



## SAFETY COMMUNICATION

October 11, 2019

To: Surgeons, Hospital Risk Managers, and Patients  
Product Field Action 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  
Lot Code(s): See attached

Dear Surgeons, Hospital Risk Managers, and Patients:

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 (Affected Product: See Attachment 1 – Lot Codes Subject to PFA # TBA). 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. 400-140F), 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 Business Reply Form and fax a copy to 866-534-9993 or email to Stericycle at [strykerortho6463@stericycle.com](mailto:strykerortho6463@stericycle.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.
2. **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 plastic part of your ankle replacement fail. The following symptoms may indicate that this complication has occurred:
  - a. increased pain
  - b. inability to bear weight
  - c. new onset grinding or other noise (crepitation) in your operated ankle
  - d. 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 plastic in your ankle is not broken.

**Please assist us in meeting our regulatory obligation by faxing back the attached Business Reply Form within 5 days of receipt of this letter.**

For patient questions, Stryker has established a dedicated call center at 1-978-274-7633.

### **Other Information**

This medical device safety communication was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

- Mail: Use postage paid, pre-addressed form FDA 3500, available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Stryker informed of any adverse events associated with this product or any other Stryker product by emailing [strykerortho6463@stericycle.com](mailto:strykerortho6463@stericycle.com).

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We regret any inconvenience this situation may cause you and if you have any questions, feel free to contact me at +41 32 641 66 97.

Sincerely,



**Per Maegaard**  
**Senior Manager Post Market Safety**  
**Stryker**

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## SAFETY COMMUNICATION BUSINESS REPLY FORM

October 11, 2019

Product Field Action Number:	2173330
Description:	STAR Total Ankle Replacement Non-Foil Packed Mobile Bearing Components
Catalog#:	400-140, 400-141, 400-142, 400-143, 400-144, 99-0028/11, 99-0028/12, 99-0028/13, 99-0028/14
Lot Codes:	See Attached

I have received the Safety Communication letter from Stryker dated October 11, 2019 providing information on the above referenced devices.

\_\_\_\_\_  
Surgeons, Hospital Risk Managers, and Patients

\_\_\_\_\_  
Date

\_\_\_\_\_  
Address/City/State/Postal Code

\_\_\_\_\_  
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:**

Fax: 1-866-534-9993 or email to [strykerortho6463@stericycle.com](mailto:strykerortho6463@stericycle.com)

**ATTACHMENT 1: LOT CODES SUBJECT TO PFA 2173330**

<b>Catalog Number</b>	<b>Lot Code</b>
400-140	0524120, 0537040, 0805005, 0805006, 0907143, 0912068, 0913038, 0913039, 0916079, 0921073, 0924012, 0924089, 0928124, 0940124, 0940126, 0942101, 0945158, 1006012, 1009067, 1010045, 1015109, 1015110, 1015111, 1036010, 1036093, 0340010, 0513067, 0524120, 0524160, 0525014, 0526013, 0537012, 0537040, 0642018, 0642020, 0642065, 0742051, 0805005, 0805006, 0808048, 0822040, 0839098, 0903117, 0904006, 0905026, 0907136, 0907143, 0912068, 0913038, 0913039, 0914056, 0916079, 0920150, 0921073, 0924012, 0924089, 0926077, 0928123, 0928124, 0933116, 0940124, 0940126, 0942101, 0945158, 1006012, 1009067, 1010029, 1010045, 1015109, 1015110, 1015111, 1020070, 1036008, 1036010, 1036013, 1036027, 1036031, 1036091, 1036093, 1037009, 1037015, 1234103, 1251137, 1251138, 1251140, 1301081, 1302210, 1311200, 1314043, 1314044, 1314046, 1317087, 1419127, 513073, 526013, 642020, 808048, 839098
400-141	0440063, 0449056, 0449057, 0449061, 0513068, 0537011, 0537041, 0538010, 0635023, 0635039, 0635089, 0635090, 0724008, 0742002, 0745004, 0808012, 0808013, 0822046, 0903118, 0904068, 0905027, 0907133, 0907138, 0907141, 0912069, 0912071, 0916100, 0917021, 0923049, 0923050, 0926074, 0926075, 0931009, 0931064, 0931089, 0932049, 0939100, 0939101, 0941064, 0942100, 0945156, 0945162, 1015113, 1015114, 1020070, 1147025, 1149054, 1302207, 1304078, 1304080, 1304085, 1309123, 1311202, 1314040, 1314042, 1314048, 1407321, 1419126, 1419129, 449056, 449057, 449061, 513068, 724008, 742002
400-142	0314052, 0328008, 0330050, 0338143, 0524106, 0524159, 0526015, 0537013, 0537042, 0538011, 0802035, 0805004, 0808049, 0839097, 0903119, 0905032, 0905033, 0907135, 0907140, 0912070, 0912074, 0916096, 0917023, 0920104, 0923054, 0924006, 0924090, 0926076, 0931088, 0945163, 0950020, 0951064, 0951092, 1006065, 1010034, 1010035, 1011047, 1015115, 1015116, 1015117, 1018054, 1023096, 1023104, 1247131, 1250134, 1302181, 1302211, 1314086, 1314087, 1317095, 1408145, 1412098, 1420089, 1420090, 524106, 524159, 538011, 805004, A/27444
400-143	0213078, 0314054, 0513069, 0513074, 0525036, 0724007, 0725002, 0742003, 0742042, 0822049, 0907120, 0907134, 0907139, 0912066, 0912073, 0912076, 0917130, 0923053, 0928057, 0932205, 0932206, 0940064, 0940065, 0945144, 0946041, 0946041, 0946100, 1005070, 1010036, 1010037, 1015118, 1023094, 1023094, 1023098, 1023098, 1407254, 1407255, 1418139, 1420127, 1420149, 1421075, 513074, 525036, 725002
400-144	0050074, 0122066, 0235119, 0314056, 0330051, 0513070, 0513075, 0525037, 0527037, 0604036, 0616063, 0641001, 0739011, 0805007, 0822045, 0904030, 0905035, 0907137, 0907142, 0915129, 0916101, 0917128, 0917129, 0932204, 0933132, 0939103, 0940060, 0945129, 0945160, 1015122, 1023089, 1023090, 1236069, 1236076, 1302183, 1311129, 1311136, 131129, 1315095, 1315097, 1421083, 513075, 739011, 8002440, 9004030
99-0028/11	0322107, 0525048, 0908026, 0912072, 0946072, 0948052, 1003051, 1003108, 1004072, 1006064, 1008002, 1236065, 1236066, 1311178, 1311179, 1311181
99-0028/12	0314672, 06420023, 0642003, 0822047, 0840092, 0912067, 0912075, 0948055, 0949037, 1004074, 1004076, 1004104, 1007054, 1010026, 1236067, 1236068, 1311182, 1311183, 1311185, 1311187, 642003
99-0028/13	0147145, 0326048, 0806121, 0822044, 0907132, 0910091, 0947093, 0948159, 1002128, 1003009, 1005022, 1007026, 1007137, 1311189, 1311190, 1311192, 1311193, 1311194
99-0028/14	0322105, 0525049, 0745031, 0822048, 0839059, 0928058, 0928060, 0947066, 0950022, 1005059, 1006066, 1008018, 1008060, 1009078, 1311195, 1311197, 1311198