Exactech®
Surgeon focused. Patient driven.™

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*** IMPORTANT NOTIFICATION***

PRODUCT ADVISORY NOTICE

Date: August 5, 2016
Subject Device: Exactech Total Knee Arthroplasty Software Application
Attention: Exactech GPS Users

The purpose of this letter is to inform you that an Advisory Notice is being sent by Exactech on behalf of BlueOrtho for the product in the table below.

Devices Potentially Affected: Exactech Total Knee Arthroplasty Software Application

Product Reference	Device Description
L00002	Total Knee Arthroplasty Software

* All versions of the software application up to the last delivered version 1.15.3

Description of Issue: Please refer to the attached notice from Blue Ortho.

Clinical Impact: Please refer to the Safety Impact stated in the attached notice from Blue Ortho.

In order to comply with applicable regulations and Exactech policies:

- **Extend this information to your accounts that may have this product in their possession.**
- **Inspect any of the subject Total Knee Arthroplasty Software application for the condition described in "Description of the Issue."**
- **Fax back or email the attached form per the Inspection Instructions.**

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 fax back form and return it to Exactech within the next 5 working days.** Thank you for your prompt attention to this matter.

[redacted]

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FIELD ADVISORY FAX NOTICE

Please check the appropriate box and complete as indicated.

☐ I acknowledge receipt of the BlueOrtho advisory notice and I have extended the attached notice to Exactech GPS users.

Date ____________________ Agency ____________________

Name (Print) ____________________ Name (Sign) ____________________

Thank you in advance for your prompt attention to this matter. **According to policy, please contact your Exactech inventory representative <u>within 5 business days</u> to confirm quantities at your location.** If you have any inventory restocking questions related to this issue, please contact Kaya Davis at kaya@exac.com or 1-800-392-2832.

[redacted]

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Addressed to:
Jim Staffiera
Dawn Davisson
Darrell Kassner
Graham Cuthbert
Joe Landry

Advisory Notice

This notice aims to inform you about an issue detected on the Total Knee Arthroplasty software application. By this notice, we communicate the action to undertake if you encounter this situation in your establishment.

Affected Devices:
Only the Total Knee Arthroplasty software application delivered by Blue Ortho is concerned by this issue.
The reference of the application delivered by Blue Ortho is the following:

L00002	**Total Knee Arthroplasty Software**

All the versions of the software application up to the last delivered version 1.15.3 are impacted by this issue [(1)].

[(1)] Following the country where the Total Knee Arthroplasty software application is marketed, all the software versions may not be available.

Description of the Issue
When connecting the Exactech GPS Station V1 or V2 to an external mouse during using the Total Knee Arthroplasty software application, if any button (middle, right or left) of the Air Mouse K10013 or K10014 is maintained pressed, then the touch screen does not function properly and freezes. The Total Knee Arthroplasty software applications do not manage properly such use of the Air Mouse.

When releasing the mouse button, the touch screen works as expected.

The issue was detected during internal manufacturing operations.

Safety Impact
If the air mouse button is maintained pressed unintentionally, this will lead to a freeze of the screen and could force the surgeon to interrupt the navigation and revert to the conventional surgical method. This could conduct to a slight increase the operating time.

Blue Ortho has not received any reports of injuries associated with this issue to date.

The clinical implication (Risk to Health) of the issue has been evaluated as Undesirable risk but Tolerable. No field removal is indicated.

Corrective actions undertaken by Blue Ortho
A software update will be developed to prevent the issue and Blue Ortho will initiate its deployment on the field. The issue will be fixed in the next version of the Total Knee Arthroplasty software application.

Action to be applied by the user

If the issue occurs and is detected, the surgeon or the surgical staff using the mouse shall release the mouse button or remove the dongle connected to the Exactech GPS Station. Freeze of the screen should stop.

To improve the user experience, Blue Ortho will deliver a new software version correcting this issue. As there is no safety impact for the final user or the patient, it is at the discretion of the distributor to determine and execute the most appropriate field action.

NB: Transmission of this Advisory Notice:

- This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which this action has an impact.
- Please maintain awareness on this notice.