

**URGENT  
PRODUCT RECALL  
UPDATE**

April 02, 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,

On January 31, 2018, Stryker Orthopaedics (“Stryker”) initiated a voluntary, lot-specific urgent recall for the Stryker knee components referenced above. Stryker has completed the technical and medical assessments and is providing this updated communication to list all known hazards potentially associated with the use of the referenced products 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:

Mislabeled device – A device packaged and labeled as a Size 6, 10mm Triathlon Augment may actually contain a Size 3, 5mm Triathlon Augment

Mislabeled device – A device packaged and labeled as a Size 3, 5mm Triathlon Augment may actually contain a Size 6, 10mm Triathlon Augment

Potential Harms:

There have been no potential harms identified due to the aforementioned potential hazard.

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](mailto: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,

Eric Petschler  
Manager, Divisional Regulatory Compliance

**STRYKER ORTHOPAEDICS  
URGENT PRODUCT RECALL  
UPDATE  
NOTIFICATION BUSINESS REPLY FORM**

April 02, 2018

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

I have received the product recall letter from Stryker Orthopaedics dated April 02, 2018 stating that the company has initiated a voluntary, lot-specific recall of the above referenced implant.

<b>We have not located any of these devices in our inventory:</b> <i>(please delete if not applicable)</i>				
<b>We have located the following devices</b> <i>(please include additional lines as necessary):</i>				
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](mailto:strykerortho6182@stericycle.com)

Fax: 1-888-266-7908

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PRODUCT RECALL  
UPDATE**

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Actions Needed

1. Hospitals/Branches/Agencies: Complete and sign the attached Recall Notification Business Reply Form and fax a copy to 1-888-266-7933 or email to [strykerortho6182@stericycle.com](mailto:strykerortho6182@stericycle.com)
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Sincerely,

  
Eric Petchler  
Manager, Divisional Regulatory Compliance

**STRYKER ORTHOPAEDICS  
URGENT MEDICAL DEVICE RECALL  
UPDATE  
NOTIFICATION BUSINESS REPLY FORM**

April 02, 2018

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**We have located the following devices (please include additional lines as necessary):**

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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)

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Email: [strykerortho6182@stericycle.com](mailto:strykerortho6182@stericycle.com)

Fax: 1-888-266-7708