ABRA® Abdominal Wall Closure Set
a Dynamic Wound Closure System

Introduction
The ABRA® Abdominal Wall Closure Set provides dynamic reduction for full thickness, retracted, midline abdominal defects with the goal of maintaining or restoring the definitive primary closure option.

Indications
The ABRA® Dynamic Wound Closure Systems are indicated for use in controlling, reducing, or closing retracted soft tissue defects.

Warnings
System is to be used by a qualified surgical practitioner.
The ABRA® Abdominal Wall Closure Set must not be left on for more than 29 days.
NO REUSE: Sterile ABRA® system components are not intended to be resterilized or reused. Stresses and fractures may be created during use and resterilization that cannot be detected by visual inspection, which may prevent thorough decontamination of the product and compromise structural integrity.

NOTE: The ABRA® Abdominal Wall Closure Set has been fully MRI-compatible since 2007. To ensure you are using MRI-compatible Button Tails, confirm that the color of the printed illustration on the Button Tails is blue. If the printing on the Button Tails is black, simply remove the Button Tails prior to the MRI procedure, then replace afterwards.

All ABRA® Dynamic Wound Closure Systems are not made with natural rubber latex.

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IFU0235A
**Overview of the Key Components**

**Button Anchor**
- Cleat (Locks elastomer)
- Front Slot
- Button pad
- Finger grip
- Button Tail Lock

**Button Tail**
- Adhesive Fabric
- Hook
- Blue ink = MRI compatible
- Black ink is not MRI compatible
(See NOTE, page 1)

**Elastomer**
- Tension markings

**Canulator**
- Handle
- Blunt Tip
- Elastomer Hole (eyelet)

The Canulator is a blunt, atraumatic muscle dividing tool. It requires a small skin incision of 3 mm to allow it to pass through the skin layer. By applying a 180° oscillating motion combined with gentle pressure, it will divide muscle fiber to create a passage for the elastomer. Correct use of the Canulator will greatly reduce the risk of herniation.

**Completed System Installation**

Completed installation of the ABRA® Abdominal Wall Closure System will resemble diagrams shown. Follow the steps below to begin the installation procedure.

**Pre-operative Instructions**

**Wound Size and Product Requirements**

**1 Operating Room Supply Requirement**
Determine total materials required based on the patient’s wound size. Each ABRA Abdominal Wall Closure Set includes materials for 10 pairs of Button Anchors (up to 30 cm of wound length). The ABRA Extender Set contains enough materials for 3 additional Button pairs (9 cm at 3 cm spacing).

Determine product requirements based on the wound size:

<table>
<thead>
<tr>
<th>Wound Size</th>
<th>Quantity</th>
<th>Materials Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>All sizes</td>
<td>1</td>
<td>CWK08 ABRA Abdominal Wall Closure Set</td>
</tr>
<tr>
<td>Length or width &gt; 30 cm</td>
<td>add 1</td>
<td>CWK08-EX ABRA Extension Kit</td>
</tr>
</tbody>
</table>
Exudate Management

ABRA Abdominal Wall Closure should always be used in combination with a Negative Pressure Wound Therapy System (supplied by other manufacturers) for exudate management. The Perforated Silicone Sheet provides viscera protection during closure and acts as an adhesion barrier, allowing the NPWT dressings to be installed over top.

Negative Pressure Wound Therapy (NPWT)

When ABRA is used in combination with NPWT:

- ABRA provides the dynamic apposition force to re-approximate the abdominal wall.
- The Silicone Sheet (viscera protector) protects the viscera from strangulation, prevents adhesions from forming, and allows active fluid transfer using NPWT, while facilitating bedside dressing changes.
- Negative Pressure Wound Therapy provides active exudate management and containment, assists in reducing abdominal volume, and adds structural stabilization of the adipose tissue.

Patient Preparation

2 The skin area, extending 20 cm from each wound margin, should be shaved and cleaned.

All necrotic tissue, adhesions and inter-layer granulation should be excised to create clean, mobile wound margins. It is important to remove any existing abdominal closure devices (such as mesh).

Observe and note peak ventilator pressure to establish a baseline.

Operative Instructions

Layout

3 With a skin marker, draw placement margins at 5 cm from the wound edge.

Note: Setting the anchors back further than 5 cm decreases the available working domain, and reduces the system’s effectiveness.

Mark anchor placement at 3 cm intervals starting from the lower aspect of the wound. The first pair of buttons should align with the lowest aspect of the fascial wound, as shown.

Tip: Use a malleable retractor to ensure marks are directly opposed to one another, and that there is an even number of marks.
Warnings
Increasing anchor spacing increases the load per anchor and can dramatically reduce effectiveness.
Do not suture or staple the ends of the incision first. This decreases its length but increases the central closing tension, creating a defect that is more difficult, or impossible, to close.

Working Around an Appliance
If you have the option, place the appliance 10 cm back from the margin to provide space for the Button Anchors in front of the appliance.
To work around an appliance, reduce the number of Button Anchors on the appliance side by one. Install two elastomers in the Button Anchor opposite the appliance (see A in diagram). Then draw one elastomer end through the Button Anchor above the appliance (B), and the other elastomer end through the Button Anchor below the appliance (C). Elastomers will be installed laterally above and below the appliance.

The elastomer can be used as a retention loop on the stoma side and placed under the appliance, if required. Some skin tearing should be expected.

Tip: Use the appliance to stencil out the area to work around.

Installing the Silicone Sheet as a Viscera Protector (Ref. #SL1217-40)
4
Silicone Sheet #SL1217-40 is a perforated viscera protector for use in combination with NPWT and to allow bed-side dressing changes.
- Use the full sheet to accommodate the entire abdominal area.
- To prevent adhesions, the Silicone Sheet must extend beyond the elastomer entry points even in the event of an inflammatory response.
- If the sheet is too large, trim only as much as necessary, or leave excess folded up as shown below.
- Wounds larger than 30 cm in width or length will require a second sheet:
  Suture two sheets together with a minimum of 8 cm of overlap between the sheets.
- Place sheet in the lower aspect of the wound with edges extending beneath the fascial layer. Progress upwards, tucking the sheet into the paracolic gutters.
- Cut Silicone Sheet, as shown, to fit around stomas. Avoid contact between the stoma and the cut edge of the sheet.
- As wound margins close, excess sheeting can be drawn together and folded over lengthwise along center of wound.

Average wound
Silicone Sheet (true if required)

Large wound
Silicone Sheets (Two sheets sutured together for large wound)
Cut Silicone Sheet to fit around stomas and appliances using either method

Minimum 8 cm overlap
(Elastomer placement shown for clarity)

Adipose Tissue
Fascia

Viscera
Silicone Sheet*

* Excess silicone sheet may be folded up as shown, or trimmed.
Making Incisions for Elastomers

5 Following the marks on the layout, make holes in the skin using a 3 mm electrocautery blade or a #11 scalpel blade.

**Note:** Keep holes small and shallow, piercing just through the dermal layer. During elastomer installation, the Canulator will stretch the skin as required and divide the fibrous muscle layer without leaving a permanent hole in the muscle, reducing the risk of herniation.

Installing the Elastomers

6 The SurgiFish is provided as extra protection for the viscera during installation of the elastomers.

Begin at the lower aspect of the wound and work upward along one margin, then the other.

A Use two fingers inside and a thumb outside to align the layers at the wound margin. Turn out to provide full visualization. Ensure skin and fascial margins are aligned in order to create a square bite. (See diagram B)

B Using minimal force and oscillating 180°, use the Canulator to divide the fat and muscle tissues through the fascia as shown. Take a 5 cm square bite (square to both skin and fascia, and 5 cm from both margins). *Graphically exaggerated for clarity.

C If it is difficult to advance the Canulator through the muscle, increase the oscillation with less forward thrust.
D Thread a maximum 5 cm of the elastomer in the eyelet (to prevent accidentally nicking the elastomer in its working range) and pull back through the skin. The eyelet retains the elastomer as it is passed.

E Complete threading elastomers on one side of the wound. 

Note: Hemostats should be used to clamp elastomer ends to prevent them from being pulled back into the wound while installing elastomers in the opposite side. Clamp close to ends to avoid nicking the elastomers within their working length.

F Complete threading elastomers on the other side.

Installing the Button Anchors

7 Install Button Anchors and secure the elastomer as shown below, but do not tension elastomer at this time.

A Face Button Anchor slot towards the wound.

B Slide the Button Anchor until elastomer is in the slot.

C Secure and Lock

Do not tension elastomers at this time.

Select the elastomer with your finger (#1), then draw back on the loose end with the opposite hand until the elastomer drops into the cleat (#2)
**Installing the Elastomer Retainer (Ref# AWC01)**

8 Use the Elastomer Retainer to prevent elastomer migration to upper and lower aspects of the wound.

A Slip the Elastomer Retainer under the elastomers resting on top of the viscera protector. Starting at the lower aspect of the wound, insert with smooth side up to ease installation, then rotate to expose elastomer slots. Always place the Elastomer Retainer at the lower aspect of the wound.

B Starting at the lower aspect of the wound, place each of the elastomers into the appropriate slot in the Elastomer Retainer.

**Note:** The Elastomer Retainer can be trimmed to match the wound length.

**How to Read and Set Elastomer Tension**

9 The black bars on the elastomer provide a visual indication of elastomer tension. Maximum working tension is indicated when the mark is stretched to twice (2X) its untensioned length. To set elastomer tension, release the elastomer from the cleat, and compare tensioned marks to untensioned marks, as shown. Secure the tensioned elastomer in the Button Anchors (see Step 7).

<table>
<thead>
<tr>
<th>Untensioned</th>
<th>1X</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 : 1 Stretch</td>
<td>1.5X</td>
</tr>
<tr>
<td>Minimum</td>
<td></td>
</tr>
<tr>
<td>2 : 1 Stretch</td>
<td>2X</td>
</tr>
<tr>
<td>Maximum</td>
<td></td>
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</table>
Elastomer Tensioning

10 It is critical to set and maintain appropriate elastomer tensions at all times. Failure to maintain correct elastomer tensions will reduce system effectiveness. Overtensioning will increase the risk of abdominal compartment syndrome, and trauma to skin and/or muscle.

Warning
If peak ventilator pressure or bladder pressure is adversely increasing during an inflammatory response, elastomer tensions should be reduced to 1.5X stretch, as required, to normalize pressure. This may need to be repeated until the inflammatory response subsides.

Wound Shape
Strive to make the wound margins parallel, usually with greater tension in the middle and less at the extremities. Never close the ends of the wound prior to closing the mid-point.

Longer wounds with parallel margins will close faster and with less tension.

Example of Tension Settings (Based on Wound Width)

| Low tension: 1.5X | High tension: 2X Max | Widest points = High tension = 2X |
| Narrower points = Low tension = 1.5X |

Note: Patients with a large pannus require high tension on the lower aspect of the wound.

Advancing the Wound Margins (“The Move”)

11 The first step in re-establishing control of the wound margins is to re-shape the abdomen by changing its aspect ratio, which will increase the volume of the abdominal cavity.

This is accomplished through a repeated sequence of tensioning elastomers, followed by massaging the musculature (a therapeutic method we call “The Move”). “The Move” will mobilize the abdominal oblique muscles from their lateral origin to their medial aspect while the elastomers maintain dynamic apposition of the musculature.

Method:
1. Set all elastomers to 2X stretch.
3. Observe margin advancement and the reduction in elastomer tension.
4. Re-set all elastomers to 2X stretch.
5. Repeat “The Move” once more.
6. Re-set all elastomers to 2X stretch.
7. Release elastomer tension to 1.5X stretch in areas such as the upper and lower aspects to adjust the wound shape. The margins should be as close to parallel as possible, with the highest tension on any elastomer at 2X stretch.

Note: Do not trim elastomer ends.
Installing Negative Pressure Wound Therapy (NPWT)

1. The silicone viscera protector is perforated to allow use with NPWT, while protecting the viscera from adhesions. Additional non-adherent dressings supplied by the NPWT manufacturer may be used over the elastomers and Silicone Sheet, and installed per the manufacturer’s instructions. Fill the wound with NPWT packing material.
2. If using suction drains under the occluding dressing, place per the manufacturer’s instructions.
3. Place the occluding dressing over the entire wound, adhering it to the space between the wound edge and the elastomers, under the front edge of Button Anchors. (Do not cover Button Anchors)
4. Attach the vacuum.
5. Follow the NPWT manufacturer’s instructions for vacuum application, draw-down and maintenance.

Re-set ABRA Tension After NPWT Installed

Once vacuum is applied, a reduction in elastomer tensions will occur. Re-set all elastomers to 2X stretch, then reduce low-tension areas to 1.5X stretch.

If there is concern that the patient may experience a post-operative inflammatory response (e.g. immune-compromised, older patients, etc.), set the maximum tension to 1.5X stretch, then reduce low-tension areas to 1.25X stretch.

Note: No significant change in wound shape or size should be expected while the vacuum is applied.

Installing the Button Tails

13. Button Tails should be installed initially in the OR.

A. Clean the skin area 10 cm beyond the Button Anchors with an alcohol wipe. A skin preparatory wipe designed to increase skin adhesion may also be used after cleaning.

B. Fold the front of the release liner under, without exposing the adhesive, then hook a Button Tail on each Button Anchor. To fully secure hook to Button Anchor, lift back of Button Anchor and tilt the hook vertically to allow it to drop into the slot.
C Starting at the widest point of the wound, slide the Button Anchors back slightly (< 0.5 cm). This important step pre-loads the Button Tails with tension, thus distributing some of the load from the Button Anchor.

Keeping the Button Tail firmly in position, peel off the liner and press onto the skin. For optimal adhesion, gently rub the entire surface of the Button Tail onto the skin. (Try not to touch the adhesive side while peeling off the liner.)

D Button Tails will overlap, but trimming the tails is usually only required to accommodate wound drains or defects.

The Button Tail uses a single contact adhesive and cannot be re-positioned once it is applied to the skin. If re-positioning is required, peel off and replace with a new Button Tail.

### Post-operative Instructions

#### Physician Care (every 24 hours)

14  
1. Re-set elastomer tensions to 2X stretch.  
2. Do “The Move”. (See Page 8)  
3. Re-set all elastomer tensions to 2X stretch, then reduce low-tension areas to 1.5X stretch.  

**Tips:**  
*Normalize fluid balance, if possible, to minimize abdominal volumes.*  
*Maintain lower respirator volumes, if possible, to minimize pressure on diaphragm.*

#### Dressing Changes

15  
NPWT dressings should be changed per manufacturer’s protocol.  

1. Remove dressings and inspect wound.  
2. Clean and dry under Button Anchors.  
3. Re-set elastomer tensions to 2X stretch.  
4. Do “The Move”.  
5. Re-set elastomer tensions to 2X stretch.  
6. Re-install NPWT dressings and draw down.  
7. Re-set all elastomer tensions to 2X stretch, then reduce low-tension areas to 1.5X stretch.  

**Tips:**  
*Ensure that the Silicone Sheet is clear of stomas and appliances. The sheet can be trimmed and drawn out of the way at the surgeon’s discretion (see Page 4).*  
*Do not cover Button Anchors with occluding dressings.*

#### Nursing Care (once per shift, or every 12 hours)

16  
1. Clean and dry the skin under the Button Anchors.  
2. Check that Button Tails are attached and engaged. Button Tails should be replaced when necessary.  

**Note:** Monitor peak ventilator pressure at all times. Sharp increases may indicate an inflammatory response and a need to call the attending physician to decrease elastomer tensions to 1.5X stretch.

Refer to Post-operative Nursing Instruction sheet (IFU0236) in Floor Pack supplied with the ABRA Abdominal Wound Closure Set or visit [www.southmedic.com](http://www.southmedic.com) for the most current version.
Close: Primary Closure

When to Close

17 A low-tension fascial closure can usually be achieved when the fascial margins have been re-approximated to within 1 cm. Closing too early may result in unacceptable increases in abdominal compartment pressure and increased risk of re-herniation. Manually assessing the force required to re-approximate fascial margins is recommended at dressing changes and prior to attempting final closure.

Primary Closure

18 Remove the Button Anchors, leaving the elastomers in place. Elastomers can be retained using hemostats clamped on the elastomer ends. Remove Button Tails, Elastomer Retainer and Silicone Sheet viscera protector. Once it is determined that a low-tension closure is feasible, remove elastomers. Suture fascia using established protocols at surgeon’s discretion.

Tip: Elastomers can be left in during initial suturing until it is concluded that a low-tension closure is feasible. This allows the system to be quickly re-installed, should it be determined that closure tension remains too high, as indicated by significant increases in peak ventilator pressures and surgeon’s assessment. If unacceptable tension exists, remove all sutures, re-install the ABRA Abdominal Wall Closure System with NPWT, and re-assess in 1-2 days.

Warnings

- If peak ventilator pressure or bladder pressure is adversely increasing during an inflammatory response, elastomer tensions should be reduced to 1.5X stretch to normalize pressure.
- Monitor the patient’s fluid balance. If appropriate, consider steps to reduce interstitial volumes. High fluid balance increases abdominal volumes and makes fascial re-approximation more difficult.
- Constipation may increase bowel volume, which may slow wound closure progress.
- The Button Anchor pad is occlusive so it is important to clean and dry under the Buttons at least once every 12 hours, or every nursing shift, to prevent skin maceration. Hydrocolloid or other dressings may be placed under the Buttons to assist in moisture collection and load distribution.
- Button Anchors and Button Tails must remain dry. Do not cover with occlusive dressings.
- The Button Tails must be maintained at all times. Improperly installed or maintained Button Tails will result in unnecessary skin tears. Replace Button Tails immediately if skin tears are observed.
- Do not trim elastomer ends. The added length may be required during an inflammatory response period.
- Do not restrain or knot the ends of the elastomer beyond the cleat of the Button Anchor.

Tips:

- During the post-operative period, the system may be loosened and the viscera protector re-positioned to allow for inspection and cleaning of the wound.
- During patient transfers, abdominal binders may be used to temporarily support the mass of adipose tissues. (Do not leave binder in place for more than 10 minutes!)