



New Device Approvals

OrCel™ Bilayered Cellular Matrix P010016

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: OrCel™ Bilayered Cellular Matrix
Manufacturer: Ortec International, Inc.
Address: 3960 Broadway, New York, NY 10032
Approval Date: August 31, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010016a.pdf>

What is it? OrCel™ is a dressing applied to wounds to protect and promote healing. It is made from cow collagen and two types of living human skin cells.

How does it work? The living human skin cells in this product produce proteins that may be helpful in healing wounds and may stimulate a patient's own skin to heal itself. OrCel™ is absorbed by the body as the wound heals.

When is it used? OrCel™ is used when healthy skin from a burn patient is transplanted to cover the burn. OrCel™ helps heal the wound made where the healthy skin was removed.

What will it accomplish? OrCel™ may help the wound heal faster than other wound dressings.

When should it not be used?

OrCel™ should not be used:

- on wounds that are infected,
- on patients who are allergic to any animal products, such as cow collagen, or
- on patients who are allergic to penicillin, streptomycin, gentamycin, or fungizone (amphotericin B).

Additional information: The SSED and Labeling are available at:

<http://www.fda.gov/cdrh/pdf/p010016.html>

(Updated 9/20/2001)