

The Butterfly™

Steep Trendelenburg Gel Bean Bag Positioner

DAVID
SCOTT
COMPANY

USE & CARE GUIDELINES



Intended use of The Butterfly™:

This product is designed as a **positioning aid to help secure a patient** during surgical procedures that utilize Trendelenburg. The Bean Bag is a moldable product that can be contoured around the patient to help “cocoon” them. The Butterfly™ is filled with thousands of tiny beads that will mold together to form a rigid surface when air is removed from the environment (via suction). With The Butterfly™, the patient is further protected from pressure spots on the rigid surface by an integrated layer of Blue Diamond® Gel. Finally, there are six (6) Securing straps designed to anchor The Butterfly™ to the Operating Table.

When properly deployed, The Butterfly™ serves as a single device positioning solution to address the “slippage” challenges of steep Trendelenburg procedures while the incorporated layer of Blue Diamond® Polymer Gel aids in the prevention of pressure injuries.

Key Features of The Butterfly™

- ✓ Upper wings can be folded back to create a broader shoulder cushion as a support (“butterfly” style) or upper wings can be molded to envelope both the chest and upper arms (“cocoon” style).
- ✓ Lower wings designed to secure hand and lower forearms in a tucked position while still offering near-full arm access for Anesthesia. Lower wing extension tucks under patient.
- ✓ One-Click valve allows suction tubing to be *disconnected* after initial evacuation.
- ✓ Wide cephalic notch design maximizes space around the head for the Anesthesiologist.
- ✓ Pressure points minimized by integrated layer of Blue Diamond® Gel.



This product is intended to be used by a licensed medical professional only. As any medical device staff should familiarize themselves with the product prior to use on a patient. David Scott cannot be held liable for misuse of this product.



Inspect Bean Bag for leaks or tears. Never use any product if integrity is in doubt.



Never Carry The Butterfly™ by the valve stem as damage can occur to the product.

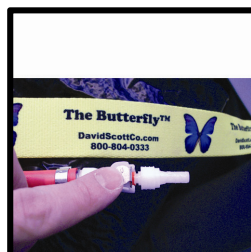
INITIAL SETUP:

Suction Valve: The white suction valve on The Butterfly™ can be *opened* or *closed*. The valve must be “*opened*” to evacuate air using vacuum suction to form the bean bag at the start of a case or to release the vacuum to un-form the bean bag at the end of a case. Once the vacuum is completed and the bean bag is formed to the desired position, the valve can be “*closed*” and the suction tubing can be disconnected. The valve is in the *closed* position when the 2 halves appear separated with a **visible gap** in the middle of the white valve stem, **air will not flow**.



Opening the Valve
(No Gap)

Fig. 1



Closing the Valve
(Visible Gap)

Fig. 2

Opening the valve is achieved by pushing the end of valve in until it clicks into place. When the valve is opened, no gap appears between the 2 halves. (Figure 1)

Closing the valve is achieved by pushing the silver tab with your thumb until an audible click is heard and the 2 parts appear separated with a visible gap in the middle of the white valve. (Figure 2)

Bead Distribution: Beads are necessary in the device for the vacuum suction to function properly. *Areas in the bean bag without beads will not mold!* Prior to placing The Butterfly™ on the operating room table, evenly distribute the beads throughout the device as best possible. This can be done using a flat hand and forearm in a sweeping motion or by *gently* shaking the bean bag.

Positioning The Butterfly™: Place The Butterfly™ flat on the OR table with the gel side facing up, the large wings towards the head of the table and the smaller wings towards the foot of the table. Center the Butterfly™ horizontally (left/right) on the OR table. (Figure 3 & 4)



Empty OR table with
Armboards

Fig. 3



Butterfly laid out on OR
table w/ armboards

Fig. 4



Fold Wings in to
secure straps

Fig. 5



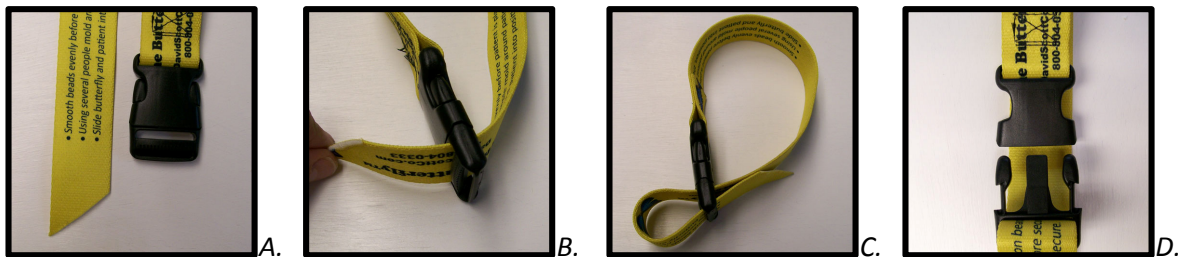
3 straps secured to
rail on each side

Fig. 6

Anchoring The Butterfly™ to the OR Table: The **yellow** securing straps should be secured to the OR table side rails *before* the patient is positioned correctly. By folding up the sides of The Butterfly™ onto the OR table Top you will have access to the six (6) securing straps. (Figure 5 & 6)

****If yellow strap is not still affixed to The Butterfly™ then please following these steps to ensure it is properly reinstalled onto The Butterfly™.**

1. Position The Butterfly on the OR table shown in Fig. 5.
2. Insert the securing strap tongue from the top down towards the Side Rail.
3. Making sure the 2 part buckle is locked together (A), feed the tongue from the backside through the upper groove (B).
4. Bend tongue back in a loop and feed through lower slot so the tongue is now on the backside of buckle (C).
5. Buckle is now ready for use (D).



The Buckle is an easy to use 2 part side release design that can be squeezed with thumb and forefinger to release. The buckle should feed down through the side rail and be secured on the front side of the OR side rail. Once it is pushed together an audible click will ensure it is snapped together. *Continued>>>*
To tighten the strap use two hands, one holding strap above the buckle and pull the tongue with the other hand, until it is snug. *This is when the slack is taken up and the Bean bag will become secure to the OR table side rail.* Continued >>>>

- ✓ *Tip:* You may want to adjust the strap so the buckle is not directly in front of the side rail.
- ✓ *Tip:* The straps should be located on the upside of the securing studs on the side rails whenever possible. This further ensures The Butterfly™ from accidental slippage.

Repeat this procedure for all six (6) straps making sure all straps are snug and cannot slip loose.



Ensure proper strap installation- several personnel may be required.

Positioning a patient on The Butterfly™: Patients should be centered horizontally (left/right) on The Butterfly™. The patient's shoulders should be even with the base of the cephalic (head) notch. Ideally, the lower edge of The Butterfly™ should be at the patient's lower lumbar, aligned with lower edge of OR table body section. If the patient needs to be moved up or down on the table, the patient should be moved on The Butterfly™ using at least four (4) persons grasping the bean bag on its body (*not the wings or securing straps*).

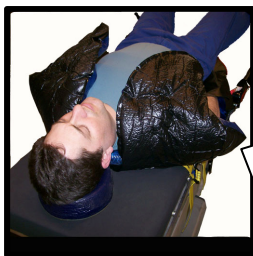


Fig.7

Upper Wings over
shoulders



Fig.8

Upper Wings as
Shoulder Bumps

Molding The Butterfly™: Once the patient is positioned correctly and The Butterfly™ is secured to the OR table, the device can be molded for secure patient positioning. As noted earlier, The Butterfly™ can be molded “cocoon” style or “butterfly” style. With 1-2 people on each side of the OR table mold the upper wings and lower wings around the patient using the desired configuration making sure to hold the Beanbag close to the patient until it takes shape around them:

Preferred
Method

- ✓ **Lower wings** with as few beads as possible in the lower wing portion, wrap over the hands with the tail of the wing (no beads in tail) tucked as far as possible beneath the patient (“cocoon” style).(Figure 9)
- ✓ **Upper wings** Folded back creating a creating a passive safety support behind the shoulders. The wing should be bent back and the tip of the wing tucked under slightly to just touch the OR table surface (“butterfly” style). Standing at patients head, or a person on each side, hold firm the shoulder bumps against the patient until air is evacuated.(Figure 8)

OR

- ✓ **Upper wings** around the shoulders and over the chest, taking care in not interfering with patients face (“cocoon” style). Standing at patients head, or a person on each side, hold wings down onto chest while air is evacuated.(Figure7)
- ✓ **Lower Wings** should be addressed in same fashion as in preferred method.



Multiple people are required at this stage of positioning. 4 people are ideal.



Fig.9

Extension wrapped over hand/wrist



Fig. 10

Extension wrapped over hand then tucked under patient

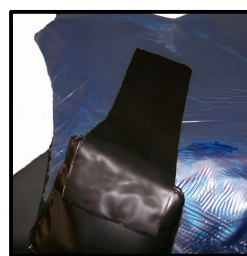


Fig. 11

Lower Wing Extension

Lower Wing-Hand Extension: This detachable wing is designed to wrap over the patients hand/wrist and then be tucked under the patient, utilizing the patient's weight to further secure the extremity in position. There are no beads in this lower wing extension. (Figure 10)

Applying Suction to and Molding The Butterfly™: It is essential that The Butterfly™ is molded correctly when the suction is applied.

Applying Suction to The Butterfly™: The one piece valve is a "click lock" design. As noted above, the valve system can be "opened" or "closed." To allow air to flow freely in or out, the valve needs to be "opened" by being pushed together / depressing the end of the white valve. It will audibly "click" together. (Figure12) To restrict air flow from flowing in or out the valve needs to be "clicked" closed by pushing the silver thumb tab down. When it "clicks" closed, the 2 halves of the valve stem are visibly separated by a gap in the middle of the valve stem. (Figure 13)



Fig. 12

Opening the Valve (No Gap)

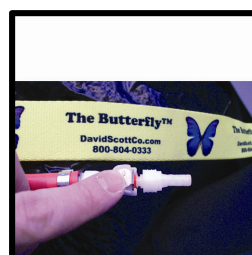


Fig. 13

Closing the Valve (Visible Gap)

The click lock valve system allows suction tubing to be removed once the system is **closed**, though leaving the suction tubing connected during the procedure will not harm the product. Nonetheless, it is recommended that the valve be **closed** once The Butterfly™ is molded to desired position.

Familiarity with the valve system will allow for easier adjustments during initial setup and if needed during surgical procedures.

The valve system is a replaceable item if it fails or is damaged, you will not need to replace the whole product in most instances.



If your suction tubing does not fit you can usually cut off the connector on the tubing.

Once desired shaping is achieved by molding the soft bean bag, *continue to support the device in the desired molded position*. Attach the suction tubing to the valve system and apply vacuum to The Butterfly™. The product will become rigid and firm around the patient very quickly. After 20-30 seconds no additional support should be required by personnel holding The Butterfly™ in position. Once The Butterfly™ is fully evacuated and firmly molded, “click” the valve to the closed position. The 2 halves of the valve stem will have a **visible gap** in the middle of the valve and **air will no longer flow** in or out of the bean bag.

If during the procedure it becomes necessary to reposition your patient please follow above procedures and ensure patient is secure at all times.



Having a thicker layer of beads will provide more support and rigidity than a thin layer.

Cleaning & Storing The Butterfly™:

After use, The Butterfly™ should be thoroughly cleaned in the same manner as any OR table pad or surface. The same cleansers currently used on OR table pads or Gel pads can be utilized. Any cleaner residue should be wiped clean with a water saturated towel.

- ✓ Storing The Butterfly™ in a **rigid form** is recommended. This will allow early detection if a leak or puncture has occurred. However, bean bags that are stored in a rigid form for extended periods will lose some of their rigidity. Alternatively, The Butterfly™ can be carefully folded along the spine with the gel facing in to prevent damage to the surface. If the bean bag is fully relaxed and the valve is still closed you will need to test The Butterfly™ before using it.

Notes:



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