Class 2 Recall Synthes Tibial Nail Wrap Holds 11 Nails and Synthes Intramedullary Nail Wrap Holds 10 Nails

See Related Information 23

Date Posted	August 20, 2015
Recall Status[1]	Open
Recall Number	Z-2425-2015
Recall Event ID	71713[24]
Product Classification	Tray, Surgical, Instrument[25] - **Product Code** FSM[26]
Product	Synthes Tibial Nail Wrap Holds 11 Nails and Synthes Intramedullary Nail Wrap Holds 10 Nails; the Nail Wrap is intended to be used as a protective sheath specifically for Universal Femoral Nails, Universal Tibial Nails, Unreamed Tibial Nail, and the Stainless Steel Tibial Nail during steam sterilization by the hospital.
Code Information	all lots of part numbers: 900.50, 900.51
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 wrap is for single use for nail sterilization but does not have sufficient testing for the device to be considered a multi-use item.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	DePuy Synthes sent an Urgent Notice Medical Device Recall letter dated July 8, 2015, to all affected customers.The letter identified the product the problem and the action needed to be taken by the customer. ACTIONS REQUIRED We have on record that your facility has received the product(s) subject to this recall. DePuy Synthes asks that you review your inventory and immediately remove the affected lots from your stock. Please take the following actions: If you DO have any of the identified devices, please take the following steps: Call DePuy Synthes at 1-800-479-6329 to obtain a Return Authorization (RA) Number. Complete the Verification Section (page 3 of this letter) by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and note the Return Authorization Number. Please include your name, title, address, telephone number and signature in the spaces provided. Return the Verification Section (page 3 of this letter) with the product to Credit/Returns, DePuy Synthes, Send a copy of the completed Verification Section to DePuy Synthes by: Fax: 888-670-4162 or Scan/email: Synthes5485@stericycle.com Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on page 3 of the notification. If you DO NOT have the identified product, please take the following steps: Complete the attached Verification Section (page 3 of this letter) by checking the appropriate box indicating that no affected product has been located. Please include your name, title, address, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device removal information. Return the documents to DePuy Synthes by: Fax: 888-670-4162 or Scan/email: Synthes5485@stericycle.com Note: If the Verification Section is answered on.