

TissuGlu® Surgical Adhesive

Patient Information Brochure

This Brochure Contains information on the following:

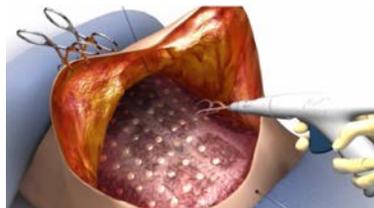
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1. What is Abdominoplasty?

An abdominoplasty, or tummy tuck, is a surgical procedure. It removes excess skin and fat and tightens muscles to create an abdomen that is smoother and firmer. After surgery, fluid can accumulate in the wound and may require treatment. Drains are often placed in a patient during surgery to manage fluid. A drain is a tube with a collection bulb that can remain in a patient for an average of 7 days. Once drains are no longer needed to manage fluid, they are removed. An aspiration may also be used to remove fluid from a wound after surgery, which uses a syringe and needle.

2. About TissuGlu® Surgical Adhesive

TissuGlu® Surgical Adhesive is a glue used during abdominoplasties (tummy tucks). During an abdominoplasty, TissuGlu® is applied in drops between the tissue layers. The pattern of TissuGlu® drops is shown in the picture below. Once applied, TissuGlu® strongly bonds the tissue layers together. This bond reduces the space between the layers where fluid may collect. After the layers heal, TissuGlu® breaks down into safe components. The safe components are then excreted by the body.



The TissuGlu® applicator is a hand-held, single-use, disposable device. The applicator is shown in the picture below. The TissuGlu® applicator delivers 3 linear drops of glue 2.5 cm apart. Each drop has an average volume of 0.025 – 0.040 mL. When the applicator is ready to be used, the Actuator Switch is turned. It has a rotating head for use in tight spaces. It also has a spacer guide on the tip. The guide allows for consistent application in a grid-like pattern.



3. After your procedure

Your doctor will let you know what to expect after your surgery. While TissuGlu® forms a strong bond holding the tissue layers together, the surgery area still needs time to heal. Your doctor will instruct you on specific wound care and recovery activities, and will let you know when to resume physical activity.

Though they are rare, complications can occur. Potential complications associated with an abdominoplasty and the use of TissuGlu include seroma (fluid) formation, wound healing issues, rash/redness, surgical site or incision infection, scarring, hematoma (bruise or swelling), incision separation, and immunological reaction. You may be more likely to have complications if you have poor circulation, diabetes, or heart, lung, or liver disease. Some minor swelling and bleeding along the incision line is expected after surgery.

Your doctor should let you know how much swelling is too much and when to contact him or her regarding fever, swelling, pain, or bleeding in the surgical area. Your surgery may include drains. If you have drains postoperatively, you should follow your doctor's advice on care of drains and the area around the drains. You will need to have the drains removed by your doctor. If your procedure was completed without placing drains, you should monitor your abdomen carefully for new swelling. Your doctor will instruct you as to when you will need to return for an office visit after surgery to check on your healing.

4. What are the Benefits to the use of TissuGlu® Surgical Adhesive?

TissuGlu® may reduce the need for drains after surgery. By using TissuGlu® instead of drains, you may:

- Return to normal activities more quickly
- Experience less discomfort and pain than when drains are used
- Have fewer invasive treatments for fluid management. The results showed that 73% of TissuGlu® patients had no treatments after surgery. However, some patients did require additional invasive treatments including reinsertion of drains.

5. What are the Risks to the use of TissuGlu® Surgical Adhesive?

Clinical studies were performed using TissuGlu®. There were no increased safety risks with the use of TissuGlu® than when drains were used. Potential complications associated with the use of the device and the tummy tuck procedures include seroma (fluid) formation. These complications may require treatments such as drain placement and/or fluid removal by needle, which may be performed in the operating room. Additional potential complications include wound healing issues, rash/redness, surgical site or incision infection, scarring, hematoma (bruise or swelling), incision separation, and immunological reaction.

In patients who received TissuGlu® instead of drains 73% (or about 3 out of 4 patients) required no treatment to remove seroma. In the patients who did need treatment to remove seroma, the treatment usually was a needle aspiration of the fluid but in some cases required reoperation.

6. Warnings

TissuGlu® use is not recommended in patients who have been previously treated with TissuGlu® due to the possible risk of allergic reaction. Repeat TissuGlu® use has not been studied. Patients should be sure to mention to their physician/surgeon if they have had previous exposure to TissuGlu®.

TissuGlu® effectiveness has not been shown in patients with body mass index > 28 or in patients who have had massive weight loss. These patients are more likely to have fluid accumulation. These patients may also have an increased risk of seroma formation.

Use in pediatric patients, i.e., individuals 22 years of age and younger, has not been clinically evaluated for safety.

7. Who Should Not Use TissuGlu® Surgical Adhesive?

Patients with known or suspected allergies to urethane-based or isocyanate-containing products. Patients should be sure to mention to their physician/surgeon if they have had previous exposure to TissuGlu® since they may be more likely to experience an allergic reaction.

8. Current Alternative Treatments

Alternative treatments to the use of TissuGlu® are:

- Using post-surgical drains to manage the risk of fluid-related complications.
- Using progressive tension or quilting suture techniques. These techniques may be used with or without drains to manage the risk of fluid-related complications.

As with the use of TissuGlu®, there may be the complication of seroma requiring either needle aspiration or reoperation. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle. As with the use of TissuGlu®, there is the possibility of fluid-related complications after these alternative treatments.

9. Summary of Clinical Information

Two clinical studies were conducted on abdominoplasty (tummy tuck) patients in the U.S. using TissuGlu®.

The first study evaluated TissuGlu® used with drains in 100 patients for managing fluid. Additionally, 50 patients received drains alone. The study compared the time to drain removal. Patients were in the study for 12 months.

The results showed that TissuGlu® was not effective in reducing the days to drain removal.

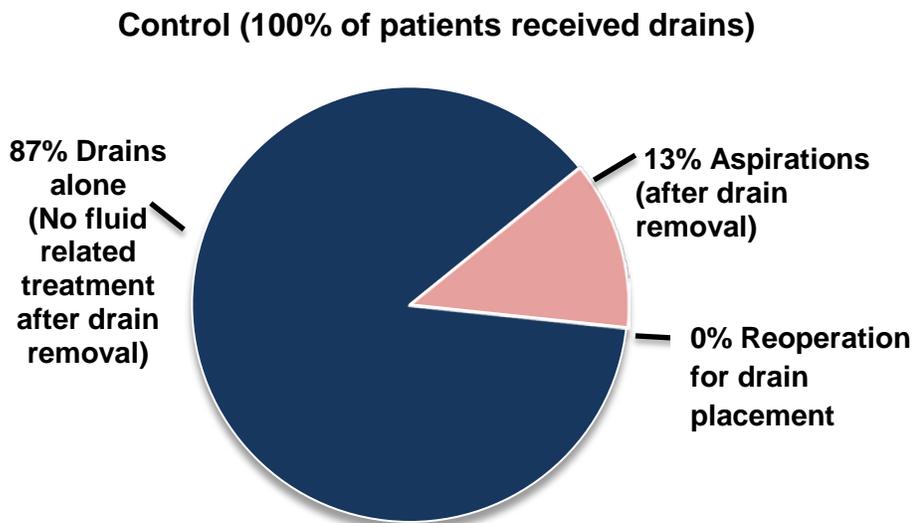
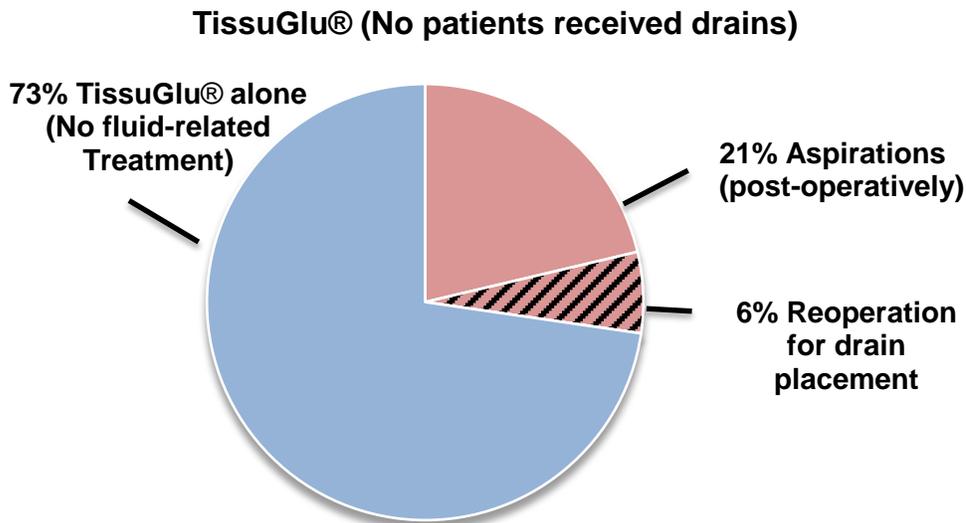
There were no differences between groups with regard to safety. There were no unanticipated adverse device events

The study results provide support for the safety of TissuGlu®.

The second study evaluated TissuGlu® as an alternative to drains for managing fluid. 66 patients received TissuGlu® and no drains. 64 Patients received drains alone. The study compared the number of treatments after surgery for each group. Patients were in the study for 3 months.

All (100%) control subjects underwent an invasive postoperative removal of their drains. The TissuGlu® patient group did not receive drain placement. Of the control patient group, 13% required additional invasive treatments without need for reoperation for drain replacement, i.e., they had needle aspiration of seromas. In the TissuGlu® treatment group, 73% of patients had no drain removal and no fluid-related invasive treatments. In the 27% of patients who did require invasive

treatments, 21% received needle aspirations alone. Six percent of the TissuGlu® group received both needle aspirations and drains for persistent seroma formation. See figure below for graphical representation of the clinical study results.



The clinical benefit of using TissuGlu® in this study was that drains were not necessary in a majority of the TissuGlu® treated patients. While the 27% post-operative treatment of TissuGlu patients is higher than the 13% re-treatment of the control group, it should be noted that the majority of TissuGlu patients (73%) had no invasive treatments at all while the entire control group had invasive treatment, i.e., drain placement and removal.

Adverse events reported in the clinical trials included seroma (fluid) formation, wound healing issues, rash/redness, surgical site or incision infection, scarring, hematoma (bruise or swelling), and incision separation. The study results provide support for the safety and effectiveness of TissuGlu® as an alternative to drains.

10. Contact your Physician if:

If you, or any future physician, have questions or concerns related your treatment with TissuGlu® contact the plastic surgeon who performed your procedure. See section 3 for important information on when to contact your doctor after your procedure.

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**TissuGlu® Surgical Adhesive
Patient Information Card**

You may keep this card with you following your procedure.
Please talk to your doctor if you have any questions about your
post-procedure discharge guidelines.

PATIENT NAME: _____

PHYSICIAN NAME: _____

PHYSICIAN PHONE: _____

PROCEDURE DATE: _____

This patient received TissuGlu® Surgical Adhesive a polyurethane based adhesive.
For questions related to TissuGlu® Surgical Adhesive contact your physician listed
above.

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