



PRODUCT SAFETY NOTIFICATION

November 4, 2019

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

Legal Manufacturer: Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland

Lot Number(s): See attached list on page 5

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Departments

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"). See attached details list of 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 A - AFFECTED PRODUCTS AND LOT NUMBERS). 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

*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

Our records indicate that you have received one or more of the Products.

1. Please inform users of this communication and forward this notice to all those individuals who need to be aware within your organization.
2. Please also complete and sign the enclosed Business Reply Form and email a copy to Gen-Y (S) Pte Ltd representative or the undersigned.
3. This form must be returned even if you do not have affected products at your facility. 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.
3. **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.



PRODUCT SAFETY NOTIFICATION

BUSINESS REPLY FORM

November 4, 2019

Product Field Action Number:	2173330
Description:	STAR Total Ankle Replacement Non-Foil Packed Mobile Bearing Components
Catalog Numbers:	400-140, 400-141, 400-142, 400-143, 400-144, 99-0028/11, 99-0028/12, 99-0028/13, 99-0028/14
Lot Numbers:	See attached List
Legal Manufacturer	Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland

I have received the Safety Notification letter dated November 4, 2019 providing information on the above referenced devices.

Surgeon/Distributor Representative
(Signature)

Date

Surgeon /Distributor Representative
(Name)

Name of Hospital/ Distributor

Stamp

Please complete this form within 5 business days and return to [REDACTED] or to your Gen-Y (S) Pte Ltd representative

ATTACHMENT A: AFFECTED PRODUCTS AND LOT NUMBERS (PFA 2173330)

Catalog Number	Lot Numbers
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