URGENT MEDICAL DEVICE RECALL

28 Aug 2019

Product Field Action #: 2171099

Product Description	Item Number	Lot Number	Quantity Affected
TRIATHLON CR FEM COMP #2 R-CEM	5510F202	EX72D	1
TRIATHLON CR FEM COMP #4 R-CEM	5510F402	HBJ3C	1
TRIATHLON CR FEM COMP #6 R-CEM	5510F602	ETE4J	1
TRIATHLON CR FEM COMP #8 R-CEM	5510F802	ARP6H	1
TRIATHLON PRIM CEM FXD BPLT #2	5520B200	HBJ6H	1
TRIATHLON PRIM TIB BASEPLATE – CEMENTED	5520B300	HA94L	1
X3 TRIATHLON CS INSERT #6 9MM	5531G609	LJB408	1
TRIATHLON CR FEM COMP #3 R-CEM	5510F302	E4L4R	1
TRIATHLON CR FEM COMP #5 R-CEM	5510F502	HAH9T	1
TRIATHLON CR FEM COMP #7 R-CEM	5510F702	E9B6L	1
TRIATHLON PRIM TIB BASEPLATE - CEMENTED	5520B400	E7T3S	1
TRIATHLON PRIM TIB BASEPLATE - CEMENTED	5520B600	E9N9T	1
X3 TRIATHLON CS INS SIZE 4 9MM	5531G409	LHT539	1
X3 TRIATHLON CS INSERT #6 11MM	5531G611	LJA438	1
X3 TRIATHLON CS INSERT #6 13MM	5531G613	LFT791	1
TRIATHLON ASYMMETRIC X3 PATELLA	5551G299	MK57	1
TRIATHLON ASYMMETRIC X3 PATELLA	5551G381	8EJ6	1

Dear Customer,

cc: Chairman Medical Board and relevant Head of Departments

Stryker has initiated an urgent, voluntary, lot-specific recall for the above referenced product. The intent of this letter is to list known hazards or harms potentially associated with the aforementioned product and list any risk mitigation factors.

Issue

Stryker has discovered that the packaging of specific units within the above-referenced product list potentially came into contact with water and/or steam. The scope of this issue is limited to specific units within each lot listed. Stryker has accounted for the product involved in the issue.

Potential Hazards/Harms

Technical and medical assessments are currently underway to determine any potential hazards associated with the use of the product. Additional communication will be forwarded upon completion of the internal investigation on this issue.

Risk Mitigation

There are no mitigation factors associated with the use of these products.

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. Hospitals/Branches/Agencies: Complete and sign the enclosed Urgent Medical Device Recall Business Reply Form and fax a copy to +65 6272 2464 email a copy to asean.pms@stryker.com

3. Hospitals Only: Please contact your Local Sales Office or your Stryker Sales Representative directly for product returns and inventory questions.

4. Branches/Agencies Only: Return all affected product available at your location to the following address:

   Stryker Orthopaedics/PFA Product Returns
   Attn: Distribution Inventory Team
   325 Corporate Drive
   Dock M-East
   Mahwah, NJ 07430
   Ref. PFA 2171099

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

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

We regret any inconvenience that this may have caused.
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
NOTIFICATION BUSINESS REPLY FORM

28 Aug 2019

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I have received the Urgent Medical Device Recall Notification from Stryker dated 28 Aug 2019 stating that it has initiated a voluntary, lot-specific recall for the above referenced product.

_____ _____

Hospital/Branch/Agency Representative (Signature) Date

_____

Hospital/Branch/Agency Representative (Print)

_____

Name of Hospital/Branch/Agency

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL OR FAX LISTED BELOW:

Fax: +65 6272 2464

Email: asean.pms@stryker.com