Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 JUN 2017

FDA ADVISORY
No. 2017-186

TO: **THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS**

SUBJECT: **VOLUNTARY RECALL OF COBRA DISTAL RADIUS FIXATOR, WITH DVR-5258**

All are hereby advised by the Food and Drug Administration (FDA) of the Cobra Distal Radius Fixator with FDA Registration Number DVR-5258, distributed by Orthoparedic International, Inc., located at #9 West Road, Light Industry and Science Park 1, 4025 Cabuyao, Laguna.

FDA REGISTRATION NUMBER	DESCRIPTION	QC NUMBER
DVR-5258	Cobra Distal Radius Fixator (Aluminum) - Blue	1601022
		1600770
		1601381
		1500222
		1501365
		1600340
		1601022

The cited medical device was voluntarily recalled by Orthopaedic International, Inc., because of customer reports on the potential defect/malfunction of the device. In the report, the Cobra Distal Radius Fixator failed to lock, due to the detected dimensional size of the device caused by excessive deburring/buffing of the product.

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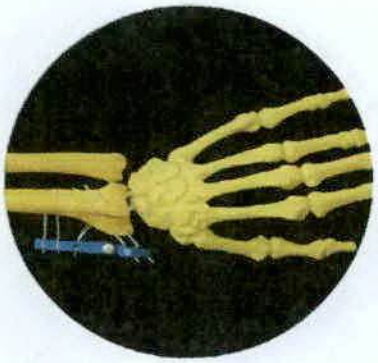
Cobra

Distal Radius External Wrist Fixation System

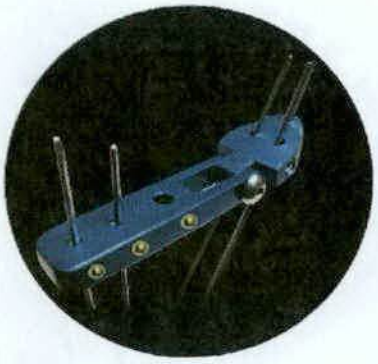
Low profile fixator frame

- For increased patient comfort.



Durable, Compact, One-size fits all

- 7.3 cm long x 6 mm thick aluminum 6-hole frame.

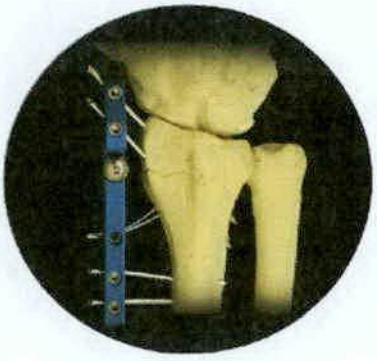


Simple and Easy Technique

- Requires only 15-30 mins of surgical procedure.

Smallest External Wrist Fixation System

- Allows immediate post-operative hand & wrist range of motion.



Radius to Radius Design

- Does not restrict the hand's and wrist's motion at all, while still fully stabilizing distal radius fractures.

Distributors, retailers, and hospitals that have any of the lot of the stated medical device product, are hereby instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots.

Any unexpected adverse events experiences, or any incident of the same causes from the use of the device such as, but not limited to the lots stated above, should be reported to the FDA immediately, at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is hereby requested.

NELA CHARADE G. PUNO, RPh
Director General

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