URGENT MEDICAL DEVICE RECALL

November 07, 2019

Product Field Action #: 2147264
Description: Crossfire 10 Degree Acetabular Insert
Affected Catalog Number: 2041C-3254
Affected Lot Number: 53778501

Dear Customer,

Stryker has initiated a 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 Crossfire 10 Degree Acetabular Insert (Part # 2041C-3254, Lot # 53778501) may have a missing locking wire in certain units within the above referenced lot. The Crossfire 10 Degree Acetabular Insert can be assembled with certain acetabular shells to provide a bearing surface for articulation with the femoral heads during Total Hip Arthroplasty. The locking wire functions as the locking mechanism between the insert and the cup.

Potential Hazards

In the event that during a Total Hip Arthroplasty, packaging is opened to reveal a Crossfire 10 Degree Acetabular Insert that is missing a locking wire, the following Hazards could occur:

- Delay in surgery while retrieving a back-up device.
- Implantation of a device that is missing a locking wire.

Potential Harms

The aforementioned hazards may result in the following potential harms:

1. Complications associated with extended surgery time of (time?) while a back-up device is retrieved.
2. Hip dislocation.
3. Revision surgery.

Risk Mitigation

1. Risk may be mitigated by performing a visual inspection of the Acetabular Insert during pre-surgery setup to see if the locking wire is present. As this defect should be easily identified by the user. If the defect is identified, the insert can be replaced prior to surgery.

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 fax a copy to **1-888-350-3903** or email to **StrykerOrtho6467@stericycle.com** within 5 Days.
5. **Hospitals Only:** Return all affected product available at your location to your local branch office.
6. Branches/Agencies: Return all affected product returned by the hospital and/or 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
   PFA #2147264

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. Should you have any queries concerning this matter please do not hesitate to contact the undersigned.

Sincerely,

Ommeed Shahrokh
Sr. Manager, Regulatory Compliance
Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM

November 07, 2019

Product Field Action #: 2147264
Description: Crossfire 10 Degree Acetabular Insert
Affected Catalog Number: 2041C-3254
Affected Lot Number: 53778501

I have received the Urgent Medical Device Recall Notification from Stryker dated November 07, 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: 1-888-350-3903

Email: StrykerOrtho6467@stericycle.com