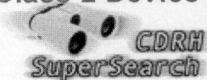


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Class 2 Device Recall Integra

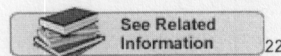


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Class 2 Device Recall Integra



Recall Date September 09, 2016

Recall Status¹ Terminated

Recall Number Z-2777-2016

Recall Event ID 73689²³

Product Classification Device, dermal replacement²⁴ - **Product Code** MDD²⁵

Product Integra Meshed Dermal Regeneration Template 5 cmx 5 cm (2 in x 2in) Rx Only Meshed Integra, Dermal Regeneration Template, (Integra template) is a bilayer membrane system for skin replacement. The dermal replacement layer is made of a porous matrix of fibers of cross-linked bovine tendon collagen and glycosaminoglycan (chondroitin-6-sulfate) that is manufactured with a controlled porosity and defined degradation rate. The epidermal substitute layer is made of a thin polysiloxane (silicone) layer to control moisture loss from the wound. Integra template is indicated for the postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. Integra template is also indicated for the repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiological condition of the patient

Manufactured by:
 Integra LifeSciences Corporation
 311 Enterprise Drive, Plainsboro, NJ 08536
 877-444-1122 USA n 609-936-5400 outside USA
 866-800-7742 fax

Code Information Catalogue No. MIDRT 8101
 Lot No. 105A00324750

Recalling Firm/Manufacturer Integra LifeSciences Corporation
 105 Morgan Ln
 Plainsboro NJ 08536-3339

For Additional Information Contact Mr. David E. Gronostajski
 609-275-2700

Manufacturer Reason for Recall Integra's post QA release review of historical product release test results for Meshed IDRT products identified the Peel Strength test average result was incorrectly calculated for a single Lot (Lot 105A00324750).

FDA Determined Cause² Under Investigation by firm

Action Integra LifeSciences Inc. sent an urgent voluntary medical device recall letter/recall acknowledgement and return form dated March 11, 2016. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to review their inventory for the affected product and immediately stop using and remove from service. Customers were asked to complete the attached form and return by email or fax as