URGENT FIELD SAFETY NOTICE (Version 1)

October 17, 2019

To:	Surgeons, Hospital Risk Managers
FSCA Number:	2173330
Description:	**STAR Total Ankle Replacement Non-Foil Packed Mobile Bearing Components**
Catalog Number(s):	400-140, 400-141, 400-142, 400-143, 400-144, 99-0028/11, 99-0028/12, 99-0028/13, 99-0028/14
Legal Manufacturer:	Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland
Lot Code(s):	All

Dear Surgeons, Hospital Risk Managers,

Stryker would like to inform you of an important Safety Communication related to the products referenced above and described in further detail in the table below (the "Products"). Our records indicate that you have received one or more of the Products.

Background

Stryker has become aware of data indicating that patients implanted with the STAR Total Ankle Replacement distributed prior to August 1, 2014 may experience a higher than expected risk of polyethylene fracture due to potential increase in polyethylene oxidation prior to or after implantation and potentially the implant geometry (as reported in published literature). Additional factors that may have contributed to these polyethylene fractures are component malalignment, surgeon learning curve, and reduced insert thickness. This safety communication is based on identifying a 13.79% polyethylene fracture rate at eight-year follow-up in the STAR Total Ankle Replacement Post-Approval Study (PAS), and over 100 polyethylene fractures reported in the FDA MDR (Medical Device Reporting) database, both of which occurred substantially more often than with comparable total ankle replacement and with fixed bearing total ankle replacements. At this time, the polyethylene component of the STAR Total Ankle Replacement manufactured and distributed subsequent to August 1, 2014 is not subject to this communication. The following table lists the specific Products that are within scope of this communication. The final non-foil packed STAR polyethylene components were produced on July 10, 2014, with a shelf-life of 5 years. These components expired on July 10, 2019.

Catalog Number*	Product Description
400-140	Sliding Core UHMPWE, 6mm
400-141	Sliding Core UHMPWE, 7mm
400-142	Sliding Core UHMPWE, 8mm
400-143	Sliding Core UHMPWE, 9mm
400-144	Sliding Core UHMPWE, 10mm
99-0028/11	Sliding Core, UHMPWE 11mm REVISION
99-0028/12	Sliding Core, UHMPWE 12mm REVISION
99-0028/13	Sliding Core, UHMPWE 13mm REVISION
99-0028/14	Sliding Core, UHMPWE 14mm REVISION

*Note: If a *specific* (but similar) catalog number does not appear above (*e.g.* 400-140**F**), it is not subject to this communication.

Potential risks associated with polyethylene mobile bearing fracture may include:

- Significant pain, newly developed and/ or persistent for a significant time
- Inflammatory response, newly developed and/ or persistent for a significant time
- Soft tissue injury e.g. blistering
- Loss of mobility in the operated ankle
- Possible damage to the metal components of the ankle after the polyethylene fractures, requiring revision of the entire total ankle replacement

These potential risks, which are associated with a broken mobile bearing, can be the risks for which revision surgery might be necessary.

Follow-up

Surgeons should closely monitor patients implanted with the Products for follow-up. The surgeon needs to be aware that the clinical presentation of polyethylene fracture can be subtle, and that two (2) subjects in the STAR Total Ankle Replacement PAS had a fractured implant diagnosed only at exploratory surgery. Ambulation on the TAR (Total Ankle Replacement) after polyethylene fracture can damage the metal components of the total ankle replacement, requiring revision of the entire TAR. During such follow-up, if the integrity of the product is in question, x-rays are required. As the changes on x-ray can be subtle, any clinical uncertainty regarding whether polyethylene fracture have occurred may be ruled out with a computerized tomography (CT) scan.

Required actions

1. Hospital Risk Managers/Surgeons: Please inform users of this communication and forward this notice to all those individuals who need to be aware within your organization. Please also complete and sign the enclosed customer response form (acknowledgement form) and fax a copy to fax no _ _ _ _ _ _ _ _ _ _ or email to XXXXX@stryker.com. This form must be returned even if you do not have affected products at your facility. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation. Product is not required to be returned as part of this communication.
    - Please provide your own communication or forward a copy of this notice directly to all potentially impacted patients.
    - Patients: Be aware that fracture of the plastic (polyethylene) part of your total ankle can be subtle. You do not need to have sustained a significant injury to have the polyethylene part of your ankle replacement fail. The following symptoms may indicate that this complication has occurred:
        - increased pain
        - inability to bear weight
        - new onset grinding or other noise (crepitation) in your operated ankle
        - worsening instability in your replaced ankle

    If you have experienced any of the above symptoms, please contact your physician. Your physician will perform a detailed examination of your operated ankle and obtain x-rays to evaluate your ankle replacement. In some cases, special studies such as computerized tomography (CT) scanning may be necessary to confirm that the polyethylene in your ankle is not broken.

Please assist us in meeting our regulatory obligation by faxing back the attached Business Reply Form within 7 calendar days of receipt of this letter.

Other Information

We confirm that the competent national authorities in your country have been informed of this safety corrective action in accordance with regulatory requirement in your country.

Your personal contact in this matter is listed below. If you have any questions regarding this measure, please contact your contact person directly.

Name: ……. Position: ……..
E-mail: …… Phone: …….

On behalf of Stryker we would like to thank you for your help and support in the timely implementation of this measure and ask for your understanding. We would like to assure you that Stryker will do its utmost to ensure that only products that meet our strict internal quality criteria are on the market.

Yours sincerely

Stryker Entity

Name

Title

Country

AKNOWLEDGEMENT FORM (FSCA)

FSCA-ID: RA2019-2173330
Type of measure: **Product Safety Communication**

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Customer no. _____

Hospital _____

Postcode, City _____

Contact person (name, position) _____

Phone no. _____

☐ Hereby we confirm the notification of Stryker Trauma about a Product safety information for above mentioned products.

We sold the products to the following institution:

Name: _____ Address: _____

Contact person: _____ Tel.-No.: _____

_____

Date / legal signature of a person of the medical institution