Class 2 Recall
MAYFIELD Composite Series Skull Clamp

See Related Information[21]

Date Classified	November 13, 2013
Recall Number	Z-0210-2014
Product	Composite Series Skull Clamp, one clamp per tote. The MAYFIELD® Skull Clamp (A3059) is a cranial stabilization device, designed to provide rigid skeletal fixation. The Skull Clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary
Code Information	The following serial numbers are affected by this recall: SS120076, SS120082, SS120083, SS120084, SS120088, SS120089, SS120090, SS120092, SS120093, SS120094, SS120095, SS120111, SS120112, SS120113, SS120114, SS120115, SS120116, SS120117, SS120118, SS120119, SS120120, SS120121, SS120122, SS120123, SS120124, SS120125, SS120126, SS120127, SS120128, SS120130, SS120131, SS120133, SS120134, SS120135, SS120171, SS120252, SS120256, SS120257
Recalling Firm/ Manufacturer	Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro, New Jersey 08536-3344
For Additional Information Contact	Integra Customer Service 855-532-1723
Manufacturer Reason for Recall	An investigation of an adverse trend of complaints for the Skull Clamp index locking knob not easily unlocking or disengaging and malfunctions of the 80 lbs. torque knob was initiated. None of the complaints resulted in a report of patient injury, adverse health consequence, or a delay / prolongation of the surgical procedure.
Action	Integra sent an Urgent: Voluntary Medical Device Recall Notification dated August 29, 2013, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Your local Integra NeuroSpecialist will set up a time with you to discuss replacement options but in the interim, Integra is asking that you do the following: 1. Review your inventory and determine if you have any MAYFIELD® Composite Series Skull Clamps (A3059). If so, stop using them immediately and remove them from service to prevent any inadvertent use of the Composite Series Skull Clamp. Either while the Integra NeuroSpecialist is on-site or independently; 2. Complete the attached form. If you do not have affected product, check the box: I do not have Composite Series Skull Clamps. 3. If you do have affected product, check the box: I do have Composite Series Skull Clamps. Record the total quantity and Serial No.(s) of all Skull Clamps in your inventory. The Serial No. is located on the clamp upright comprised of two letters (SS) followed by six numerals. 4. Complete the other information and return by email or fax as indicated on the form, or give it to the Integra NeuroSpecialist who will return it for you. For assistance returning and exchanging these products or any other questions that you may have, please contact Integra Customer Service at 1-855-532-1723. We sincerely apologize for any inconvenience this may have caused and thank you for your cooperation.
Quantity in Commerce	37 units
Distribution	US Distribution including the states of AL, AR, CA, CT, FL, GA, IA, IL, MS, NY, OH, SC, TN, and TX. No product was distributed to Canada or any other foreign countries

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