Class 2 Recall Synthes Cranial Flap Tube Clamp and Crimping Device for Cranial Tube Clamp

Date Posted: September 23, 2015
Recall Status: Open
Recall Number: Z-2811-2015
Recall Event ID: 7213924

Product: Synthes Cranial Flap Tube Clamp and Crimping Device Product Usage: The Synthes Cranial Flap Tube Clamp System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure.

Code Information: Part Number 329.315.460.001 460.001.015 460.002.460.002.015 460.003.460.003.015 460.008.460.008.015 460.009.460.009.015 460.010.460.010.015 460.010.460.100.015

Recalling Firm/Manufacturer: Synthes (USA) Products LLC
For Additional Information Contact: Customer Support 610-719-6500

Manufacturer Reason for Recall: The Synthes Cranial Flap Tube Clamp and Crimping Device for Cranial Tube Clamp had been labeled MR Safe although they do not have the testing protocols currently required to designate them as MR Safe.

Action: DePuy Synthes sent an URGENT: FIELD SAFETY NOTIFICATION / MEDICAL DEVICE LABELING CORRECTION letter, dated August 31, 2015 to affected customers. The letter identified affected product, problem and actions to be taken. Customers were instructed to: "Update and review the package insert (GP1345-D)." "Discard outdated package insert noted in the table above."

9/28/2015