Composite Cultured Skin - H990013

FDA approved this device under the Humanitarian Device Exemption (HDE) program http://www.fda.gov/cdrh/ode/hdeinfo.html. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Composite Cultured Skin
Manufacturer:	Ortec International, Inc.
Address:	3960 Broadway, New York, NY 10032
Approval Date:	February 21, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/H990013a.pdf

What is it? Composite Cultured Skin (CCS) is a wound dressing used to help treat a rare skin condition in children. It is made of living human cells taken from the skin of healthy donors. The cells are grown on a sponge made from cow collagen. (Collagen is a protein found in skin and bones.)

How does it work? When applied to a wound, CCS serves as a temporary protective dressing which provides a favorable environment for the body's cells to grow. In this way, it aids in wound healing.

When is it used? CCS is used in children with a rare inherited disease called recessive dystrophic epidermolysis bullosa (RDEB). In RDEB, blisters and sores appear on the skin, especially the fingers and toes. Sometimes this produces scarring that makes the fingers and toes grow together, so that the hand looks like a mitten. The surgeon rebuilds the affected hand, using pieces of the child's own skin for grafts and flaps as needed.

What will it accomplish? CCS may be used along with pieces of the child's own skin to cover wounds created during the rebuilding of the affected hand. CCS benefits patients by reducing the number and size of surgical wounds created (i.e., donor sites) as the child's own skin is taken from other parts of the body for grafts and flaps. In this manner CCS may also reduce the risk of associated complications.

When should it not be used? CCS should not be used:

- on infected wounds,
- in patients with known allergies to cow collagen and other products made from animals,

- In patients with known allergies to certain drugs, including penicillin, streptomycin, gentamicin, and fungizone (amphotericin B),
- during reconstructive surgery on parts of the hand where considerable flexbility is required (e.g., the primary coverage of joint and web spaces between fingers

Before this product is used, patients or family members should let the surgeon know about any possible allergies.

Who should use this device? The device should also be used only by surgeons:

- trained in the surgical management of RDEB patients with "mitten hand" deformities,
- trained or experienced in the use of this device, and
- prepared to provide patient monitoring

Additional information: The Summary of Safety and Probable Benefit will be available at: http://www.fda.gov/cdrh/ode/H990013sum.html

Other: 4/4/01, JAMA article by Bernard A. Schwetz, D.V.M., Ph.D., (Acting Principal Deputy Commissioner, Food and Drug Administration) - http://jama.ama-assn.org/issues/v285n13/ffull/jfd10003-3.html

(Updated 4/09/2001)