Australian Government

Department of Health
Therapeutic Goods Administration

Glenn Street
Exactech Australia Pty Ltd
5/13 Hoyle Avenue, Castle Hill
NSW 2154 Australia

By Email: glenn@gsenterprises.com.au

3/11/2021

Our Ref: RC-2021-RN-01874-1
Your Ref: N/A

Dear Glenn,

Subject: Knee and ankle inserts packaged in out of specification vacuum bags

Ultra-High Molecular Weight Polyethylene Liners

ARTGs: 277743, 285503, 285502, 285911, 285907, 285442 and 308700

Cancelled ARTGs: 277745, 278343, 286119 and 285677

Thank you for your notification of the above-mentioned subject.

Pursuant to the current URPTG, this recall action has been classified as per the below summary:

Hazard Classification:	**Class II**
Type of Recall:	**Hazard Alert**
Recall Level:	**Hospital**
Reason for Recall:	**After extensive testing, Exactech have recently confirmed that most of Exactech inserts manufactured since 2008 were packaged in out-of specification vacuum bags that are oxygen resistant but do not contain a secondary barrier layer that further augments oxygen resistance. The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. For inserts with greater than five years of shelf life, increased oxidation of the inserts can lead to premature polyethylene wear resulting in a revision surgery.**

Product Distribution:	**TBC**
Customer Actions:	**For surgeons, Exactech is recommending the following actions** **1. For patients who have been implanted with polyethylene devices in non-conforming bags that were greater than five years old at the time of implantation and who have not been seen in over 12 months, we recommend a return to the office/clinic for a routine clinical exam and a routine set of knee x-rays to identify premature polyethylene wear (standing AP, lateral, and sunrise views).** **2. For patients who exhibit abnormal wear the surgeon could consider revision to a new Exactech knee insert.** **For customers including agency, distributors and/or healthcare facilities, Exactech is suggesting the following actions:** **1. Inspect inventory and quarantine any affected stock with an expiry date prior to 31 August 2025 and return to Exactech** **2. All remaining knee and ankle UHMWPE devices labelled with an 8-year shelf life not packaged in EVOH/Nylon bags will be relabelled with a 5-year shelf life from the date of manufacture**

Proposed recall action correspondence:

- The strategy for this recall action is acceptable; and
- The text of the Customer Letter and Acknowledgement Form **is acceptable following implementation of the tracked changes in the attached document(s), after-which they** may be sent immediately.

The above information will be notified to the various state and territory recall coordinators for therapeutic goods. Additionally, this information will be published in the public domain via the TGAs searchable database, System for Australian Recall Actions (SARA). If you would prefer the recall summary information, which will be publicly available, to include different contact details to that included in your customer letter, please advise us within the next 24 hours.

Both the recall notification and SARA publication will occur on the second working day following the date of this agreement letter.

Please note:
1. **Addressing of Recall Letters** - Recall correspondence is to be addressed in accordance with pages 49-50 of the 2019 URPTG. A sample is given of page 56. In particular, where hospitals are involved, letters should be addressed to the "Chief Pharmacist" for medicines and to the "Chief Executive Officer" for device recalls. More targeted letters are acceptable on a case-by-case basis.

2. Dispatch of Recall Letters – Recall Action letters are required to be dispatched to affected customers within 2 clear working days of receiving this agreement letter. Recall envelopes as described on page 54 of the URPTG must be used where mail distribution is the chosen method of communication. It is also acceptable to dispatch this notification electronically (facsimile or email) subject to the ability to confirm receipt. If the Recall Action letter is dispatched via email, the subject line must reflect the appropriate title of the letter submitted, e.g. URGENT MEDICINE RECALL/URGENT PRODUCT DEFECT CORRECTION, followed by the name of the affected product.

Please advise the TGA if you are not able to initiate this Recall Action within 2 working days.

3. **Recall Actions for Consumer Goods that are also Therapeutic Goods** – When a therapeutic good is also a consumer good, regardless of the level of action, the person carrying out the recall is required under the *Competition and Consumer Act 2010* (Schedule 2, Section 128 *'Notification requirements for a voluntary recall of consumer goods'*) to provide the Minister for Consumer Safety, written notification within 2 days after commencing the Recall Action. This can be done via the instructions outlined in Attachment 1 which also contains the URPTG definition of a Consumer Therapeutic Good.

4. Progress Reporting Requirements - In accordance with the responsibilities of sponsors (Step 10) in the URPTG, there is a requirement to submit a total of **three reports on the progress of the Recall Action as per the dates given in the table below. Typically these are at two weeks, six weeks and a 12 week close out report after the date of this correspondence**. An alternate timeframe or additional reports may be agreed on a case-by-case basis. Templates are given in Attachment 2 and this represents the minimum information expected, alternatively a suitable email will suffice. In the event all actions are completed prior to the specified dates given below, the report may be submitted earlier.

Report type:	**2 week**	**6 week**	**Close out**
Latest Due Date:	**17/11/2021**	**15/12/2021**	**03/02/2022**

5. TBS Update – As part of conducting this recall action, Sponsors are requested to verify that the relevant staff contact details given in the TBS Portal are up to date as per the guidance given in this link: https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators

Should you require any additional advice or further assistance with this recall, do not hesitate to contact me directly.

Yours sincerely,

Isabella De Sousa
Recalls Section
Manufacturing Quality Branch

Phone: 02 6289 4613
Email: recalls@health.gov.au

(Signed electronically)

Attachment 1:

NOTIFICATION OF A CONSUMER GOOD RECALL ACTION TO THE ACCC

Pursuant to subsection (7) of Section 128 of the *Competition and Consumer Act 2010.*

As per page 76 of the *2019 Uniform Recall Procedure for Therapeutic Goods* (URPTG), this recall action is to be reported to the ACCC, if the product involved is a *therapeutic good* and also a *consumer good.*

The definition of consumer goods from the Australian Consumer Law is "… *goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption…"*

To make a report to the ACCC for a recall of a good that is both a therapeutic good and a consumer good, complete and submit the webform on the ACCC website by clicking on the link below:
https://www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall

General information regarding ACCC recalls may be obtained here:
https://www.productsafety.gov.au/recalls/guidance-for-suppliers/conducting-a-recall

Should you need further assistance in determining whether or not your *therapeutic good* is also a *consumer good*, please contact the ACCC directly by:

- Emailing the ACCC Recalls inbox Recalls@accc.gov.au

or

- Phoning the ACCC Recalls Hotline on: (02) 6243 1262

In the event you have doubt as to the status of your product in view of the above, **please do not report this action to the ACCC** unless the above determination has clearly been made and the product fits the definition of a *consumer good.*

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Attachment 2: Reporting Requirements

Reports should be submitted electronically to the Recalls Section via recalls@health.gov.au

Please include the relevant TGA Recall reference number in the email subject line – e.g. RC-XXXX-RN-XXXXX-X

2 WEEK REPORT REQUIREMENTS:

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. e.g. the approved letter has been dispatched to all the customers previously provided to the TGA.	**[ ] YES**	**[ ] NO.** Please explain:
2. Has a signed copy of the customer letter been provided to TGA Recalls?	**[ ] YES**	**[ ] NO.** Please ensure a signed copy of the letter is provided.
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain:
4. Have the initial investigation findings changed the scope of the recall/correction e.g. Additional units or products have not been identified with the same defect	**[ ] NO**	**[ ] YES.** Please advise:
5. For any product exported from Australia, have the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia. Please list countries product has been exported to.	**[ ] YES** **[ ] No exports**	**[ ] NO.** Please explain:

6 WEEK REPORTING REQUIREMENTS:

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% And; <u>Detail attempts made to contact non-responding customers:</u>
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[ ] YES** **[ ] No goods left to recall or correct.**	**[ ] NO.** Please advise when this is expected to occur:
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please detail:

3 MONTH CLOSE OUT REPORTING REQUIREMENTS (or by the previously agreed time):

1. (a) Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?*; or **1. (b) Correction - Have ALL units been corrected or have ALL customers been supplied with the correction?** ***A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.**	**[ ] YES**	**[ ] NO.** Please explain & advise when this is expected to occur: Please provide a list of non-responding customers:
2. What was the root cause of the defect that led to the recall/corrective action?	Please detail:	
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	Please detail:	
4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% And; Detail attempts made to contact remaining customers