

*****URGENT MEDICAL DEVICE RECALL*****

Date: May 7, 2018
Attention: Exactech Agents, Representatives, and Distributors in Possession of Affected Products
Product: Optetrak Logic CC Stem Extension, 22mm x 160mm

The purpose of this letter is to inform you that a RECALL is being performed by Exactech for the product in the table below.

Catalog Number	Product Description	Serial Number
02-012-60-2216	Optetrak Logic CC Stem Extension, 22mm x 160mm	5370045

Description of Issue: The Optetrak Logic CC Stem Extension, 22mm x 160mm may potentially have non-conforming internal threads.

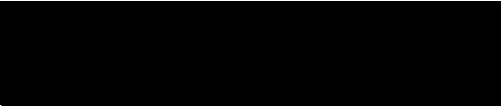
Clinical Impact: The threads may be stripped during assembly, which could potentially result in the threads being unusable and lead to surgical delay. Or, the non-conforming internal threads could reduce the surface area contact and potentially decrease the integrity of the screw to serve as a secondary locking measure for the stem extension.

In order to comply with applicable regulations and Exactech policies:

- Immediately cease distribution or use of this product.
- Extend this information to your accounts that may have this product in their possession.
- Identify and quarantine any of the subject devices in your inventory.
- Complete and return the attached *Recall Acknowledgement Form* and *Recall Inventory Response Form* to Exactech via email at recalls@exac.com.

Please note that we are required by regulation to identify accounts that have received shipment of affected inventory. The domestic and international regulatory authorities may choose to audit certain sites based on their compliance with this action. Our concern is for the health and safety of patients and the users of our products. Actions of this type are collaborative efforts and require your participation to be effective.

Please complete the attached response forms and return them to Exactech within the next 5 business days.



Graham Cuthbert
Sr. Manager, Regulatory Affairs
Post Market Surveillance

A Great Day in the O.R.

RECALL ACKNOWLEDGEMENT FORM

ATTENTION: Courtney Ware, Post Market Surveillance Specialist
EMAIL: recalls@exac.com
REGULATORY ACTION: Urgent Medical Device Recall
DESCRIPTION: Optetrak Logic CC Stem Extension, 22mm x 160mm

By signing below, I acknowledge I have received the notice above and will take any required actions in accordance with the Urgent Medical Device Recall Notice.

Printed Name: _____ **Title:** _____

Agency Name: _____

Agency Address: _____

Telephone: _____

Signature: _____ **Date:** _____

RECALL INVENTORY RESPONSE FORM

Please check the appropriate box and complete as indicated.

I ***do not have any*** of the subject Optetrak Logic CC Stem Extension, 22mm x 160mm (ref: 02-012-60-2216; sn: 5370045) in my inventory.

I ***have one or more*** of the subject Optetrak Logic CC Stem Extension, 22mm x 160mm (ref: 02-012-60-2216; sn: 5370045) in my inventory.

➤ Total Quantity of subject devices I agree to return to Exactech: _____

➤ Serial Numbers of affected devices returning: _____

Date

Agency

Name (Print)

Thank you for your prompt attention to this matter. Once you have returned this Recall Inventory Response Form to recalls@exac.com, you will be contacted by an Exactech representative to arrange for product return and replenishment.