Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

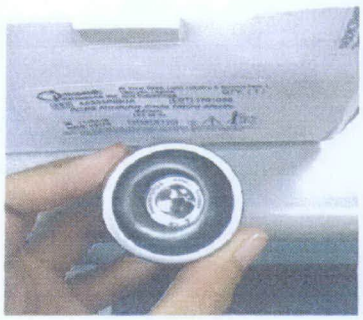
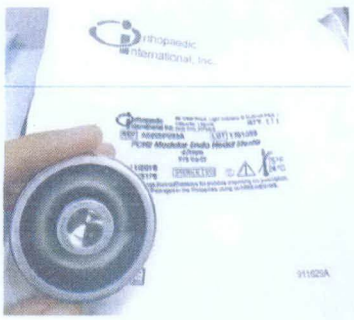
15 OCT 2018

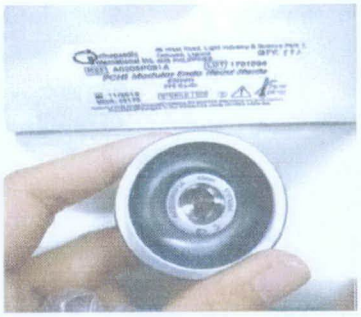
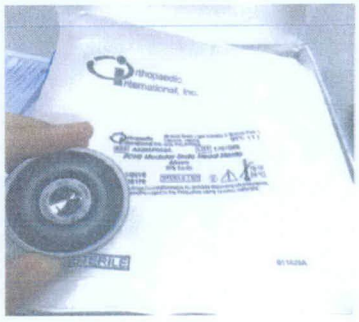
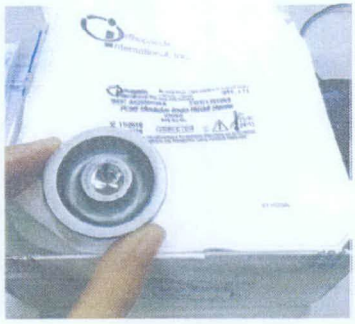
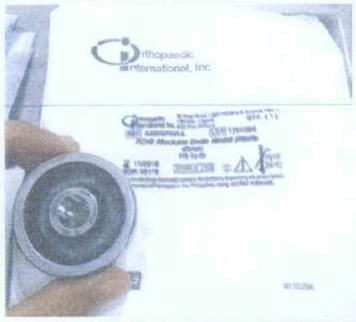
FDA ADVISORY
No. 2018-300

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **PRODUCT RECALL OF PCHS MODULAR ENDO HEAD-STERILE**

All concerned healthcare professionals and establishments are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary product recall of specific QC Numbers of implant PCHS Modular Endo Head – Sterile, MDR No. 05178 (see photos of the product below), manufactured by Orthopaedic International, Inc.

Part Number	Part Description	QC Number	Picture
A0205P090A	PCHS Modular Endo Head-Sterile – 44mm	1707058	
A0205P093A	PCHS Modular Endo Head-Sterile – 47mm	1707059	

Part Number	Part Description	QC Number	Picture
A0205P091A	PCHS Modular Endo Head-Sterile – 45mm	170764	
A0205P092A	PCHS Modular Endo Head-Sterile – 46mm	170765	
A0205P091A	PCHS Modular Endo Head-Sterile – 45mm	170763	
A0205P091A	PCHS Modular Endo Head-Sterile – 45mm	170764	

Orthopaedic International, Inc. claims that it received an incident report that wrong size of the above-mentioned medical device was packed. According to Orthopaedic International, Inc. switch of implants may have been a result of product mix up during batch processes, and that it conducted product recall to ensure that there is no mix up of implants. After a thorough checking of the recalled products, Orthopaedic International, Inc. disclosed that results revealed zero error and showed correct product size in comparison to their packaging, label and marking.

Although there is no mix up of implants, all concerned healthcare professionals and establishments are still advised to be vigilant as the said implants and related products may have mix up/switch during processing and packaging.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

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