

Part Number	Description
11-104211	MLRY-HD LAT POR FMRL 11MM
11-104212	MLRY-HD LAT POR FMRL 12MM
113644	COMP PRIMARY STEM 4MM STD
141314	BIOMET FINNED PRI STEM 40MM
141316	BIOMET FINNED PRI STEM 80X10MM
141318	BIOMET FINNED PRI STM 80X12.5
141320	BIOMET FINNED PRI STEM 80X15MM
163667	32MM MOD HEAD COCR -6MM NECK
163668	32MM MOD HEAD COCR -3MM NECK
163669	32MM MOD HEAD COCR STD NECK
163670	32MM MOD HEAD COCR +3MM NECK
163674	32MM COCR MOD HD +6MM NO SKIRT

Dear Risk/Recall Manager,

This notification is to inform you of an Urgent Medical Device Recall initiated by Biomet Orthopedics ("Biomet") which involves the above listed Part Numbers. See page 2 of the distributor recall notice for specific lot numbers affected.

This implant(s) has been consigned and/or invoiced to your account. Biomet has initiated this action following an investigation which identified that the labels have an incorrect GTIN (Global Trade Identification Number) code.

**There is no possible adverse health outcome expected for the patient as the label condition does not affect the product itself.**

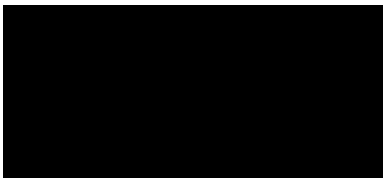
This action requires the immediate location and discontinued use of the product and its return to Biomet.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online: [www.fda.gov/Safety/MedWatch/HowToReport/default.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) (form available to fax or mail), or
- Call FDA (800)FDA-1088

Thank you in advance for your assistance and prompt attention. On behalf of Biomet, I apologize for any inconvenience this may cause. Questions related to this notice should be directed to (574) 372-1570, Monday through Friday, 8 a.m. to 5 p.m.

Sincerely,



Field Action Specialist, Regulatory Compliance

 [@biomet.com](mailto: [REDACTED]@biomet.com)

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