DIRECTIONS FOR USE



MESH APPLICATION

The application of **exofin fusion**® system requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of **exofin fusion**® (i.e., cleanse, irrigate, debride, obtain hemostasis, and close deep layers such that there is no tension on the skin). The skin edges must be closely approximated prior to application of the mesh, such that significant manual approximation is not required during mesh application.



2 Pat the wound dry with sterile gauze to assure direct tissue contact for adherence of the mesh and the liquid skin adhesive to the skin.



3 Remove the formed tray from the sealed bag and aseptically transfer the entire tray to the sterile field. Remove the lid from the tray to access the device components.



4 exofin fusion® is applied in a 2-step process with 6 mesh pieces and 2 applicators for dispensing the liquid skin adhesive. Steps for application of **exofin fusion**® are illustrated below. Hold a mesh piece, mesh side up (Fig. 1). Flip the mesh strip and remove larger piece of backing paper from mesh (Fig. 2). Apply mesh to one side of incision so the pressure-sensitive adhesive adheres to patient's skin ensuring the mesh extends at least 1 cm from each end of the incision. (Fig. 3).



5 Press gently to ensure intimate contact of the mesh to the selected side of the incision. (Fig 4).



Remove remaining backing. Gently pull the mesh perpendicularly over the incision while adjusting with fingers or forceps to achieve skin edge approximation and affix the remainder of the mesh to the other side of the incision (Fig. 5). Ensure the mesh is placed at least 1 cm from each of the ends of the incision.



If there are areas where the mesh is loose, gently pass a gloved finger or instrument over the affected area to ensure complete adherence of the mesh to the skin. If the mesh is still not adhered to the skin, carefully cut any affected segments of the mesh and remove them from the skin. Ensure the skin edges are clean and dry and reapply new mesh according to the directions for use, overlapping the end of the existing mesh by approximately 1 cm. The liquid skin adhesive should be applied over the entire mesh and slightly over on to the surrounding skin. The adhesive should be applied immediately after the mesh has been properly placed over the incision.

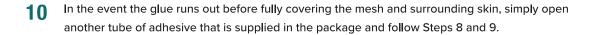


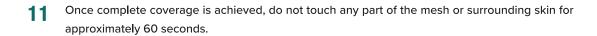


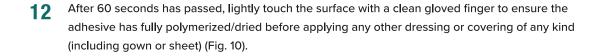
Remove backing

ADHESIVE APPLICATION

- Activate the liquid topical skin adhesive by twisting the connector containing the applicator tip onto the 8 tube to break the sterile seal (Fig. 6). DO NOT OPEN ADHESIVE UNTIL READY TO APPLY.
- While holding the tube in a horizontal position, squeeze the tube at the "X" near the crimped end 9 to release the pressure and air from the tube (Fig. 7). Activate the adhesive by pointing applicator tip down and expressing three drops onto a surgical drape (Fig 8). Turn the applicator tip toward the patient and begin squeezing the tube from the bottom with gentle pressure until adhesive begins to flow. Once adhesive begins to flow from the applicator tip, continue squeezing and applying pressure to the tube while moving upward toward the tip while painting the surface of the mesh, including slightly off the mesh to the surrounding skin, until the entire mesh surface is fully covered (Fig. 9). Pat the deployed mesh dry gently with dry sterile gauze in the event of bodily fluid seepage without disturbing skin edge approximation prior to spreading the adhesive over the mesh.







Mesh should remain in place on the patient up to 14 days after application with proper aftercare. 13

NOTE: DO NOT APPLY A SECOND COAT OF ADHESIVE TO MESH PATCH WITH ADHESIVE.







Express air



Express three drops



Apply adhesive



Let dry



Remove

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