

Risk of Device Component Breaking in Patients with Stryker's STAR Ankle: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is advising patients, caregivers, and health care providers about the higher than expected risk of the polyethylene (plastic) component of the device breaking (fracture), as early as three to four years after implantation in all Scandinavian Total Ankle Replacement devices (STAR Ankle). Fracture of the plastic component of the STAR Ankle may lead to surgery to repair or replace the device.

Based on the FDA's recent analysis of FDA-required post approval studies (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=362876&c_id=295) and adverse event reports, the potential risk of the plastic component breaking may exist for all STAR Ankle devices, regardless of the date of manufacture or distribution.

The FDA believes the STAR Ankle remains appropriate for certain patient populations, such as older patients with lower activity levels. Based on the additional medical literature and real-world evidence, patients with more active life styles, osteoarthritis (disease where the protective joint tissue breaks down and causes pain and swelling), or age younger than 55 years old may have a higher than expected risk of the plastic component breaking. The FDA is providing the recommendations below to help patients and health care providers monitor for signs of possible fracture of the plastic component in the STAR Ankle.

Recommendations for Patients Who Have or are Considering the STAR Ankle, and Caregivers

- If you are considering a STAR Ankle, discuss all available treatment options for painful arthritic ankle joints with your health care provider. There are benefits and risks associated with all medical devices and procedures.

If You Have a STAR Ankle

- Talk to your health care provider if you experience any new worsening pain, inability to bear weight, new grinding or other noise, or instability in your STAR Ankle.
- Be aware, your health care provider may perform a physical examination of your operated ankle and obtain X-rays to evaluate your STAR Ankle. In some instances, computed

tomography (CT), a cross-sectional computer scan, may be necessary to assess if the plastic component in your ankle is broken.

- If you suspect or experience a problem with your STAR ankle, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).

Recommendations for Health Care Providers Who Treat and Follow Patients with a STAR Ankle

- Review the **Recommendations for Patients Who Have or are Considering STAR Ankle, and Caregivers** listed above and with your patients.
- As part of shared decision-making, discuss the benefits and risks of all relevant treatment options for painful arthritic ankle joints with your patients.
- Read and carefully follow the Instructions for Use for the STAR ankle.
- Surgeons should closely monitor patients with the STAR Ankle for potential fractures of the plastic component of the device.
- If surgeons suspect a fractured plastic component (for example, there is pain or noise from the device), consider performing X-rays to further evaluate the device integrity. Changes on X-rays can be subtle; if X-rays are negative and a polyethylene fracture is still suspected, a CT scan may be needed to determine whether a plastic component fracture has occurred. Be aware that the clinical presentation (the presence of signs or symptoms) of fracture in plastic materials such as polyethylene can be subtle even in a CT scan and, infrequently, may be diagnosed only on exploratory surgery.
 - Thinner (6mm) plastic components appear to be more prone to fracture.
 - Younger patients (under 55 years old) and patients with a primary diagnosis of osteoarthritis may have higher risk of plastic component fracture and subsequent revision surgery.

Device Description

The STAR Ankle is indicated for use as a non-cemented total ankle prosthetic (“artificial joint”) and used to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis. The STAR Ankle, which is comprised of a tibial plate, a mobile-bearing polyethylene component, and a talar component, is designed to allow for some of normal ankle mobility and function. The mobile-bearing device component is made from sterilized polyethylene.

This device was approved in the Premarket Approval (PMA) application, P050050 (https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050050A.pdf) with two post-approval studies required by the FDA.

- The first post-approval study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=362876&c_id=295) was a long-term (eight-year) follow-up of a cohort of patients who were enrolled before the device was approved in 2009.
- The second post-approval study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=362876&c_id=299) was a new enrollment, prospective, multicenter, single arm two-year study of the same device designed to examine the performance of the STAR Ankle compared to the STAR Ankle performance in the first study. The second study included patients with and without the new packaging. Of note, this communication does not include the results from this post-approval study due to its short follow-up (that is, two years).

Higher than Expected Component Fracture Rates in the STAR Ankle

Based on the results of the long-term post-approval study, the plastic component fractured at a cumulative rate of 13.8% (12/87) at eight-year post-implantation, with all fractures requiring additional surgery. Fractures were also observed as early as three to four years after implantation, which was unexpected. This higher fracture rate and earlier than expected occurrence are concerning when compared with other comparable total ankle replacement devices, and may also be underestimated as two polyethylene fractures were not diagnosed until surgical exploration in this study. The concern about fracture rate in the post-approval study has been previously acknowledged and communicated by the device manufacturer. However, Stryker's (manufacturer of STAR Ankle) communication excluded devices manufactured after August 1, 2014, when changes were made in the inner-pouch foil packaging to limit the material degradation of the polyethylene component.

Given the long-term post-approval study only included patients implanted before the packaging change, the FDA evaluated available postmarket data (for example, adverse events in medical device reports) to assess the potential for fracture of the plastic device component to occur in patients with the devices manufactured after the packaging change. Since 2009, at least 1,841 adverse event reports have been received for the STAR Ankle. The FDA concluded that about 300 of these reports described events of fractured plastic components and included STAR Ankle devices manufactured before and after the 2014 packaging change. Of note, although the MDR system is a valuable source of information, this passive surveillance system has limitations, including incomplete, inaccurate, untimely or biased data in the reports. In addition, the

incidence or prevalence of the plastic fracture cannot be determined from this reporting system alone due to potential under-reporting, duplicate reporting of events, and the lack of information about the total number of patients with the implants.

In addition, the FDA reviewed data provided by the manufacturer on 244 STAR Ankle implants that were removed (including devices manufactured after the 2014 packaging change), which showed 72 plastic component fractures. Fractures were observed more frequently in thinner plastic device components (6mm thickness) as opposed to thicker components (7mm-9mm), with only one fracture observed in the 11-14mm thickness range. Most of the plastic component fractures showed material oxidation degradation after three to four years of implantation and exhibited loss of mechanical properties. However, the FDA does recognize that the sample size of the removed implants with plastic component fractures was small (n=72).

The FDA considers plastic component fractures in the STAR Ankle may be attributed to multiple factors, including device design (component thickness), material (degradation), surgical factors, and patient factors (such as younger patients with higher activity levels). **Therefore, while the long-term fracture rate is not known in devices manufactured after the 2014 packaging change, all patients who have the device implanted or are considering getting the device should be aware of the risk of plastic component fracture, which may subsequently require re-operation.**

FDA Actions

The FDA continues to work with Stryker to better understand the factors which contribute to the plastic component fracture based on results from post-approval studies and other data sources. The FDA will also continue to review medical literature, real-world evidence, FDA-required post approval studies, adverse event reports, registry data, and information from patients, health care providers, orthopedic professional societies, and the manufacturer.

In addition, the FDA will continue to work with Stryker to ensure that patients and providers are aware of the potential risk of plastic component fracture, to identify any potential mitigation measures, and to ensure that the product labeling addresses the concern.

The FDA will keep the public informed of any significant new information.

Reporting Problems to the FDA

If you suspect or experience a problem with your device, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect the STAR Ankle device has malfunctioned or contributed to a serious injury or adverse outcome, the FDA encourages you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>).

Health care professionals employed by facilities that are subject to the FDA's user facility reporting requirements (<https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>) should follow the reporting procedures established by their facilities.

Hospitals are required to report some adverse events related to medical devices. Federal regulations require user facilities to report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must also report a medical device-related serious injury to the manufacturer or to the FDA, if the medical device manufacturer is unknown.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>) or call 800-638-2041 or 301-796-7100.