stryker

URGENT
PRODUCT RECALL

January 31, 2018

Product Field Action Number: 1719393
Description: Triathlon TS Augments Sizes 3 and 6
Affected Catalog Number(s): 5545-A-301, 5546-A-601
Affected Lot Number(s): ER9WA1A, ER9WA1D, ER9WA1E, ER9MA5A

Dear Customer,

Stryker Orthopaedics ("Stryker") has initiated a voluntary, lot-specific recall for the Stryker knee components referenced above. The intent of this letter is to list known hazards potentially associated with the use of the implant and list any risk mitigation factors.

Issue:

Stryker has discovered that the product/lot combinations referenced above may contain the incorrect size implant from what is labeled on the box.

Potential Hazards:

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:

The Triathlon TS augments are laser marked with lot and catalog number. Although the product packaging for these four lots may not match the product contained within, the laser marked details on the implant would increase the likelihood that the surgeon or surgical staff would recognize that the incorrect implant was contained in the package.

The Size 3 and 6 Augments are also visibly different in size. The Augment implant can be compared to the corresponding size Augment trial (P/N: 5545-T-301 and 5546–T-601) which would alert a user to a size mismatch.

Actions Needed

1. Hospitals/Branches/Agencies: Complete and sign the attached Recall Notification Business Reply Form and fax a copy to 1-888-266-7908 or email to strykerortho6182@stericycle.com

2. Hospitals: Please inform users of this Urgent Product Recall and forward this notice to all those individuals who need to be aware within your organization.

3. Branches/Agencies: Return all affected products from your inventory locations to the following address.

Stryker Orthopaedics/PFA Product Returns
Attn: Distribution Inventory Team
325 Corporate Drive
Dock M-East
Mahwah, NJ 07431
Ref. PFA 1719393

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

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

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at (201) 831-6693.

Sincerely,

[redacted]

Eric Petschler
Manager, Divisional Regulatory Compliance

STRYKER ORTHOPAEDICS
URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM

January 31, 2018

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Affected Lot Number(s): ER9WA1A, ER9WA1D, ER9WA1E, ER9MA5A

I have received the product recall letter from Stryker Orthopaedics dated January 31, 2018 stating that the company has initiated a voluntary, lot-specific recall of the above referenced implant.

We have not located any of these devices in our inventory: *(please delete if not applicable)*				
We have located the following devices (*please include additional lines as necessary*)**:**				
Product	**Product Reference**	**Lot Number(s)**	**Qty**	**Qty Quarantined**
5545-A-301	TRI LM/RL TIB AUG SZ3 5MM	ER9WA1A		
5545-A-301	TRI LM/RL TIB AUG SZ3 5MM	ER9WA1D		
5545-A-301	TRI LM/RL TIB AUG SZ3 5MM	ER9WA1E		
5546-A-601	TRI LM/RL TIB AUG SZ6 10MM	ER9MA5A		

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 BY USING THE EMAIL OR FAX LISTED BELOW:

Email: strykerortho6182@stericycle.com

Fax: 1-888-266-7908