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New Device Approval

Indermil™ Tissue Adhesive - P010002



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Indermil™ Tissue Adhesive

Distributor: United States Surgical, a division of Tyco Healthcare Group, LP.

Address: 150 Glover Avenue Norwalk, CT 06856

Approval Date: May 22, 2002

Approval Letter: <http://www.fda.gov/cdrh/pdf/P010002a.pdf>

What is it? The device is a glue similar to "Superglue" that is used to closed small skin cuts, lacerations (tears in skin), or surgical incisions (wounds from sharp objects such as a scalpel).

How does it work? It is applied by an applicator to the skin. Once it comes into contact with the skin, the glue hardens rapidly.

When is it used? Indermil™ tissue adhesive is used to close topical skin incisions object including laparoscopic (scope to see inside the abdomen) incisions, and trauma-induced lacerations in areas of low skin tension that are simple, thoroughly-cleansed, and have well-defined skin edges. Indermil™ may be used with, but not in place of, stitches placed deep in the skin.

What will it accomplish? The device will hold the edges of skin wounds together so the skin can heal.

When should it not be used? Indermil™ tissue adhesive is not to be applied:

- below the skin,
- in areas with dense natural hair,
- near or on the eye,
- on areas of where skin pulls tightly when moved such as the elbows, knees, or knuckles,
- to wounds that show evidence of infection or gangrene,
- to the skin of patients with known pre-operative systemic infections, uncontrolled diabetes, or diseases or conditions that are known to interfere with the wound healing process, and
- to the skin of patients with a known allergy to cyanoacrylate (a plastic) or formaldehyde (a preservative).

NOTE: The glue will stick quickly to any surface, so medical professionals should take precautions to ensure that the glue does not come into contact with unintended areas.

Additional information: Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/P010002.html>

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