Class 2 Recall
InteGrip Acetabular Augment

See Related Information[21]

Date Posted	February 03, 2014
Recall Status[1]	Open
Recall Number	Z-0906-2014
Product Classification	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented[22] - **Product Code** LPH[23]
Product	***REF 186-01-08***InteGrip ACETABULAR AUGMENT***SMALL 8mm. Use with 48/50mm Shell.***EXACTECH, Gainesville, FL 32653-1630. The Exactech Novation InteGrip Acetabular Augments are indicated for use in skeletally mature individuals undergoing primary or revision surgery for hip replacement and whose orthopedic surgeon desires a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.
Code Information	Catalog Numbers: 186-01-08, 186-01-11, 186-01-13, 186-02-08, 186-02-11, 186-02-13, 186-03-11, 186-03-08, 186-03-11, 186-03-13, 186-04-08, 186-04-11, 186-04-13, 186-05-08, 186-05-11, 186-05-13.
Recalling Firm/ Manufacturer	Exactech, Inc. 2320 NW 66th Ct Gainesville, Florida 32653-1630
For Additional Information Contact	Kaya Davis 800-392-2832
Manufacturer Reason for Recall	Exactech is recalling the InteGrip Acetabular Augments due to an out of range condition for an in-vitro biological evaluation standard.
Action	Exactech sent an "Important Product Recall Notice" dated September 11, 2013, to all affected customers. The letter identified the product and the action needed to be taken by the customers. Customers were instructed to cease distribution or use of the products. Extend this information to your accounts that may have this product in their possession. Verify if you have any of the subject InteGrip Acetabular Augments (catalog numbers 186-01-08 to 186-05-13) in the specified lots. Complete and fax back the attached form. Further questions, please call 1-800-392-2832.
Quantity in Commerce	235
Distribution	USA Distribution including the states of : FL, VA, NY, OH, ME, TX, CO, and GA.
Total Product Life Cycle	TPLC Device Report[24]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[25]

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