URGENT MEDICAL DEVICE RECALL

21 August 2019

Product Field Action Number:	2144473
Description:	TRIATHLON FEMORAL DISTAL AUGMENT 10MM - SIZE 2 LEFT TRIATHLON FEMORAL DISTAL AUGMENT 10MM - SIZE 2 RIGHT TRIATHLON FEMORAL DISTAL AUGMENT 15MM - SIZE 2 LEFT TRIATHLON FEMORAL DISTAL AUGMENT 15MM - SIZE 2 RIGHT
Affected Catalog Number(s):	5541-A-201 5541-A-202 5542-A-201 5542-A-202
Affected Lot(s):	Affected LOTS shipped to Singapore: 5541-A-201 – LOT: AEB7H, AYX3Y, AVG7Z & SSVR 5541-A-202 – LOT: ASV7B, AO74U, BAB7Y & TPTI 5542-A-201 – LOT: AAG7R, AOG3T, BAE4X & A7H4U 5542-A-202 – LOT: AOG7L, A7O3V & AGT3G
Expiration Date on Product:	All lots with an expiration date on or before 31 June 2024.

Dear Customer,
cc: Chairman Medical Board and relevant Head of Departments

Stryker has initiated a voluntary, lot-specific recall for the Triathlon Femoral Distal Augment, 10 mm – Size 2 Left, Triathlon Distal Augment 10 mm – Size 2 Right, Triathlon Femoral Distal Augment 15 mm – Size 2 Left and Triathlon Distal Augment 15 mm – Size 2 Right. The intent of this letter is to list known hazards and harms potentially associated with the above referenced products and list any risk mitigation factors.

Issue:

Stryker has discovered that the above-mentioned Triathlon Femoral Distal Augments (10 and 15 mm, Size 2, Left and Right) protrude beyond the medial periphery of the mating femoral component.

Triathlon Femoral Distal Augments are used with the Triathlon TS Femoral Component during a Total Knee Arthroplasty (TKA) Revision procedure or with a Triathlon Primary PS Femoral Component during a TKA procedure.

Potential Hazards:

If a Triathlon Femoral Distal Augment Size 2, 10 or 15 MM is used with the Triathlon TS Femoral Component during a Total Knee Arthroplasty (TKA) Revision procedure or with a Triathlon Primary PS Femoral Component during a TKA procedure, the following potential hazards may occur:

- The distal augment overhang could potentially result in the exposed edge contacting the soft tissue surrounding the medial condyle
- Metallic debris in wound
- Sharp/abrasive corner of the overhanging distal augment

Potential Harms:

The aforementioned hazards may result in the following potential harm(s):

- Complications associated with extended surgery time of 20 minutes while retrieving a replacement Distal Augment.
- Metal debris in wound may cause local inflammation or synovitis.
- Tissue damage
- Pain requiring revision surgery

Risk Mitigation:

1. Medial overhang of the Triathlon Femoral Distal Augment Size 2, 10 or 15 MM should be obvious to the surgeon during assembly to its mating femoral component, potentially reducing the probability of implanting the device.
2. Larger bone on medial side of the femur may prevent the Triathlon Femoral Distal Augment Size 2, 10 or 15 MM from overhang past resected bone.

Actions Needed:

1. Please inform users of this Urgent Medical Device Recall and forward this notice to all those individuals who need to be aware within your organization.
2. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. A response is required, even though you may not have any physical inventory on site anymore.
3. Quarantine and discontinue use of the recalled devices.
4. Hospitals/Branches/Agencies: Complete and sign the enclosed Urgent Medical Device Recall Business Reply Form and email a copy to asean.pms@stryker.com
5. Hospitals/Branches/Agencies: Return all affected instruments available at your location to your Stryker representative.

Reporting of Adverse Events

Please report any adverse events or product quality problems associated with this device to Stryker. Healthcare Professionals may also report any suspected adverse events associated with these devices to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to Stryker will be investigated and subsequently reported to HSA.

Our records indicate that you have received the above referenced device(s). It is our responsibility to ensure that customers who may have received this affected device also receive this important communication.

Please assist us in meeting our regulatory obligation by faxing back the attached Urgent Medical Device Recall Business Reply Form within 5 days.

We regret any inconvenience this action may cause you.
If you have any questions regarding the return of product, product replacement, or credit eligibility, **please contact your local Sales Office or Stryker Sales Representative for assistance.**

Sincerely,

[redacted]

Chia Nee Lim
Senior QA Specialist
Stryker ASEAN
[redacted]
ASEAN.PMS@stryker.com
Telephone: +65 66625905

URGENT MEDICAL DEVICE RECALL
BUSINESS REPLY FORM

21 August 2019

Product Field Action Number:	2144473
Description (Catalog #):	TRIATHLON FEMORAL DISTAL AUGMENT 10MM - SIZE 2 LEFT TRIATHLON FEMORAL DISTAL AUGMENT 10MM - SIZE 2 RIGHT TRIATHLON FEMORAL DISTAL AUGMENT 15MM - SIZE 2 LEFT TRIATHLON FEMORAL DISTAL AUGMENT 15MM - SIZE 2 RIGHT
Affected Catalog Number(s):	5541-A-201 5541-A-202 5542-A-201 5542-A-202
Affected Lot(s):	Affected LOTS shipped to Singapore: 5541-A-201 – LOT: AEB7H, AYX3Y, AVG7Z & SSVR 5541-A-202 – LOT: ASV7B, AO74U, BAB7Y & TPTI 5542-A-201 – LOT: AAG7R, AOG3T, BAE4X & A7H4U 5542-A-202 – LOT: AOG7L, A7O3V & AGT3G
Expiration Date on Product:	All lots with an expiration date on or before 31 June 2024.

I have received the Urgent Medical Device Recall letter from Stryker dated 21 August 2019 providing information on the voluntary, lot-specific recall of the above referenced devices.

_____ _____

Hospital or Stryker Branch Name Date

_____

Hospital/Agent/Risk Rep or Stryker Branch Rep
(Signature)

Please complete this form within 5 business days and return it via email to ASEAN.PMS@stryker.com or hand to your Stryker product representative.