Class 2 Device Recall Integra

See Related Information[22]

Recall Date	September 09, 2016
Recall Status[1]	Terminated
Recall Number	Z-2777-2016
Recall Event ID	73689[23]
Product Classification	Device, dermal replacement[24] - **Product Code** MDD[25]
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 Cause [2]	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