

# ***Affluent Healthcare Sdn Bhd***

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REF: MDR2021-01

27<sup>th</sup> September 2021

## **URGENT: MEDICAL DEVICE RECALL**

### ***Exactech Knee Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts labeled with an 8-year shelf life***

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Exactech Inc (manufacturer) is voluntarily recalling all Exactech Knee and Ultra-High Molecular Weight Polyethylene(UHMWPE) inserts labeled with an 8-year shelf life in the Optetrak Hi-Flex Knee System, Optetrak Logic Posterior Stabilized (PS) System and Optetrak Knee System – CR.

#### **Reason for Recall:**

These inserts were packaged in vacuum bags that did contain a nylon barrier, which does substantially limit oxygen transmission, but did not contain an additional oxygen barrier layer consisting of Ethylene Vinyl Alcohol (EVOH) as specified on the packaging drawing.

Use of vacuum bags without an EVOH layer may result in elevated transmission of oxygen to the UHMWPE insert packaged therein which can potentially result in increased oxidation of the material relative to inserts packaged with EVOH over time.

As a result of extensive packaging material and UHMWPE insert testing by Exactech, data indicate that product within scope of this recall still performs as intended if implanted within 5 years of manufacture.

As of August 5, 2021, all products manufactured by Exactech are being packaged in EVOH vacuum bags to ensure adequate oxygen barrier properties and protection from oxidation of polyethylene inserts throughout the 8-year shelf life.

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## **Clinical Impact:**

Exposure to oxygen over time can allow oxidation of the UHMWPE implant leading to a reduction of mechanical properties, which may ultimately require revision of the implant (UHMWPE Component); however, Exactech's testing and risk assessment confirms that the Nylon bags without the EVOH oxygen barrier properties perform similarly to Nylon bags with the EVOH oxygen barrier through 5 years of shelf life.

## **Actions to be taken by the customer/user:**

There is no action required by the customer/user as all affected items are quarantined by the local distributor, Affluent Healthcare Sdn Bhd.

## **Product Recall List :**

*Refer to Attachment 1: Table of Device*

## **Actions taken by Exactech:**

Exactech will be removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months, per the strategy outlined in Table 1 below. At this time, only UHMWPE products labeled with an 8-year shelf life are affected. There are no other Exactech UHMWPE products impacted by this recall (e.g. those products already labeled with a 5-year shelf life).

**Table 1: 12-Month Recall Strategy**

Phase I:	Immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags (See Attachment 1 - Phase I Product List).
Phase II:	Between 05/31/2022 to 08/31/2022 recall all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags (A new Recall Notification and Phase II Product Scope will be provided at the beginning of Phase II).

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## **Other information:**

Should you require further information, please do not hesitate to contact:

Mr Ng Tiong Fatt

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Enclosed with this letter you will find:

- 1.) **Attachment 1: Table of Device** Details which contains list of affected products
- 2.) **Acknowledgement and Receipt Form** which is required to be sign and return to company

Authorised by:

Ng Tiong Fatt

Sales Director

Date: