de la bonne étanchéité du pansement. Le pansement doit se contracter et avoir un aspect plissé. Aucun sifflement ne doit se faire entendre. En cas d'absence d'intégrité évidente, vérifier l'étanchéité du champ adhésif et du tampon SENSAT.R.A.C.™, les raccords de la tubulure ainsi que le positionnement du réservoir, et s'assurer que les clamps sont ouverts. Fixer l'excès de tubulure afin d'éviter toute tension involontaire, qui pourrait en affecter l'étanchéité.

**Surveillance du volume de liquide collecté :** le pansement est conçu de manière à drainer efficacement le liquide du compartiment abdominal et à assurer une répartition uniforme de la pression négative. Lors de l'administration de la thérapie par pression négative, le volume des exsudats recueillis dans le réservoir et la tubulure doit être fréquemment relevé.

**Saignements : les patients présentant des plaies abdominales doivent être surveillés étroitement pour détecter tout saignement, les plaies étant susceptibles de contenir des vaisseaux sanguins cachés et peu visibles. Si des saignements soudains ou abondants sont observés dans le pansement, la tubulure ou le réservoir, arrêter immédiatement la thérapie par pression négative, prendre les mesures appropriées pour arrêter les saignements et appeler immédiatement le médecin. La thérapie par pression négative n'est pas conçue pour prévenir, réduire ou arrêter les saignements. (Se reporter aux MISES EN GARDE, section Saignements).**

## RÉSOLUTION DES ALARMES

Les alarmes de l'unité de thérapie doivent toutes être vérifiées rapidement. Pour obtenir des informations détaillées sur la résolution des alarmes, consulter le manuel d'utilisation de l'unité de thérapie.

En cas d'alarme de prise d'air, colmater la prise d'air à l'aide d'un champ adhésif pour assurer une bonne étanchéité du pansement.

**AVERTISSEMENT :** en raison de la grande quantité d'exsudats dans les plaies abdominales, la thérapie par pression négative doit être interrompue uniquement pour soigner la plaie et changer le pansement. L'interruption de la thérapie peut engendrer une perte d'étanchéité.

## CHANGEMENTS DE PANSEMENT

Le pansement doit être changé toutes les 24 à 72 heures, ou plus fréquemment suivant une évaluation continue de l'état de la plaie et de la présentation du patient. Des changements plus fréquents peuvent être nécessaires en cas d'infection ou de contamination abdominale.

Se reporter au paragraphe **Conditions d'application** de la section **MISES EN GARDE**.

À chaque changement du pansement, toujours remplacer l'ensemble des éléments du pansement par des éléments conservés dans un emballage stérile non ouvert.

## RETRAIT DU PANSEMENT

Retirer l'ancien pansement et le jeter conformément au protocole hospitalier. Inspecter la plaie intégralement, notamment les gouttières paracoliques, afin de s'assurer qu'il ne reste aucun résidu provenant des éléments du pansement. En cas d'utilisation de tampons intra-abdominaux, il est possible que les tampons utilisés soient plus secs que prévu. Vérifier les tampons avant le retrait et, si nécessaire, procéder à une réhydratation pour empêcher les adhérences et les lésions des structures adjacentes.

**MISE EN GARDE :** se reporter au paragraphe **Retrait du pansement de la section MISES EN GARDE**.

## EXPLICATION DES SYMBOLES UTILISÉS

Ne pas utiliser si l'emballage est endommagé ou ouvert

Fabricant

Usage unique

Date de fabrication

Ne pas restériliser

Contenu de l'emballage

Consulter le mode d'emploi

**Rx Only** **AVERTISSEMENT :** selon la loi fédérale américaine, ce dispositif ne peut être loué/ vendu que sur prescription d'un médecin.

Contient des phtalates

Référence

Méthode de stérilisation - Rayonnement

Numéro du lot

Limite d'utilisation

Protéger de l'humidité



Toujours compter et noter le nombre de pièces de mousse placées dans la plaie.

Références disponibles sur demande. Contacter KCI au 1-800-275-4524 (États-Unis).

Kaplan M. Managing the open abdomen. Ostomy Wound Management, 2004 Jan; 50(1A suppl); C2, 1-8.

Kaplan M, Banwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S. Guidelines for the Management of the Open Abdomen. WOUNDS. 2005 Oct; 17(Suppl 1); S1524.

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Barker DE, Kaufman HJ; Vacuum Pack Technique of Temporary Abdominal Closure; A 7-Year Experience with 112 Patients. Presented at the 59th Annual Meeting of the American Association for the Surgery of Trauma. September 16-18, 1999. Boston Mass.

Brock WB, Barker DE; Temporary Closure of Open Abdominal Wounds; The Vacuum Pack. Presented at the 66th Annual Scientific Meeting of the Southeastern Congress, Lake Buena Vista, Florida. February 6-10, 1994.

Sherck J, Seiver A; Covering the "Open Abdomen"; A Better Technique. Presented as a Poster at the 66th Annual Scientific Meeting and the Postgraduate Course Program. Southeastern Surgical Congress. Atlanta, Georgia. January 31-February 4, 1998.

## INFORMATIONS DE CONTACT

Pour toute question concernant ce produit, la maintenance ou des informations supplémentaires sur les produits et services KCI, contacter KCI ou un représentant agréé.

Aux États-Unis, composer le 1-800-275-4524 ou consulter le site [www.acelity.com](http://www.acelity.com) ou [www.openabdomen.com](http://www.openabdomen.com).

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En dehors des États-Unis, consulter le site [www.kci-medical.com](http://www.kci-medical.com).

## INFORMATIONS RELATIVES AU FABRICANT



**Manufactured For:**

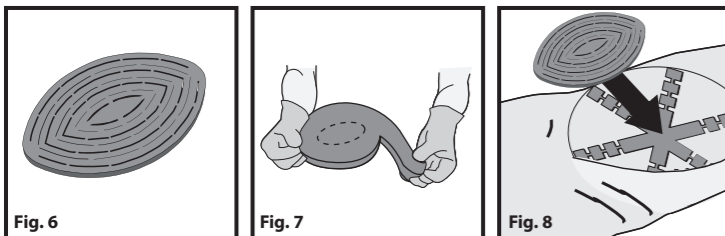
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## APPLICAZIONE DELLA SCHIUMA PREFORATA



La schiuma preforata (Fig. 6) fornita con la medicazione per addome aperto ABTHERA ADVANCE™ ha lo scopo di:

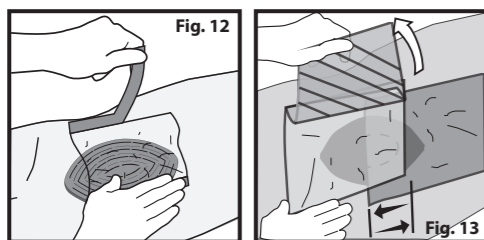
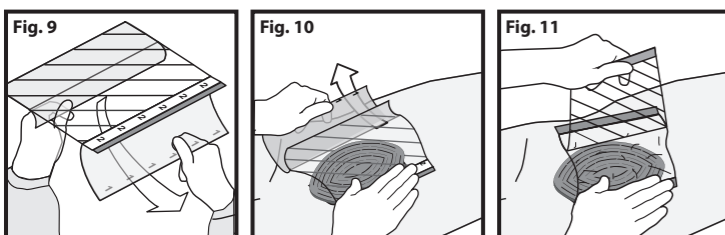
- Trasferire la pressione negativa dall'unità terapeutica a pressione negativa allo strato protettivo viscerale, per favorire la rimozione attiva dei liquidi.
- Fornire tensione mediale sul collasso della schiuma, per mantenere la funzionalità della fascia.

1. Strappare o tagliare la schiuma preforata in base alle esigenze, come illustrato in alto (Fig. 7). La schiuma deve essere applicata direttamente sopra lo strato protettivo viscerale, a contatto con i bordi della ferita. Evitare qualsiasi contatto tra la schiuma alla cute integra. È possibile utilizzare soltanto uno o entrambi i pezzi di schiuma preforata, a seconda del profilo della ferita.
2. Posizionare delicatamente la schiuma preforata nella cavità della ferita, sopra lo strato protettivo viscerale (Fig. 8).

**NOTA:** verificare il contatto schiuma-schiuma, per garantire la distribuzione uniforme della pressione negativa.

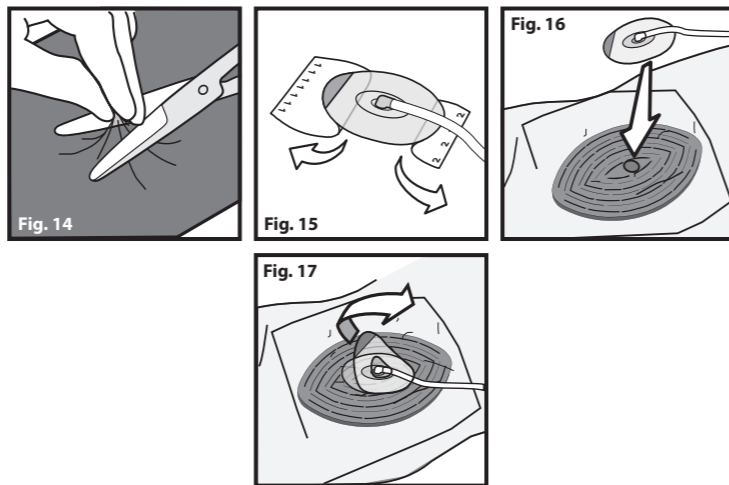
**NOTA:** registrare sempre il numero complessivo di pezzi di schiuma utilizzati nella medicazione e trascriverlo sulla pellicola e sulla cartella clinica del paziente.

## APPLICAZIONE DELLA PELLICOLA



1. Tenendo la pellicola, tirare parzialmente un lato dello strato 1 in modo da esporre la superficie adesiva (Fig. 9). Trattenere il lembo dello strato 1 per evitare che aderisca nuovamente alla pellicola.
2. Tenere il lato adesivo della pellicola rivolto verso il basso, per coprire la schiuma e la cute integra, facendo in modo che copra un bordo di almeno 8 - 10 cm di tessuto perilesionale (Fig. 10). Utilizzare la pellicola in eccesso per sigillare eventuali punti difficili, se necessario.  
**NOTA:** per evitare traumi alla cute perilesionale, non tirare o allungare la pellicola sopra la medicazione in schiuma. Ridurre al minimo le pieghe cutanee, poiché possono dare luogo a perdite di pressione negativa (consultare la sezione **Proteggere la cute perilesionale nelle PRECAUZIONI**).
3. Rimuovere il materiale protettivo che ancora ricopre la linguetta 1 e picchiettare attorno alla pellicola per garantire un'aderenza perfetta.
4. Rimuovere lo strato di stabilizzazione 2 a righe verdi (Fig. 11).
5. Rimuovere dalla pellicola le linguette di manipolazione preforate blu (Fig. 12).  
**NOTA:** se si utilizzano vari pezzi di pellicola, verificare che i bordi si sovrappongano in modo da garantire una tenuta ermetica (Fig. 13).

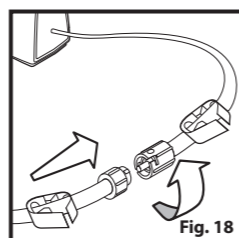
## APPLICAZIONE DEL PAD SENSAT.R.A.C.™



**NOTA:** non tagliare il pad o inserire il tubo nella medicazione in schiuma. Ciò potrebbe causare l'occlusione del tubo, inducendo l'unità terapeutica a pressione negativa a generare un allarme, e possibili lesioni alle viscere sottostanti.

1. Scegliere la sede di applicazione del pad. Prestare particolare attenzione al flusso di liquidi e alla posizione del tubo, per consentire un flusso ottimale ed evitare di collocarlo sopra le sporgenze ossee o i solchi del tessuto.
2. Afferrare la pellicola con due dita e praticarvi un foro (non una fessura) di **2,5 cm** di diametro (Fig. 14). Non è necessario tagliare la schiuma.  
**NOTA:** praticare un foro anziché una fessura, poiché quest'ultima potrebbe richiudersi durante la terapia.
3. Applicare il pad, che presenta un disco centrale e un'area adesiva circostante.
  - Rimuovere con delicatezza entrambi gli strati protettivi 1 e 2 per esporre l'adesivo (Fig. 15).
  - Posizionare l'apertura del pad nel disco centrale direttamente sul foro nella pellicola (Fig. 16).
  - Esercitare una lieve pressione sul disco centrale e sull'area circostante per garantire la completa adesione del pad.
4. Tirare la linguetta blu per rimuovere lo strato di stabilizzazione del pad (Fig. 17). L'applicazione della medicazione è terminata.

## APPLICAZIONE DELLA TERAPIA A PRESSIONE NEGATIVA V.A.C.®



**NOTA:** esclusivamente per l'uso con la terapia a pressione negativa erogata dalle unità terapeutiche INFOV.A.C.™ o V.A.C.ULTA™. Per istruzioni complete sull'utilizzo, fare riferimento al manuale d'uso dell'unità terapeutica.

**NOTA:** il tubo del pad SENSAT.R.A.C.™ non è compatibile con i sistemi di aspirazione ospedalieri.

**AVVERTENZA:** prima di avviare la terapia, leggere attentamente le informazioni di sicurezza del sistema terapeutico a pressione negativa.

1. Togliere il contenitore dalla confezione e inserirlo nell'unità terapeutica assicurandosi che sia bloccato in posizione.  
**NOTA:** poiché il materiale di drenaggio delle ferite addominali è in genere abbondante, è opportuno utilizzare un contenitore da 1000 cc (o ml). Assicurarsi che sia disponibile un numero sufficiente di contenitori di scorta.  
**ATTENZIONE:** quando si utilizzano contenitori da 1000 cc (o ml), tenere presente fattori quali corporatura, peso e condizioni cliniche del paziente, tipo di ferita, capacità di monitoraggio e ambito previsto per la terapia.  
**NOTA:** se il contenitore non è perfettamente inserito nell'unità, viene generato un allarme.
2. Collegare il tubo del pad SENSAT.R.A.C.™ al tubo del contenitore e assicurarsi che il morsetto su ciascun tubo sia aperto (Fig. 18). Posizionare i morsetti lontano dal paziente.
3. Accendere l'unità terapeutica e selezionare la modalità di terapia continua a 125 mmHg per consentire un drenaggio adeguato dei liquidi. Si consiglia di non impostare la terapia a pressione negativa al di sotto dei 125 mmHg.  
**ATTENZIONE:** non utilizzare una terapia intermittente / Terapia DYNAMIC PRESSURE CONTROL™ con la medicazione per addome aperto ABTHERA ADVANCE™.

4. Avviare la terapia. Ispezionare la medicazione per verificare la tenuta ermetica. La medicazione deve collassare e presentare delle pieghe. Non si deve udire alcun sibilo. Se si rilevano anomalie, verificare la tenuta ermetica della pellicola e del pad SENSAT.R.A.C.™, controllare i raccordi dei tubi e assicurarsi che il contenitore sia perfettamente inserito e che i morsetti siano aperti. Sistemare i tubi in modo da evitare eventuali tensioni che potrebbero compromettere la tenuta ermetica.

**Monitoraggio delle perdite di fluidi:** la medicazione è concepita per rimuovere in modo efficace i liquidi dal comparto addominale e distribuire uniformemente la pressione negativa. Quando si utilizza l'unità terapeutica a pressione negativa, è opportuno controllare frequentemente il volume di essudato presente all'interno del contenitore e del tubo.

**Emorragia: i pazienti con ferite addominali sono particolarmente esposti al rischio di emorragie, poiché tali ferite possono contenere vasi sanguigni nascosti, non immediatamente visibili. Devono essere pertanto sottoposti a monitoraggio costante. Se si osserva un aumento improvviso del volume di sangue nella medicazione, nel tubo o nel contenitore, interrompere immediatamente la terapia a pressione negativa, adottare le misure necessarie per arrestare l'emorragia e consultare un medico. La terapia a pressione negativa non è concepita per prevenire, ridurre al minimo o arrestare l'emorragia (consultare la sezione Emorragia in AVVERTENZE).**

## RISOLUZIONI DEGLI ALLARMI

Intervenire tempestivamente in presenza di allarmi generati dall'unità terapeutica. Per istruzioni complete sulla risoluzione degli allarmi, fare riferimento al manuale d'uso dell'unità terapeutica.

In presenza di un allarme generato in seguito a una perdita, sigillare il punto in cui si è verificata la perdita con altra pellicola per assicurare la tenuta ermetica.

**ATTENZIONE:** poiché le ferite addominali sono caratterizzate da un'abbondante produzione di essudato, interrompere la terapia a pressione negativa soltanto per il trattamento della ferita e il cambio della medicazione, per evitare di compromettere la tenuta ermetica.

## CAMBIO DELLA MEDICAZIONE

La medicazione deve essere cambiata ogni 24-72 ore o con frequenza superiore, in base alle condizioni della ferita e del paziente. In caso di infezione o contaminazione addominale, può essere necessario cambiare la medicazione con maggiore frequenza.

Consultare la sezione **Indicazioni per l'applicazione** nelle **AVVERTENZE**.

Ogni volta che si cambia la medicazione, sostituirla sempre tutti i componenti con altri provenienti da una confezione sterile chiusa.

## RIMOZIONE DELLA MEDICAZIONE

Rimuovere e smaltire la medicazione precedente attenendosi al protocollo dell'istituto. Ispezionare accuratamente la ferita, incluse le docce paracoliche, per accertarsi di avere rimosso tutti i componenti della medicazione. Se si utilizza il packing intra-addominale, è possibile che il materiale utilizzato risulti più asciutto del previsto. Pertanto, prima di rimuoverlo controllarlo e, se necessario, inumidirlo per prevenire aderenze o danni alle strutture adiacenti.

**AVVERTENZA:** Consultare la sezione **Rimozione della medicazione** nelle **AVVERTENZE**.

## SPIEGAZIONE DEI SIMBOLI UTILIZZATI

	Non utilizzare se la confezione è aperta o danneggiata		Produttore
	Esclusivamente monouso		Data di produzione
	Non sterilizzare		Informazioni sul contenuto
	Consultare le Istruzioni per l'uso	<b>Rx Only</b>	<b>ATTENZIONE:</b> la legge federale statunitense autorizza la vendita o il noleggio di questo dispositivo esclusivamente dietro prescrizione medica.
	Contiene ftalati	<b>REF</b>	Numero di catalogo
	Metodo di sterilizzazione - Radiazioni	<b>LOT</b>	Numero di lotto
	Data di scadenza		
	Conservare in un luogo asciutto		



Contare e registrare sempre il numero di pezzi di schiuma utilizzati nella ferita.

Documentazione disponibile su richiesta. Negli Stati Uniti, contattare KCI al numero 1-800-275-4524.

Kaplan M. Managing the open abdomen. Ostomy Wound Management, 2004 Jan; 50(1A suppl); C2, 1-8

Kaplan M, Barwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S, Guidelines for the Management of the Open Abdomen. WOUNDS. 2005 Oct; 17(Suppl 1); S1524

Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. The American Journal of Surgery, 2001 Dec; 182(6); 630-8

Barker DE, Kaufman HJ; Vacuum Pack Technique of Temporary Abdominal Closure: A 7-Year Experience with 112 Patients. Presented at the 59th Annual Meeting of the American Association for the Surgery of Trauma. September 16-18, 1999. Boston Mass.

Brock WB, Barker DE; Temporary Closure of Open Abdominal Wounds; The Vacuum Pack. Presented at the 66th Annual Scientific Meeting of the Southeastern Congress, Lake Buena Vista, Florida. February 6-10, 1994

Sherck J, Seiver A; Covering the "Open Abdomen"; A Better Technique. Presented as a Poster at the 66th Annual Scientific Meeting and the Postgraduate Course Program. Southeastern Surgical Congress. Atlanta, Georgia. January 31-February 4, 1998.

## CONTATTO PER INFORMAZIONI

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Fuori dagli Stati Uniti visitare il sito Web [www.kci-medical.com](http://www.kci-medical.com)

## INFORMAZIONI SUL PRODUTTORE

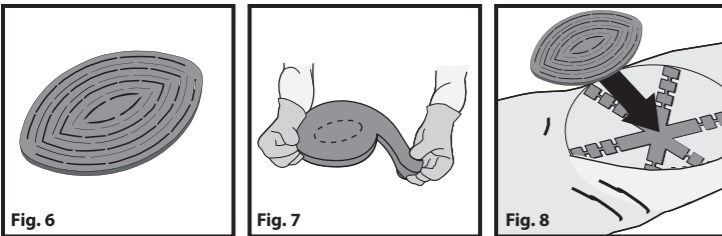
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## APLICACIÓN DEL APÓSITO DE ESPUMA PERFORADA



La espuma perforada (**Fig. 6**) que se proporciona con el apósito para abdomen abierto ABTHERA ADVANCE™ está diseñada para:

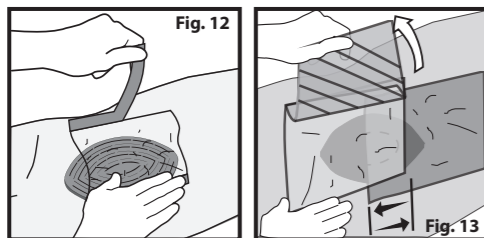
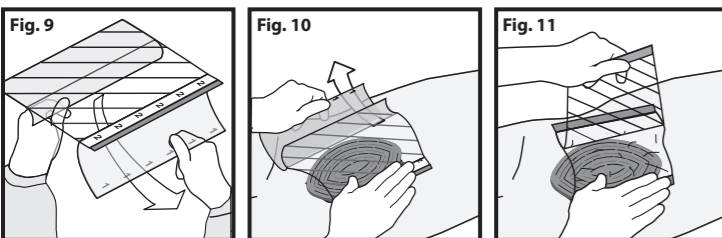
- Transferir la presión negativa desde la unidad de terapia de presión negativa hasta la capa de protección visceral a fin de favorecer una extracción activa de los líquidos.
- Proporcionar tensión medial cuando se comprima el apósito para ayudar a mantener el dominio de la fascia.

- Rasgue o corte la espuma perforada al tamaño necesario como se muestra arriba (**Fig. 7**). El apósito de espuma debe ajustarse directamente sobre la capa de protección visceral y estar en contacto con todos los extremos de la herida. Impida que el apósito de espuma se superponga sobre la piel intacta. Puede utilizar una o las dos piezas que incluye el apósito de espuma perforada, en función del perfil de la herida.
- Coloque lentamente el apósito de espuma perforada en la cavidad de la herida sobre la capa de protección visceral (**Fig. 8**).

**NOTA:** Asegúrese de que las piezas de apósito de espuma están en contacto entre sí para que haya una distribución uniforme de la presión negativa.

**NOTA:** Anote siempre el número total de piezas de espuma utilizadas en el apósito y registre el número tanto en la lámina adhesiva como en la historia del paciente.

## APLICACIÓN DE LA LÁMINA ADHESIVA

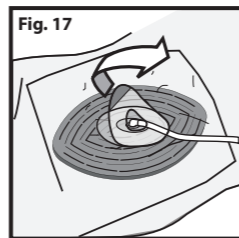
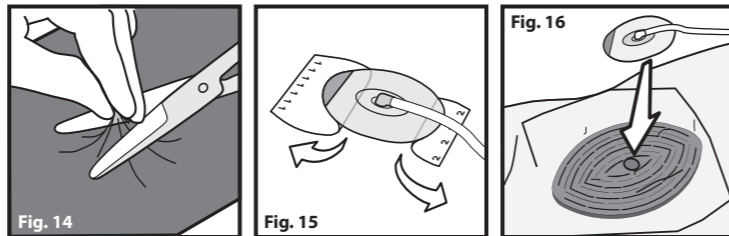


- Mientras sujeta la lámina adhesiva, tire hacia atrás parcialmente de una cara de la capa 1 para exponer el adhesivo (**Fig. 9**). Asegúrese de mantener hacia atrás la solapa de la capa 1 para evitar que vuelva a adherirse.
- Coloque la cara adhesiva orientada hacia abajo de forma que cubra el apósito de espuma y la piel intacta; asegúrese de que la lámina adhesiva cubre al menos un borde de 8 a 10 cm del tejido intacto circundante a la herida (**Fig. 10**). Si es necesario, utilice cualquier sobrante de lámina adhesiva para sellar las zonas difíciles.
 

**NOTA:** Para evitar traumatismos en la piel circundante a la herida, no estire demasiado la lámina adhesiva sobre el apósito de espuma. Minimice las arrugas, ya que son una fuente de fuga de presión negativa (consulte la sección «Protección de la piel circundante» en PRECAUCIONES).
- Retire la parte restante del material de la pestaña 1 y presione alrededor de la lámina adhesiva para garantizar un sellado oclusivo.
- Retire la capa 2 de estabilización con rayas verdes (**Fig. 11**).
- Retire las pestañas de manipulación azules de la lámina adhesiva (**Fig. 12**).
 

**NOTA:** Si utiliza varias piezas de lámina adhesiva, asegúrese de que los bordes de las piezas se solapan entre sí para obtener un sellado perfecto (**Fig. 13**).

## APLICACIÓN DE LA ALMOHADILLA SENSAT.R.A.C.™



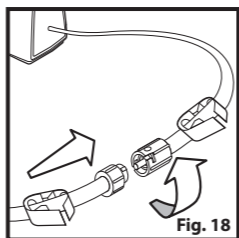
**NOTA:** No corte la almohadilla ni inserte el tubo en el apósito de espuma, ya que puede ocluir los tubos y provocar una alarma en la unidad de terapia de presión negativa y podrían producirse lesiones en las vísceras subyacentes.

- Elija el sitio de aplicación de la almohadilla. Preste especial atención a la colocación del tubo para permitir un flujo óptimo y evite colocarlo sobre prominencias óseas o en pliegues del tejido.
- Pellizque la lámina adhesiva y corte un orificio de **2,5 cm** (no una raja) en la lámina adhesiva (**Fig. 14**). No es necesario cortar la espuma.

**NOTA:** Corte un orificio y no una raja, ya que ésta podría sellarse durante el tratamiento.

- Aplique la almohadilla, que tiene un disco central y un reborde exterior adhesivo alrededor.
  - Retire suavemente las capas 1 y 2 del dorso para exponer el adhesivo (**Fig. 15**).
  - Coloque la abertura del disco central de la almohadilla directamente sobre el orificio de la lámina adhesiva (**Fig. 16**).
  - Aplique una suave presión sobre el disco central y el reborde exterior para asegurar la adherencia completa de la almohadilla.
- Tire hacia atrás de la pestaña azul para retirar la capa de estabilización de la almohadilla (**Fig. 17**). La aplicación del apósito ha finalizado.

## APLICACIÓN DE LA TERAPIA DE PRESIÓN NEGATIVA V.A.C.®



**NOTA:** Para uso exclusivo con terapia de presión negativa suministrada mediante unidades de terapia INFOV.A.C.™ y V.A.C.ULTA™. Consulte el manual del usuario de la unidad de terapia si desea leer las instrucciones de uso al completo.

**NOTA:** El tubo de la almohadilla SENSAT.R.A.C.™ no es compatible con los sistemas de vacío hospitalarios.

**ADVERTENCIA:** Consulte toda la información de seguridad sobre terapia de presión negativa antes de iniciar la terapia.

- Retire el contenedor del paquete e introdúzcalo en la unidad de terapia hasta que quede fijado en su posición.
 

**NOTA:** Es frecuente que las heridas abdominales tengan drenajes copiosos. Considere la posibilidad de utilizar un contenedor de 1.000 cc/ml. Compruebe que cuenta con el suministro suficiente de contenedores listo para su uso.

**PRECAUCIÓN:** Antes de decidirse por un contenedor de 1.000 cc/ml, tenga en cuenta el tamaño, el peso y el estado del paciente, el tipo de herida, la capacidad de vigilancia y el entorno asistencial.

**NOTA:** Si el contenedor no queda bien acoplado, la unidad de terapia emitirá una alarma.
- Conecte el tubo de la almohadilla SENSAT.R.A.C.™ al tubo del contenedor y asegúrese de que la pinza de ambos tubos está abierta (**Fig. 18**). Coloque las pinzas lejos del paciente.
- Encienda la unidad de terapia y seleccione un ajuste de 125 mm Hg en modo continuo para obtener un flujo de extracción de líquidos eficiente. No se recomienda utilizar valores de terapia de presión negativa inferiores a 125 mmHg.
 

**PRECAUCIÓN:** No utilizar tratamiento intermitente o tratamiento DYNAMIC PRESSURE CONTROL™ con el apósito para abdomen abierto ABTHERA ADVANCE™.

- Inicie la terapia. Examine el apósito para garantizar la integridad del sellado. El apósito debe comprimirse y tener un aspecto arrugado. No deben percibirse sonidos sibilantes. Si existe cualquier indicio de falta de integridad, compruebe la lámina adhesiva y el sellado de la almohadilla SENSAT.R.A.C.™, las conexiones de los tubos y la inserción del contenedor; asimismo, asegúrese de que las pinzas están abiertas. Asegúrese de que los tubos son lo suficientemente largos como para evitar que estén tensos, ya que esto podría alterar el sellado.

**Control de la salida de líquidos:** el apósito está diseñado para extraer de forma eficaz los líquidos del compartimento abdominal y para distribuir uniformemente la presión negativa. Al tratar a pacientes con la unidad de terapia de presión negativa, deben examinarse con frecuencia los volúmenes de exudado en el contenedor y el tubo.

**Hemorragias: debe vigilarse estrechamente la posibilidad de hemorragia en los pacientes con heridas abdominales, ya que en este tipo de heridas pueden existir vasos sanguíneos ocultos, difíciles de localizar. Si se observa una hemorragia repentina o un aumento de sangre en el apósito, el tubo o el contenedor, apague inmediatamente la terapia de presión negativa, adopte las medidas necesarias para detener la hemorragia y póngase en contacto con el médico. La terapia de presión negativa no está diseñada para prevenir, reducir al mínimo o detener hemorragias (consulte la sección «Hemorragias» en ADVERTENCIAS).**

## RESOLUCIÓN DE ALARMAS

Es preciso atender todas las alarmas de la unidad de terapia de manera conveniente. Consulte el manual de usuario de la unidad de terapia para obtener información completa sobre la resolución de las alarmas.

Si se produce una alarma de fuga, coloque lámina adhesiva adicional en la zona de la fuga para garantizar la integridad del sellado.

**PRECAUCIÓN:** Dado que las heridas abdominales exudan gran cantidad de líquido, la terapia de presión negativa sólo debe interrumpirse para curar la herida o cambiar el apósito. Si se interrumpe la terapia, es posible que se pierda la integridad del sellado.

## CAMBIOS DE APÓSITO

Los cambios de apósito deberán realizarse en periodos de 24 a 72 horas, o con mayor frecuencia en función de la evaluación continua del estado de la herida y del paciente. Podría ser necesario realizar cambios de apósito más frecuentes en caso de infección o contaminación abdominal.

Consulte la sección «Entorno de aplicación» en ADVERTENCIAS.

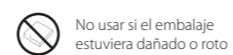
Cada vez que cambie el apósito, sustituya siempre todos los componentes por otros de un paquete estéril sin abrir.

## RETIRADA DEL APÓSITO

Retire y deseche el apósito anterior según el protocolo del centro médico. Inspeccione la herida en su totalidad, incluidos los surcos paracólicos para asegurarse de que ha retirado el apósito completo. Si existe un cerclaje intrabdominal, el material puede estar más seco de lo previsto. Examine el material antes de retirarlo y rehidrátelo si fuera necesario para evitar que se adhiera a las estructuras adyacentes y que se dañe.

Consulte la sección «Retirada del apósito» en ADVERTENCIAS.

## EXPLICACIÓN DE LOS SÍMBOLOS UTILIZADOS



No usar si el embalaje estuviera dañado o roto



Fabricante



Un solo uso



Fecha de fabricación



No reesterilizar



Información sobre el contenido



Consulte las Instrucciones de uso



Contiene ftalatos



Método de esterilización: radiación



Número de catálogo



Fecha de caducidad



Número de lote



Mantener seco



Cuente siempre el número total de piezas de apósito que se utilizan en la herida y registre el número.

Las referencias están disponibles previa solicitud. Póngase en contacto con KCI en el 1 800 275 4524 (en los EE. UU.).

Kaplan M. Managing the open abdomen. Ostomy Wound Management, enero 2004; 50(1A suppl); C2, 1-8

Kaplan M, Banwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S, Guidelines for the Management of the Open Abdomen. WOUNDS. Octubre 2005; 17(Suppl 1); S1524

Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. The American Journal of Surgery, diciembre 2001; 182(6); 630-8

Barker DE, Kaufman HJ; Vacuum Pack Technique of Temporary Abdominal Closure; A 7-Year Experience with 112 Patients. Presentado en la 59.ª Annual Meeting of the American Association for the Surgery of Trauma. 16-18 septiembre, 1999. Boston Mass.

Brock WB, Barker DE; Temporary Closure of Open Abdominal Wounds; The Vacuum Pack. Presentado en el 66.º Annual Scientific Meeting of the Southeastern Congress, Lake Buena Vista, Florida. 6-10 febrero, 1994

Sherck J, Seiver A; Covering the «Open Abdomen»; A Better Technique. Presentado como póster en el 66.º Annual Scientific Meeting y el Postgraduate Course Program. Southeastern Surgical Congress. Atlanta, Georgia. 31 de enero al 4 de febrero, 1998.

## INFORMACIÓN DE CONTACTO

Si tiene alguna duda en relación con este producto o su mantenimiento, o si desea información adicional sobre los productos y servicios de KCI, póngase en contacto con KCI o con un representante autorizado de KCI, o bien:

En Estados Unidos, llame al 1 800 275 4524, o visite [www.accelity.com](http://www.accelity.com) o [www.openabdomen.com](http://www.openabdomen.com). KCI USA, Inc. 12930 IH10 West, San Antonio, TX 78249

Fuera de Estados Unidos, visite [www.kci-medical.com](http://www.kci-medical.com).

## INFORMACIÓN DEL FABRICANTE



**Manufactured For:**

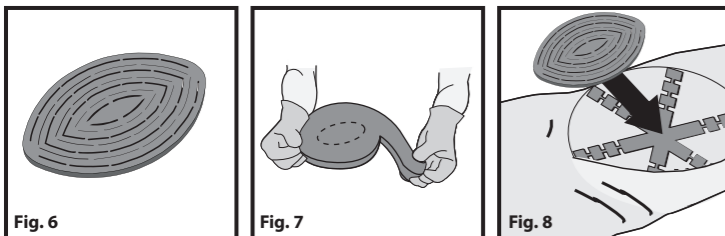
KCI USA, Inc.  
12930 IH 10 West  
San Antonio, TX 78249 USA  
1-800-275-4524  
[www.accelity.com](http://www.accelity.com)

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## ANLÆGGELSE AF DEN PERFOREREDE SVAMP



Den perforerede svamp (fig. 6), der leveres med ABTHERA ADVANCE™ Forbinding til det åbne abdomen, er beregnet til at:

- Overføre undertryk fra NPT-enheden til det viscerale beskyttelseslag for at fremme aktiv væskefjernelse.
- Leverer medial spænding, når svampene er faldet sammen for at hjælpe med at bevare fascialt domæne.

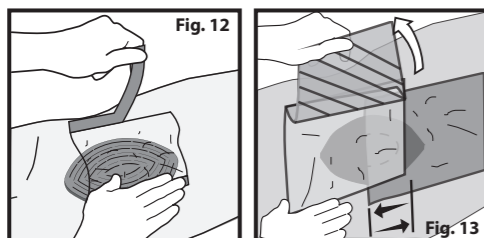
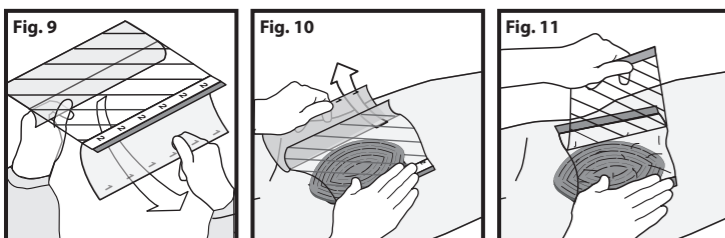
1. Riv eller klip den perforerede svamp til den ønskede størrelse som vist ovenfor (fig. 7). Svampen skal passe direkte over det viscerale beskyttelseslag og være i kontakt med alle sårkanter. Sørg for, at svampen ikke berører intakt hud. Det ene stykke eller begge stykker perforeret svamp kan bruges afhængigt af sårets kontur.

2. Læg forsigtigt den perforerede svamp ind i sårhulen over det viscerale beskyttelseslag (fig. 8).

**BEMÆRK:** Sørg for, at der er svamp-til-svamp-kontakt for jævn fordeling af undertrykket.

**BEMÆRK:** Det samlede antal svampestykker, som er brugt i forbindingen, skal tælles og dokumenteres på filmen og i patientjournalen.

## ANLÆGGELSE AF FILM



1. Tag fat i filmen, og træk delvist den ene side af lag 1 tilbage for at blottlægge klæbestoffet (fig. 9). Sørg for at holde fligen på lag 1 tilbage for at undgå, at den igen klæber sig til filmen.

2. Anbring filmen med klæbesiden nedad for at dække svampen og den intakte hud, således at filmen dækker mindst 8 - 10 cm af kanten på intakt væv i sårområdet (fig. 10). Brug om nødvendigt overskydende film til at forsegle vanskelige steder.

**BEMÆRK:** For at undgå traume i huden omkring såret må filmen ikke strækkes eller strammes over svampeforbindingen. Minimer folder, da de kan forårsage lækage i undertrykket (se afsnittet **FORHOLDSREGLER, Beskyt huden i sårområdet**).

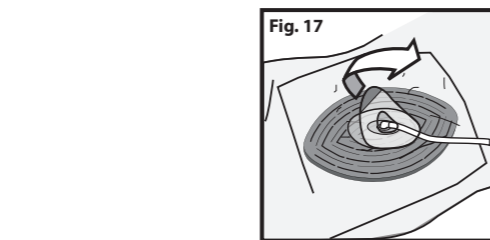
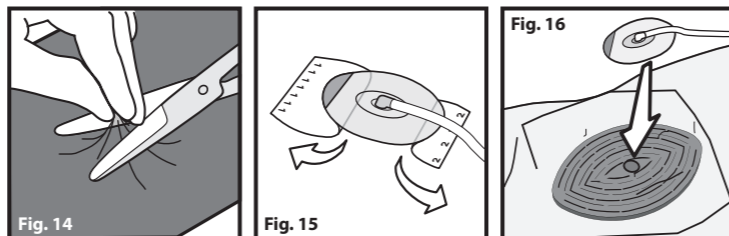
3. Fjern den resterende bagklædning på flig 1, og klap rundt om filmen for at sikre en komplet forsegling.

4. Fjern det grønstribeede stabiliseringslag 2 (fig. 11).

5. Fjern de perforerede blå håndteringsflige fra filmen (fig. 12).

**BEMÆRK:** Når der anvendes flere stykker film, skal det sikres, at kanterne af filmen overlapper hinanden for at opnå forsegling (fig. 13).

## ANLÆGGELSE AF SENSAT.R.A.C.™ PAD



**BEMÆRK:** Klip ikke pad'en af, og indsæt ikke slangen i svampeforbindingen. Dette kan tilstoppe slangen og få NPT-enhedens alarm til at lyde, og det kan medføre skade på underliggende viscera.

1. Vælg det sted, hvor pad'en skal anlægges. Tag specielt hensyn til væskeflow og slangens placering for at give optimalt flow, og undgå placering over knoglefremspring eller inde i vævets folder.

2. Knib filmen, og klip et **2,5 cm** hul gennem filmen (ikke en revne) (fig. 14). Det er ikke nødvendigt at klippe ind i svampen.

**BEMÆRK:** Klip et hul snarere end en revne, fordi en revne muligvis lukker sig under terapien.

3. Anlæg en pad, der har en central disk og en omgivende ydre klæbende kappe.

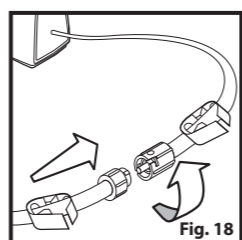
• Fjern forsigtigt bagklædningen på både lag 1 og lag 2 for at blottlægge klæbestoffet (fig. 15).

• Anbring pad-åbningen i den centrale disk direkte over hullet i filmen (fig. 16).

• Tryk let omkring den centrale disk og den ydre kappe for at sikre, at pad'en sidder helt fast.

4. Træk den blå flig tilbage for at fjerne padstabiliseringslaget (fig. 17). Anlæggelsen af forbindingen er gennemført.

## BRUG AF V.A.C.® UNDERTRYKSTERAPI



**BEMÆRK:** Kun til brug med undertryksterapi fra INFOV.A.C.™ eller V.A.C.ULTA™ NPT-enheder. Se brugervejledningen til terapienheden for fuldstændige oplysninger om brug.

**BEMÆRK:** Slangen til SENSAT.R.A.C.™ Pad er ikke kompatibel med hospitalsvakuumsystemer.

**ADVARSEL: Læs al sikkerhedsinformation i forbindelse med undertryksterapi, før terapien igangsættes.**

1. Tag beholderen ud af pakken, og sæt den i terapienheden, indtil den klikker på plads.

**BEMÆRK:** Abdominale sår har ofte megen drænage. Overvej at bruge 1000 cc/ml beholderen. Sørg for, at der er nok beholdere, og at de er let tilgængelige.

**FORSIGTIG:** Det følgende skal tages i betragtning, når 1000 cc/ml beholderen anvendes: patientens størrelse, vægt og tilstand, sårtypen, mulighederne for monitorering og plejesituationen.

**BEMÆRK:** Hvis beholderen ikke sidder helt på plads, udsender terapienheden en alarm.

2. Tilslut slangen fra SENSAT.R.A.C.™ Pad'en til beholderens slange, og sørg for, at klemmerne på begge slanger er åbne (fig. 18). Anbring klemmerne væk fra patienten.

3. Tænd for terapienheden, og vælg en terapiindstilling med 125 mmHg og kontinuerlig tilstand for at få effektiv væskefjernelse. Indstillinger for undertryksterapi under 125 mmHg anbefales ikke.

**FORSIGTIG:** Brug ikke intermitterende terapi / DYNAMIC PRESSURE CONTROL™ Terapi sammen med ABTHERA ADVANCE™ Forbinding til det åbne abdomen.

4. Start terapien. Undersøg forbindingen for at sikre forseglings integritet. Forbindingen skal falde sammen og se rynket ud. Der må ikke kunne høres hvislende lyde. Hvis der er tegn på, at forbindingen ikke slutter tæt, skal du kontrollere forseglingen af filmen og SENSAT.R.A.C.™ Pad'en, slangeforbindelserne og beholderens tilkobling samt sørge for, at klemmerne er åbne. Fastgør overskydende slange for at undgå utilsigtet spænding på slangen, som kan bryde forseglingen.

**Overvåg væsketab:** Forbindingen er beregnet til effektivt at fjerne væske fra det abdominale kompartment og fordele undertryk jævnt. Ved behandling af patienter med NPT-enheden skal mængden af eksudat i beholderen og slangen undersøges jævnlige.

**Blødning: Patienter med abdominale sår skal overvåges nøje for blødning, da disse sår kan indeholde skjulte blodkar, der måske ikke er umiddelbart synlige. Hvis der observeres pludselig eller øget blødning i forbindingen, slangen eller beholderen, skal du straks slukke for undertryksterapi, udføre de relevante foranstaltninger for at stoppe blødningen og kontakte lægen. Det er ikke formålet med undertryksterapi at forhindre, minimere eller stoppe blødning. (Se ADVARSLER, afsnittet Blødning).**

## AFHJÆLPNING AF ÅRSAGER TIL ALARMER

Alle alarmer fra terapienheden skal behandles så hurtigt som muligt. Se brugervejledningen til terapienheden for fuldstændige oplysninger om afhjælpning af alarmer.

I tilfælde af en lækagealarm skal kilden til lækagen lappes med yderligere film for at sikre, at forseglingen er tæt.

**FORSIGTIG:** Da abdominalsår er yderst eksudative, må undertryksterapi kun stoppes i forbindelse med pleje af såret eller skift af forbindingen. Hvis terapien afbrydes, kan det bryde forseglingen.

## FORBINDINGSSKIFT

Forbindingskift skal foretages for hver 24 til 72 timer eller hyppigere baseret på en kontinuerlig vurdering af sårets tilstand og patientens status. Overvej hyppigere forbindingskift ved infektion og abdominal kontaminering.

Se afsnittet **Forhold ved anlæggelse** under **ADVARSLER**.

Når forbindingen skiftes, skal alt forbindingsmateriale altid udskiftes med materiale fra en uåbnet, steril pakke.

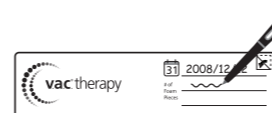
## FJERNELSE AF FORBINDINGEN

Brugte forbindinger skal fjernes og bortskaffes i henhold til institutionens protokoller. Efterse såret i sin helhed, inklusive den parakoliske rende, for at sikre, at alle dele af forbindingen er blevet fjernet. Hvis intraabdominal pakning bruges, kan pakningsmaterialet være mere tørt end forventet. Vurder pakningsmaterialet inden det fjernes, og rehydrer det eventuelt for at forhindre, at det klæber til eller beskadiger omgivende strukturer.

**ADVARSEL: Se afsnittet Fjernelse af forbindingen under ADVARSLER.**

## SYMBOLFORKLARING

	Må ikke anvendes, hvis emballagen er beskadiget eller har været åbnet		Producent
	Kun til engangsbrug		Fremstillingsdato
	Må ikke steriliseres igen		Indholdsoplysninger
	Læs brugervejledningen	<b>Rx Only</b>	<b>FORSIGTIG:</b> I henhold til amerikansk lovgivning må dette udstyr kun sælges/udlejes til eller på ordination af en læge.
	Indeholder phthalater	<b>REF</b>	Katalognummer
	Steriliseringsmetode - bestråling	<b>LOT</b>	Lotnummer
	Udløbsdato		
	Opbevares tørt		



Tæl og dokumenter altid antallet af svampe, der anvendes i såret.

Referencer kan fås på forespørgsel. Kontakt KCI på 1-800-275-4524 (i USA).

Kaplan M. Managing the open abdomen. Ostomy Wound Management, 2004 Jan; 50(1A suppl); C2, 1-8

Kaplan M, Banwell P, Orgill DP, Ivatury RR, Demetriades D, Moore FA, Miller P, Nicholas J, Henry S, Guidelines for the Management of the Open Abdomen. WOUNDS. 2005 Oct; 17(Suppl 1); S1524

Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. The American Journal of Surgery, 2001 Dec; 182(6); 630-8

Barker DE, Kaufman HJ; Vacuum Pack Technique of Temporary Abdominal Closure; A 7-Year Experience with 112 Patients. Presented at the 59th Annual Meeting of the American Association for the Surgery of Trauma. September 16-18, 1999. Boston Mass.

Brock WB, Barker DE; Temporary Closure of Open Abdominal Wounds; The Vacuum Pack. Presented at the 66th Annual Scientific Meeting of the Southeastern Congress, Lake Buena Vista, Florida.

February 6-10, 1994

Sherck J, Seiver A; Covering the "Open Abdomen"; A Better Technique. Presented as a Poster at the 66th Annual Scientific Meeting and the Postgraduate Course Program. Southeastern Surgical Congress. Atlanta, Georgia. January 31-February 4, 1998.

## KONTAKTOPLYSNINGER

Hvis du har spørgsmål om produktet eller vedligeholdelse, eller hvis du ønsker yderligere oplysninger om KCI's produkter og services, bedes du kontakte KCI eller en autoriseret repræsentant for KCI eller:

I USA ringe på 1-800-275-4524 eller gå ind på [www.acylity.com](http://www.acylity.com) eller [www.openabdomen.com](http://www.openabdomen.com). KCI USA, Inc. 12930 IH 10 West, San Antonio, TX 78249

Uden for USA gå ind på [www.kci-medical.com](http://www.kci-medical.com).

## PRODUCENTINFORMATION

**Manufactured For:**  
KCI USA, Inc.  
12930 IH 10 West  
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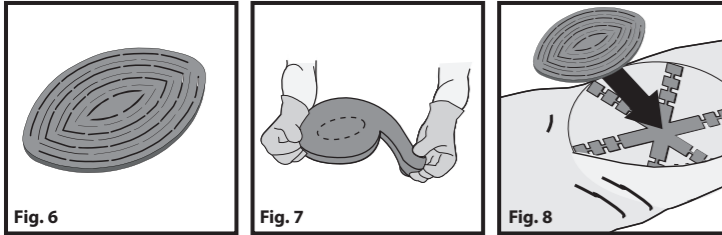








## APLICAÇÃO DO CURATIVO PERFURADO



O curativo perfurado (**Fig. 6**) fornecido com o Curativo para Abdome Aberto ABTHERA ADVANCE™ deve ser usada para:

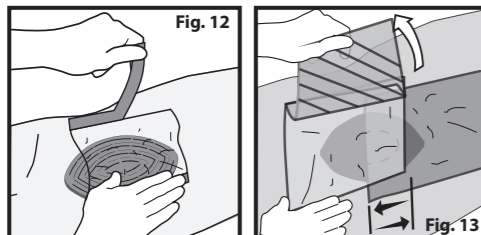
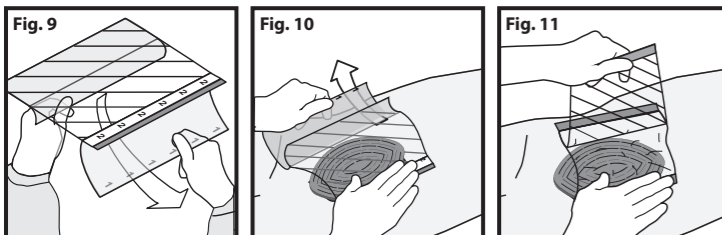
- Transferir a pressão negativa da Unidade de Terapia com Pressão Negativa para a Camada de Proteção Visceral e promover a remoção de fluido ativo.
- Fornecer tensão medial ao retrair o curativo de modo a manter o domínio fascial.

1. Rasgue ou corte o curativo perfurado no tamanho necessário, como mostrado acima (**Fig. 7**). O curativo deve encaixar diretamente acima da Camada de Proteção Visceral e manter contato com todas as extremidades da lesão. Não permita que o curativo se sobreponha à pele intacta. Uma ou ambas as partes do curativo perfurado fornecido podem ser usadas, dependendo do perfil da lesão.
2. Coloque suavemente o curativo perfurado na cavidade da lesão sobre a Camada de Proteção Visceral (**Fig. 8**).

**OBSERVAÇÃO:** *Certifique-se de que haja contato ao longo de todo o curativo para a distribuição uniforme da pressão negativa.*

**OBSERVAÇÃO:** *Observe sempre o número total de partes do curativo utilizado e registre na película adesiva e no prontuário do paciente.*

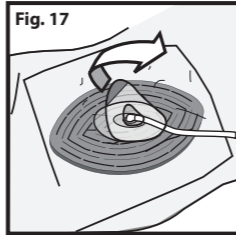
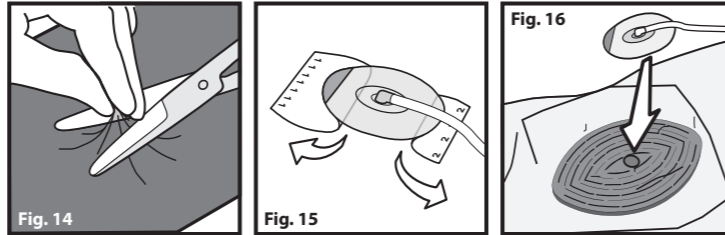
## APLICAÇÃO DA PELÍCULA ADESIVA



1. Segurando a película adesiva, puxe parcialmente um lado da camada 1 para expor o adesivo (**Fig. 9**). Lembre-se de segurar a presilha da camada 1 para evitar que ela grude novamente na película adesiva.
2. Coloque a película adesiva com o lado adesivo para baixo a fim de cobrir a esponja e a pele intacta, assegurando que a película cubra, pelo menos, de 8 a 10 cm da borda do tecido intacto perilesional (**Fig. 10**). Use qualquer excesso da película adesiva para vedar áreas difíceis, se necessário.
3. Remova a lingueta 1 remanescente do material restante e passe levemente a mão sobre a película adesiva para garantir uma vedação oclusiva.
4. Remova a camada 2 de estabilização com faixas verdes (**Fig. 11**).
5. Remova as linguetas azuis de manuseio perfuradas da película adesiva (**Fig. 12**).

**OBSERVAÇÃO:** *Ao usar várias partes de película adesiva, certifique-se de que as bordas da película se sobreponham para obter a vedação (**Fig. 13**).*

## APLICAÇÃO DO COLETOR SENSAT.R.A.C.™



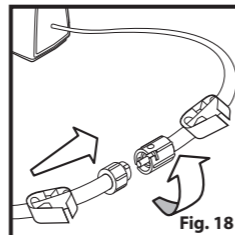
**OBSERVAÇÃO:** *Não corte o coletor nem insira a tubulação no curativo de esponja. Isso pode obstruir a tubulação e ativar o alarme na Unidade de Terapia com Pressão Negativa, podendo causar ferimentos na víscera subjacente.*

1. Escolha o local de aplicação do coletor. Considere particularmente o fluxo de fluido e o posicionamento da tubulação para permitir o fluxo ideal e evitar colocação sobre proeminências ósseas ou em dobras no tecido.
2. Pince a película adesiva e corte um orifício de **2,5 cm** (e não uma fenda) na película (**Fig. 14**). Não é necessário cortar a esponja.
3. Aplique o coletor, que possui um disco central e uma borda adesiva externa circundante.

- Remova cuidadosamente as camadas posteriores 1 e 2 para expor o adesivo (**Fig. 15**).
- Coloque a abertura do coletor no disco central diretamente sobre o orifício da película adesiva (**Fig. 16**).
- Aplique pressão delicadamente sobre o disco central e a borda adesiva para garantir a completa adesão.

4. Puxe a lingueta azul para remover a camada de estabilização do coletor (**Fig. 17**). A aplicação do curativo está concluída.

## APLICAÇÃO DA TERAPIA COM PRESSÃO NEGATIVA V.A.C.®



**OBSERVAÇÃO:** *Somente para uso com Terapia com Pressão Negativa aplicada pelas Unidades de Terapia INFOV.A.C.™ e V.A.C.ULTA™. Consulte o manual do usuário da unidade de terapia para obter instruções de uso completas.*

**OBSERVAÇÃO:** *A tubulação do coletor SENSAT.R.A.C.™ não é compatível com sistemas a vácuo hospitalares.*

**ADVERTÊNCIA: Consulte todas as Informações de Segurança do Sistema de Terapia com Pressão Negativa antes de iniciar a terapia.**

1. Remova o reservatório da embalagem e o insira na unidade de terapia até que esteja bem encaixado.
 

**OBSERVAÇÃO:** *As lesões abdominais frequentemente apresentam fluidos abundantes. Considere o uso de um reservatório de 1.000 cc / ml. Assegure-se de que exista um número adequado de reservatórios disponível para uso imediato.*

**CUIDADO:** *Considere o tamanho e o peso do paciente, o estado do paciente, o tipo de lesão, os recursos de monitoramento e a unidade de terapia ao usar o reservatório de 1.000 cc / ml.*

**OBSERVAÇÃO:** *Se o reservatório não estiver corretamente encaixado, a unidade de terapia acionará um alarme.*
2. Conecte a tubulação do coletor SENSAT.R.A.C.™ à tubulação do reservatório e verifique se o grampo de cada tubo está aberto (**Fig. 18**). Posicione a presilha longe do paciente.
3. Ligue a energia da unidade de terapia e selecione a configuração de terapia de modo contínuo de 125 mmHg para obter taxas eficazes de remoção de fluido. Configurações de terapia com pressão negativa abaixo de 125 mmHg não são recomendadas.
 

**CUIDADO:** *não use terapia intermitente/Terapia DYNAMIC PRESSURE CONTROL™ com o Curativo para abdome aberto ABTHERA ADVANCE™.*

4. Inicie a terapia. Verifique a integridade da vedação do curativo. O curativo deve estar retraído e ter uma aparência enrugada. Não pode haver sons de vazamento. Se houver alguma evidência de falta de integridade, verifique as vedações do Coletor SENSAT.R.A.C.™ e da película adesiva, as conexões da tubulação e a inserção do reservatório; as presilhas devem estar abertas. Assegure-se de que exista sobra de tubos para prevenir tensão inadvertida na tubulação, que pode romper a vedação.

**Monitorar a saída de fluidos** – O curativo foi desenvolvido para remover, de forma eficiente, o fluido do compartimento abdominal e distribuir uniformemente a pressão negativa. Ao tratar pacientes com a Unidade de Terapia com Pressão Negativa, o volume de exsudato no reservatório na tubulação deve ser examinado com frequência

**Hemorragia: pacientes com lesões abdominais devem ser monitorados atentamente quanto a hemorragias, pois essas lesões podem conter vasos sanguíneos escondidos que talvez não sejam facilmente perceptíveis. Caso seja observado aumento da hemorragia ou hemorragia súbita no curativo, na tubulação ou no reservatório, interrompa imediatamente a Terapia com Pressão Negativa, tome as medidas necessárias para cessar a hemorragia e entre em contato com o médico. A Terapia com Pressão Negativa não foi desenvolvida para prevenir, minimizar ou cessar hemorragias. (Consulte a seção ADVERTÊNCIAS, Hemorragia).**

## RESOLUÇÕES DE ALARME

Todos os alarmes da unidade de terapia devem ser verificados periodicamente. Consulte o manual do usuário da unidade de terapia para obter instruções de uso completas sobre alarme.

Em caso de alarme de vazamento, vede a fonte de vazamento com película adesiva adicional para garantir a integridade da vedação.

**CUIDADO:** *Devido ao fato de as lesões abdominais serem altamente exsudativas, a Terapia com Pressão Negativa somente deverá ser interrompida para a limpeza da lesão e a troca de curativos. A interrupção da terapia pode resultar na perda da integridade da vedação.*

## TROCAS DE CURATIVOS

As trocas de curativo devem ocorrer entre 24 e 72 horas ou podem ocorrer com mais frequência, com base em uma avaliação contínua da condição da lesão e do estado clínico do paciente. Considere trocas de curativo mais frequentes na presença de infecção ou contaminação abdominal.

Consulte a seção **Configuração de aplicação em ADVERTÊNCIAS**.

Sempre que o curativo for trocado, substitua todos os componentes do curativo por componentes de uma embalagem estéril fechada.

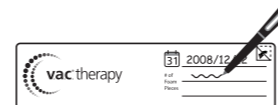
## REMOÇÃO DO CURATIVO

Remova e descarte o curativo anterior segundo o protocolo da instituição. Examine a lesão completamente, incluindo as goteiras paracólicas, para garantir que todas as partes dos componentes do curativo tenham sido removidas. Se houver tamponamento intra-abdominal, o material do tamponamento pode estar mais seco do que o previsto. Avalie o material do tamponamento antes da remoção e, se necessário, reidrate para evitar aderência ou danos nas estruturas adjacentes.

**ADVERTÊNCIA: Consulte a seção Remoção do Curativo em ADVERTÊNCIAS.**

## EXPLICAÇÃO DOS SÍMBOLOS USADOS

	Não usar se a embalagem estiver danificada ou aberta		Fabricante
	Usar apenas uma vez		Data de fabricação
	Não reesterilizar		Informações do conteúdo
	Consulte as instruções de uso		<b>Rx Only</b> <b>CUIDADO:</b> a legislação federal (EUA) restringe a venda/o aluguel deste dispositivo à solicitação de um médico.
	Contém Ftalatos		Número do catálogo
	Método de esterilização - Radiação		Número do lote
	Usar até		
	Manter seco		



Sempre conte e registre o número de peças de esponjas utilizadas na lesão.

Referências disponíveis sob solicitação. Entre em contato com a KCI pelo telefone 1-800-275-4524 (nos EUA).

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## INFORMAÇÕES DE CONTATO

Em caso de dúvidas relacionadas ao produto, à manutenção ou para obter mais informações sobre os produtos e serviços da KCI, contate a KCI diretamente ou um representante autorizado, ou:

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KCI USA, Inc., 12930 IH 10 West, San Antonio, TX 78249

Fora dos Estados Unidos, acesse [www.kci-medical.com](http://www.kci-medical.com).

## INFORMAÇÕES SOBRE O FABRICANTE

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