### Class 2 Recall
**InteGrip Acetabular Augment**

**Date Posted**
February 03, 2014

**Recall Status**
Open

**Recall Number**
Z-0906-2014

**Product Classification**
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Un cemented

**Product**
***REF 180-01-08*** 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, 186-03-08, 186-02-11, 186-02-13, 186-02-13, 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**
Kayla Davis
800-362-2832

**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 1-800-362-2832.

**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

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 875.5524

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pm.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPHA/pma.cfm
12. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfdocs/cfPLC/inspect.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm


2/10/2014