



New Device Approvals

DERMAGRAFT® - P000036

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: DERMAGRAFT®
Manufacturer: Advanced Tissue Sciences
Address: 10933 North Torrey Pines Road, La Jolla, CA 92037-1005
Approval Date: September 28, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000036a.pdf>

What is it? DERMAGRAFT® is a skin substitute used to help in the wound closure of diabetic foot ulcers. It is made from human cells known as fibroblasts, placed on a dissolvable mesh material.

How does it work? When the DERMAGRAFT® is placed on the ulcer, the mesh material is gradually absorbed and the human cells grow into place and replace the damaged skin. The living cells in DERMAGRAFT® produce many of the same proteins and growth factors found in healthy skin, which help replace and rebuild the damaged tissue in the diabetic foot ulcer.

When is it used? DERMAGRAFT® is used on:

- full-thickness diabetic foot ulcers that have been present for longer than six weeks and
- ulcers that extend deeper into the skin where the blood vessels are, but do not involve tendon, muscle, joint capsule or bone.

What will it accomplish? DERMAGRAFT® will help to close diabetic foot ulcers that have been present longer than six weeks where the wound is not closing.

When should it not be used? DERMAGRAFT® should not be used on infected ulcers or ulcers with sinus tracts (tunneling). It should not be used on patients allergic to products derived from cows because there is bovine serum in the packaging solution.

Additional information: The SSED and Labeling is available at:
<http://www.fda.gov/cdrh/pdf/p000036.html>

Other: NIH:

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-00-009.html>

<http://www.niddk.nih.gov/health/diabetes/feet/feet2/prevent.htm>

<http://www.nlm.nih.gov/medlineplus/ency/article/001214.htm#complications>

(Updated 10/5/2001)