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

See Related Information[23]

Date Posted	September 23, 2015
Recall Status[1]	Open
Recall Number	Z-2811-2015
Recall Event ID	72139[24]
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 329.315 460.001 460.001.01S 460.002 460.002.01S 460.003 460.003.01S 460.008 460.008.01S 460.009 460.009.01S 460.010 460.010.01S 460.100 460.100.01S 460.107 460.107.01S with Lot Numbers 4146716, 4154144, 4206682, 4206683, 4213557, 4214824, 4216603, 4216604, 4240689, 4240690, 4241741, 4248462, 4249395, 4249396, 4264386, 4278302, 4278304, 4283035, 4283036, 4283037, 4283038, 4283039, 4283040, 4283041, 4285956, 4289103, 4295084, 4295085, 4298044, 4303093, 4326975, 4326979, 4326981, 4329355, 4331263, 4331265, 4331266, 4344659, 4344678, 4378973, 4482201, 4485317, 4488093, 4488094, 4490608, 4490609, 4496716, 4496915, 4496916, 4501971, 4504043, 4508068, 4513458, 4513459, 4513460, 4513461, 4516371, 4519406, 4519407, 4521408, 4525905, 4550062, 4550063, 4550064, 4550065, 4551164, 4551165, 4551166, 4561400, 4561401, 4572176, 4574481, 4580884, 4586704, 4605094, 4661414, 4669482, 4669483, 4675725, 4695343, 4705970, 4723148, 4753792, 4753794, 4777999, 4778000, 4906228, 4906229, 4914498, 4917681, 4934562, 4944809, 4956361, 4956363, 4983255, 4983256, 4983257, 5007806, 5041856, 5041857, 5041858, 5046857, 5046859, 5098159, 5113496, 5113497, 5134868, 5134869, 5143883, 5204105, 5230669, 5234395, 5234396, 5245233, 5245237, 5251710, 5292433, 5308690, 5308733, 5341509, 5370371, 5370375, 5438364, 5452452, 5465222, 5655435, 5667092, 5697537, 5726966, 5726967, 5726968, 5726969, 5726970, 5726971, 5801281, 5801284, 5801285, 5801287, 6036379, 6036381, 6168066, 6188888, 6188890, 6268389, 6268390, 6272370, 6322541, 6364587, 6553805, 6861415, 6983782, 7032568, 7505227, 7640627
Recalling Firm/ Manufacturer	Synthes (USA) Products LLC 1301 Goshen Pkwy West Chester, Pennsylvania 19380-5986
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. " Forward this Field Safety Notification to anyone in your facility that needs to be informed, especially personnel that conduct MR testing. " If the package insert has been forwarded to another facility, contact that facility. " Complete the attached Verification Section (page 3 of this notification). Please include your name, title, address, telephone