ABThera™

Active Abdominal Therapy

INSTRUCTIONS FOR USE

ABThera™ Open Abdomen Negative Pressure Therapy System

Nur zur Verwendung mit dem Abdominal-Unterdruck-Wundbehandlungssystem ABThera™ von KCI
Uitsluitend voor gebruik met het KCI ABThera™ negatieve druk therapiesysteem voor open buik behandeling
A utiliser uniquement avec le système de thérapie par pression négative pour abdomen ouvert ABThera™ de KCI
Da usare esclusivamente con il sistema terapeutico a pressione negativa ABThera™ per addome aperto
Para usar exclusivamente con el sistema de terapia de presión negativa para abdomen abierto ABThera™ de KCI
Må kun bruges med KCI ABThera™-terapisystem med undertryk til åbent abdomen
Endast för användning med KCI ABThera™ undertrycksterapisystem för öppet sår i buken
Apenas para uso com o Sistema de terapia de pressão negativa KCI ABThera™
Sadece KCI ABThera™ Açık Abdomen Negatif Basınç Tedavi Sistemiyle kullanılmak üzere
Μόνο για χρήση με το Σύστημα θεραπείας ανοικτής κοιλιακής χώρας με αρνητική πίεση KCI ABThera™
Käytettäväksi ainoastaan KCI:n ABThera™ – avoimen vatsaontelon alipainehoitojärjestelmän kanssa
Bare for bruk med KCI ABThera™-behandlingssystem med undertrykk for åpent abdomen

From the Makers of V.A.C.® Therapy

KCI®

INSTRUCTIONS FOR USE

OPEN ABDOMEN
NEGATIVE PRESSURE THERAPY SYSTEM

SAFETY INFORMATION

IMPORTANT: As with any prescription medical device, failure to consult a physician and carefully read and follow all ABThera™ (NPT) 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™ (NPT) System 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™ (NPT) System 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 system is for use in open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome.
- The ABThera™ (NPT) System is intended for use in the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating theater.

CONTRAINDICATIONS:

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

Management of the open abdomen has been documented in case reports and consensus panel literature. Please refer to the **References List** section at the end of the dressing application instructions.

WARNINGS

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 turn off the ABThera™ (NPT) System, take appropriate measures to stop bleeding, and contact the physician. The ABThera™ (NPT) System 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 Anastamoses
- Trauma
- Radiation
- Inadequate wound hemostasis
- Non-sutured hemostasic 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 a temporary abdominal closure **does not** eliminate the possibility of elevation in intra-abdominal pressure (IAP). When using the ABThera™ (NPT) System, IAP monitoring (for clinical or diagnostic signs and symptoms of elevated IAP) should continue as indicated by patient condition, in accordance with institutional clinical practice or guidelines. If intra-abdominal hypertension (IAH) or abdominal compartment syndrome (ACS) is observed, note intra-abdominal pressures and turn off power to the ABThera™ (NPT) System, discontinuing negative pressure. After full expansion of the perforated foam, obtain new intra-abdominal pressure measurement. If IAH / ACS persists without negative pressure (and collapse of midline perforated foam), discontinue the use of ABThera™ (NPT) System and address the underlying condition as medically indicated. If IAH / ACS resolves or improves without negative pressure (and collapse of midline perforated foam), consider providing ABThera™ Therapy without medial tension (refer to **Perforated Foam Application**).

Use of Visceral Protective Layer: When using the ABThera™ (NPT) System, ensure that the Open Abdomen 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, common complications 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 an ABThera™ 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 ABThera™ Dressing components are not bioabsorbable. Always remove all dressing components from the abdomen at every dressing change.

Keep Negative Pressure On: Never leave the ABThera™ 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 these instructions for use. Either apply a new ABThera™ 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 ABThera™ Drape has an acrylic adhesive coating, which may present a risk of an adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives. If a patient has a known allergy or hypersensitivity to such adhesives, donot use the ABThera™ 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.

Magnetic Resonance Imaging (MRI) – Therapy Unit: The ABThera™ (NPT) Unit is MR unsafe. Do not take the device into the MR environment.

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

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

Application Setting: ABThera™ Dressing applications and changes should be performed under strict sterile conditions in the surgical suite. If dressing change is performed outside the surgical suite, 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 the ABThera™ (NPT) System, 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 ABThera™ Dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with the ABThera™ (NPT) System, 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 the ABThera™ (NPT) System. 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 dressing 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 ABThera™ (NPT) System 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.

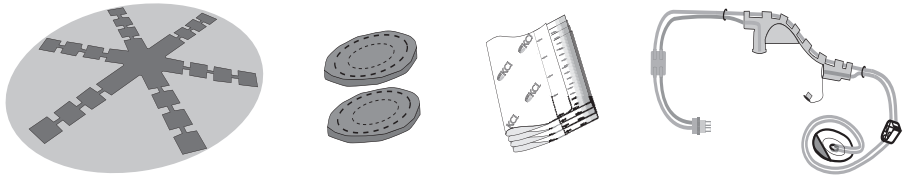
Protect Periwound Skin: Consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile / friable periwound skin with additional drape, hydrocolloid or other transparent film.

- 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 tubing assembly 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™ (NPT) System, please contact your local KCI Clinical Representative.

ABThera™ DRESSING APPLICATION INSTRUCTIONS

ABThera™ Dressing Components



Visceral Protective Layer (1) | Perforated Foam (2) | Drape (4) | Tubing Set with Interface Pad (1)

WOUND PREPARATION

WARNING: Review all ABThera™ (NPT) System 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.

ABThera™ VISCERAL PROTECTIVE LAYER APPLICATION

Size the Visceral Protective Layer by folding or cutting.

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.

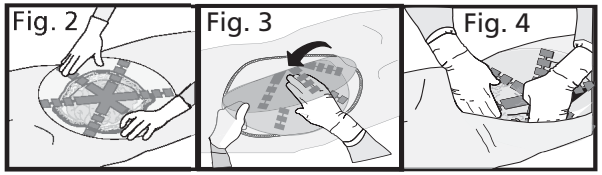
NOTE: The Visceral Protective Layer is fenestrated to allow for active fluid removal when negative pressure is applied and is designed to allow application of this layer directly over omentum or exposed internal organs.

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. 2).
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 (see Fig. 1). ***Do not cut near or through foam extensions***. Orient the Visceral Protective Layer accordingly before cutting.

Fig. 1

Folding Visceral Protective Layer to Size

1. Hold dressing by the edge and slightly lift. Then slowly lower dressing into the paracolic gutter, while 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.

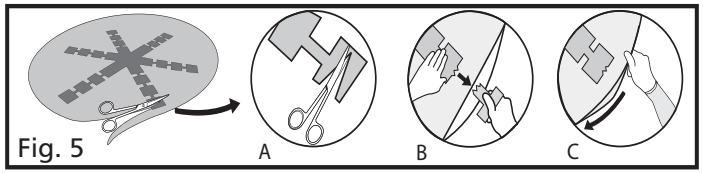


Cutting Visceral Protective Layer to Size

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).

   NOTE: 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

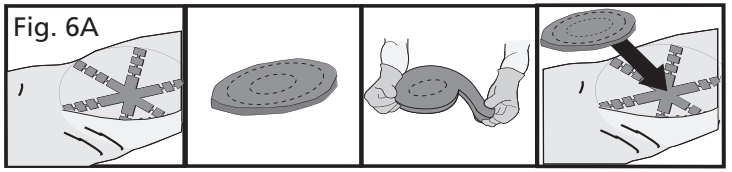
NOTE: The perforated foam provided with the ABThera™ (NPT) System is intended to:

1. Transfer negative pressure from the ABThera™ (NPT) Unit to the Visceral Protective Layer to promote active fluid removal.
2. Provide medial tension upon foam collapse to help maintain fascial domain.

Application of ABThera™ (NPT) System with Medial Tension

1. Tear or cut perforated foam to needed size as shown below (Fig. 6A) to provide ABThera™ Therapy **with** medial tension. The foam should fit directly over the Visceral Protective Layer being in contact with all wound edges if medial tension is desired. 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. 6A). Ensure that perforated foam does not go below the level of the abdominal incision or wound. Do not force foam into any area of the wound.

   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.

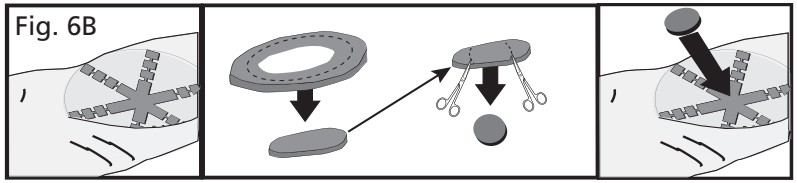


Application of ABThera™ (NPT) System without Medial Tension (refer to **Intra-abdominal Pressure Monitoring** section under **WARNINGS**).

In some patients who are experiencing persistent IAH or ACS with the open abdomen, medial tension may not be preferred due to potential for continued elevation of intra-abdominal pressures. In patients at risk for or experiencing persistent IAH / ACS due to:

- ongoing hemorrhage with abdominal packing in place
- persistent or worsening bowel edema
- significant ongoing resuscitation which may result in worsening bowel edema

consider providing ABThera™ Therapy **without** medial tension provided by the perforated foam. To provide negative pressure therapy to the Visceral Protective Layer **without** medial tension, place only a small section (3 inch [7.6 cm] round) of the perforated foam over the center section of the Visceral Protective Layer (Fig. 6B).

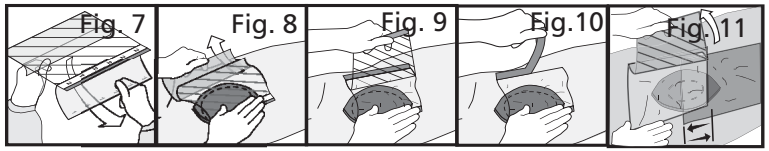


ABThera™ DRAPE APPLICATION

1. Holding the ABThera™ Drape, partially pull back one side of layer 1 to expose adhesive (Fig. 7). 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 a 8-10 cm border of intact periwound tissue (Fig. 8). 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 (see Fig. 9 below).
5. Remove perforated blue handling tabs from drape (see Fig. 10 below).

   NOTE: When using multiple pieces of drape, ensure that the edges of the drape overlap in order to achieve a seal (see Fig. 11 below).

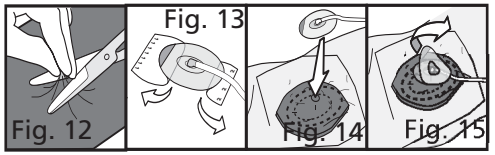


TUBING SET / INTERFACE PAD APPLICATION

NOTE: Do not cut off the Interface Pad or insert the tubing into the foam dressing. This may occlude the tubing and cause the ABThera™ (NPT) Unit to alarm and could injure underlying viscera.

1. Choose Interface Pad application site. Give particular consideration to fluid flow and tubing position to allow for optimal flow and avoiding 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. 12). 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 Interface Pad, which has a central disc and a surrounding outer adhesive skirt.
   - Gently remove both backing layers 1 and 2 to expose adhesive (Fig. 13).
   - Place Interface Pad opening in central disc directly over hole in drape (Fig.14).
   - Apply gentle pressure on the central disc and outer skirt to ensure complete adhesion of the Interface Pad.
4. Pull back on blue tab to remove pad stabilization layer (Fig. 15). ABThera™ Dressing application is complete. See the **PREPARATION FOR USE** section.



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**.

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 ABThera™ Dressing is changed, always replace all ABThera™ Dressing components with components from an unopened sterile package.

REFERENCE LIST

- *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.*

References available on request. In the US, please call KCI at 1-800-275 4524.

ABThera™ (NPT) UNIT

The ABThera™ (NPT) Unit should not be opened, disassembled or otherwise modified by the user, and should be replaced as a unit. All assembly, operations, adjustments, modifications, maintenance and repairs must be carried out by authorized qualified personnel.

Electrical Shock Hazard - do not open any electrical cover on the ABThera™ (NPT) Unit. Refer to qualified service personnel.

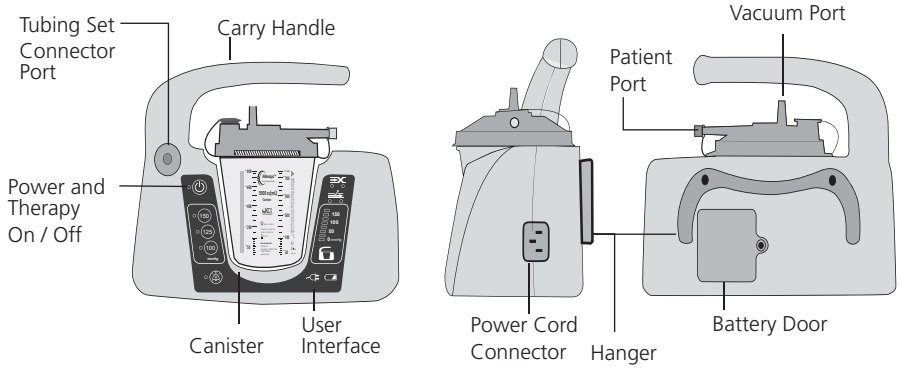


Fig. 1

USER INTERFACE

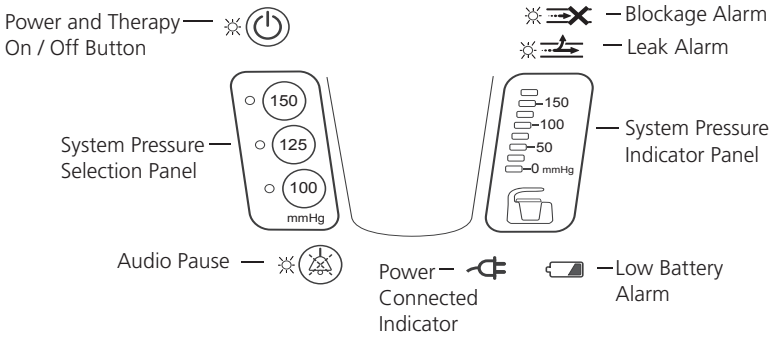


Fig. 2

1000 cc / mL CANISTER

The ABThera™ (NPT) canister is a single-use, latex free, non-sterile, 1000 cc / mL clear container with graduated markings at 100 cc / mL increments up to 800 cc / mL.

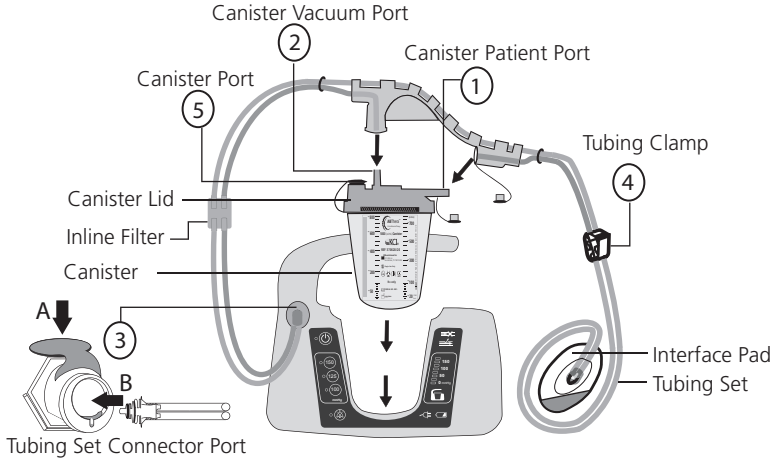
NOTE: Never reuse a canister.

NOTE: The ABThera™ (NPT) System has been designed and tested for use with the ABThera™ Canister ONLY. Using other types of canisters could lead to system performance issues.

PREPARATION FOR USE

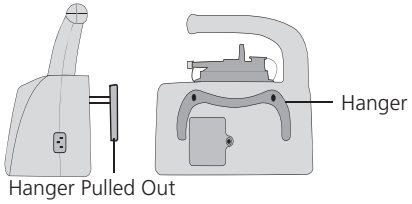
NOTE: Tubing Set is not compatible with hospital vacuum sources.

Place canister lid onto canister. Place canister into ABThera™ (NPT) Unit ensuring graduated markings on the canister can be viewed. Attach tubing set to canister lid; see picture and steps 1-5 below.



1. Slide Tubing Set onto Canister **Patient Port** ①.
2. Push Tubing Set down onto the Canister **Vacuum Port** ②.
3. Plug Tubing Set into connector port; the release latch on the connector port must be in the down position **A** before tubing is plugged in, see ③ A & B above. A click will indicate proper connection. Push release latch down to unplug tubing set.
4. Ensure Tubing Clamp is open ④.
5. Ensure Canister Access Port Cap is securely in place ⑤. Canister's Access Port is for adding isolyzer (not provided by KCI).

ABThera™ (NPT) UNIT PLACEMENT



The ABThera™ (NPT) Unit is equipped with a hanger for footboard placement. To place ABThera™ (NPT) Unit on a footboard, pull out spring-loaded hanger on back of unit. Place ABThera™ (NPT) Unit over footboard and gently allow the hanger to retract.
If desired, ABThera™ (NPT) Unit may be placed on a solid, level surface near the same level as the patient's abdomen.

BEGINNING THERAPY

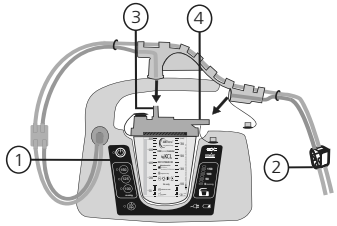
Monitor Fluid Output: The ABThera™ Dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with the ABThera™ (NPT) System, the volume of exudate in the canister and tubing should be frequently examined.

1. Ensure the ABThera™ Dressing has been applied as described in the ABThera™ Dressing Application section.
2. Plug ABThera™ power cord into ABThera™ (NPT) Unit. See Fig. 1 for power cord connection location.
3. Plug ABThera™ power cord into AC wall outlet. Power Connected Indicator on the User Interface will illuminate with a blue backlight (Fig. 2).
4. Press and hold the Therapy On / Off button for two seconds to turn therapy unit on and start therapy (Fig. 1). The green light next to the Therapy On / Off button will illuminate.
   NOTE: The system will automatically default to 125 mmHg.
   NOTE: The pump will begin running then slow down as it nears the selected pressure. When selected pressure is reached, pump will stop running and only come on to maintain pressure.
5. Push the desired pressure on the system pressure selection panel (Fig. 2). A green light next to the selection will illuminate.
6. With therapy on, assess dressing to ensure integrity of seal.
   - Dressing should have a slightly wrinkled appearance when therapy is active.
   - There should be no hissing sounds.
   - If there is any evidence of an air leak around dressing or tubing connectors, refer to **Leak Alarm** in the **Alarms** section.

STOPPING THERAPY / CHANGING THE CANISTER

CAUTION: Follow standard precautions as the system may contain body fluids.

1. Press and hold the Therapy On / Off button for approximately three seconds to power off Therapy Unit ①.
2. Squeeze tubing clamp several clicks to close ②.
3. Lift up tubing set from canister's **Vacuum Port** ③.
4. Pull tubing set away from canister's **Patient Port** ④ and cap tubing set using tethered cap.
5. Ensure caps on canister's lid are secured before removing canister. Canister Vacuum Port does not have a cap, canister filter prevents fluid from exiting.



6. Lift canister straight up and out of therapy unit.
7. To continue therapy, insert new canister. ***Never reuse a canister***.
8. Connect tubing set to canister, restart therapy. (see **Preparation for Use** section).
   NOTE: Tubing set is included with dressing kit and replaced at time of dressing change.
   NOTE: The ABThera™ (NPT) System will automatically default to 125 mmHg.
9. Dispose of the canister according to local hospital or facility protocols.

An additional supply of dressings and canisters may be ordered by contacting your local KCI representative. In the US, please call KCI at 1-800-275-4524.

ALARMS

BLOCKAGE / CANISTER FULL ALARM

When the system senses a blockage or canister full condition, an amber LED next to the Blockage / Canister Full Alarm icon will illuminate. Two consecutive beeps repeating every 15 seconds will sound during this alarm condition. Alarm can be silenced for five minutes. See **Audio Pause Button** section for details.

When alarm condition has been resolved, the LED will turn off.

To Resolve this Alarm Condition:

- Check for a full canister
- Check for kinked or pinched tubing and straighten
- Ensure tubing clamp is open

LEAK ALARM

When the system senses an air leak, one amber LED next to the Leak Alarm icon will illuminate. Two consecutive beeps repeating every 15 seconds will sound during this alarm condition.

Alarm can be silenced for five minutes. See **Audio Pause Button** section for details.

When alarm condition has been resolved, the LED will turn off.

To Resolve this Alarm Condition:

- Press down firmly around the edge of the drape and Interface Pad to seal leak. Use extra drape if necessary to reinforce the dressing.
- Check all tubing connections and canister caps for leaks.

LOW BATTERY ALARM

When the system senses a low battery condition, an amber LED on the Low Battery Alarm icon will illuminate. Two consecutive beeps repeating every 15 seconds will sound during this alarm condition.

The alarm can be silenced for five minutes. See **Audio Pause Button** for details.

To Resolve this Alarm Condition:

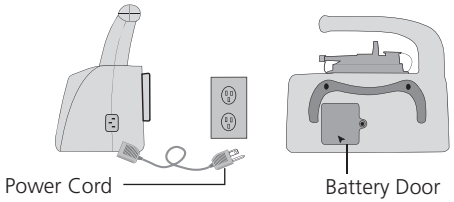
When the Low Battery Alarm turns on, approximately one hour of therapy remains. The ABThera™ (NPT) Unit should be plugged into an AC power supply immediately.

AUDIO PAUSE BUTTON

Press the **Audio Pause Button** during an alarm condition to silence the audible alarm for five minutes. An amber LED next to the button will illuminate to indicate the audible alarm has been silenced.

Press the button again to reinstate the audible alarm. When the alarm condition has been resolved, the audible alarm will cancel automatically and the LED light will turn off.

AC POWER / BATTERY



- ABThera™ (NPT) Unit should remain plugged into an AC power source while in use or in storage to keep batteries charged.
- ABThera™ (NPT) Unit operates on an auto-ranging AC / DC power supply with a hospital grade power cord.
- When fully charged the ABThera™ (NPT) Unit will provide battery power in order to maintain therapy during patient transport. Plug ABThera™ power cord into an AC power source immediately after transport to maintain battery charge.
- When unplugged, ABThera™ (NPT) Unit will switch from AC to battery power without user intervention or therapy loss.
- Battery will fully recharge in approximately eight hours.

AUTOMATIC SHUTDOWN

While operating on battery power, if battery charge falls below a critical level (approximately two hours or one hour after low battery alarm sounds) the ABThera™ (NPT) Unit will automatically turn off. When plugged into an AC outlet, the ABThera™ (NPT) Unit will remain Off until the Power On / Off button is pressed at which time therapy will resume (refer to **Keep Negative Pressure On** under **WARNINGS**). See also **Low Battery Alarm** in the **Alarms** section.

CARE AND CLEANING

Between patient use and if the product becomes soiled while in use in the hospital or other healthcare organization, disinfectants containing quaternary ammonium compounds or other similar disinfectant products may be used to clean the ABThera™ (NPT) Unit. All visible organic material should be cleaned from the device prior to disinfection. Use personal protective equipment (PPE) and hand hygiene protocols in accordance with local protocols for cleaning and disinfection.

CAUTION: Avoid spilling fluid on any part of the ABThera™ (NPT) Unit. Fluids remaining on electronic controls can cause corrosion which can cause the electronic components to fail. Component failure may cause the ABThera™ (NPT) Unit to operate erratically, possibly producing potential hazards to patient or care providers.

MANUFACTURER INFORMATION

Manufactured for:
KCI USA, Inc.
San Antonio Texas, 78219
www.kci1.com

EC REP
KCI Medical Products (UK) Ltd.
Wimborne, Dorset, BH21 7SH
United Kingdom
www.kci-medical.com

SYMBOLS USED

Do not use if package is damaged or open

Keep Dry

Date of Manufacture

Single Use Only

Non Sterile

Manufacturer

Refer to Instruction Manual

Use By

EC REP
Authorized Representative in the European Community

Not for regular waste disposal

Consult Instructions for Use

3182664
ETL Listed, Conforms to UL Std. 60601-1 certified to CAN/CSA C22.2 Std. No. 601.1.

Type B applied part

Biological Risk

CE 0473
Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive

STERILE R Sterilized with radiation

Rx only **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

SPECIFICATIONS*

Dimensions	11.0 in H x 11.25 in L x 6.0 in D
	27.94 cm x 28.6 cm x 15.2 cm
Weight	
Therapy Unit only	5.7 lbs / 2.6 kg
Pressure options	100-150 mmHg, 13.3-20 kPa
Canister Volume	1000 cc / mL
Environmental Conditions	
Storage Conditions	
Temperature Range	-20° F (-29° C) to 140° F (60° C)
Operating Conditions	
Temperature Range	50° F (10° C) to 100° F (38° C)
Altitude Range	
Optimum Performance	0 to 8,000 ft (0 to 2438 m)

Electrical	
Power Supply Input	100 V~ - 240 V~, 50/60 Hz
Power Supply Current	2.5 A max (100 V)
	0.9 A (100 V~), 0.4 A (240 V~)
Current Leakage	<100 Microamps (115 V)
	<300 Microamps (230 V)
Battery Run Life	2 hours (approximately)
Battery Charge Time	8 hours (approximately)
IEC Classification	
Medical Equipment	
Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.	
Type B Applied Part	
IPX1	

* Specifications subject to change without notice.

CONTACT INFORMATION

For questions regarding this product, supplies, maitenance 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.kci1.com or www.abthera.com

Outside the US, visit www.kci-medical.com

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