

Hintermann Series H3 Total Ankle Replacement Has a Higher-Than-Expected Risk of Device Failure: FDA Safety Communication



Date Issued: February 29, 2024

The U.S. Food and Drug Administration (FDA) is alerting patients, caregivers, and health care providers about a **higher-than-expected risk of device failure with the Hintermann Series H3 Total Ankle Replacement (TAR) system, manufactured by DT MedTech LLC.**

The FDA is evaluating [interim post-approval study \(PAS\) results](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=601967&c_id=5490) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=601967&c_id=5490) for the Hintermann Series H3 TAR system and other real-world data. For patients with the Hintermann Series H3 TAR system, the results suggest a higher rate of failure, specifically, additional surgery (removals or revisions of metal components, at least 16.1%) associated with the implanted device compared with the rate in the premarket clinical studies (9.9%). When all types of revisions are included in the interim PAS results (such as revisions of the plastic component as well as the metal component), the rate of additional surgery is at least 28.5%.

The FDA is working with the manufacturer to evaluate data from all available sources to better understand potential causes of the higher failure rate.

Recommendations for Patients and Caregivers

- **Patients who are considering a Hintermann Series H3 TAR system:**
 - Discuss all available treatment options for painful arthritic ankle joints with your health care provider.
 - Know there are benefits and risks associated with all joint replacement medical devices and procedures.
- **Patients who have a Hintermann Series H3 TAR system:**
 - If the system is functioning well, and you have no new or worsening pain or symptoms, the FDA does not recommend surgery to remove it.
 - Contact your health care provider if you are experiencing any of the following:
 - any new or worsening pain or swelling,
 - inability to use your ankle or bear weight,
 - grinding or other noise, or
 - weakness around your implanted device.
 - Be aware, your health care provider may perform a physical examination of your operated ankle and obtain X-rays to evaluate it. In some instances, a CT scan may be necessary to assess if the plastic component in your Hintermann Series H3 TAR system is broken.
 - Report any problems or complications experienced with your TAR system to the FDA. Your report, along with information from other sources, can provide information that helps improve patient safety.

Recommendations for Health Care Providers

- Review and discuss the **Recommendations for Patients and Caregivers** above 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.
- When making treatment recommendations, consider that there is a higher risk of device failure with the Hintermann Series H3 TAR system compared with the rate in the premarket clinical studies.
- Read and carefully follow the Instructions for Use for the Hintermann Series H3 TAR system.
- Monitor patients with the Hintermann Series H3 TAR system for device problems such as loosening and fractures of the implant components of the device.
- For suspected device problems, such as a fractured plastic (polyethylene) component, consider performing X-rays to further evaluate the device integrity.

- Be aware that changes on X-rays can be subtle. If X-rays are negative and 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 and the signs or symptoms of fracture in plastic materials such as polyethylene can be subtle even in a CT scan.
- Report any problems or complications experienced by patients with Hintermann Series H3 TAR systems to the FDA.

Device Description

Mobile-bearing TARs consist of a metal plate in the lower leg (tibial), a mobile plastic (polyethylene) component (inlay), and a metal ankle (talar) component. They are indicated for use as a non-cemented total ankle prosthesis ("artificial joint") and used to replace a painful arthritic ankle joint (<https://medlineplus.gov/ency/article/007254.htm>), due to osteoarthritis (<https://medlineplus.gov/ency/article/000423.htm>), post-traumatic osteoarthritis, or rheumatoid arthritis (<https://medlineplus.gov/ency/article/000431.htm>).

The Hintermann Series H3 TAR system was approved in the United States in 2019 with the following two post-approval studies (PAS) required by the FDA:

- a long-term study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=601967&c_id=5490) with 10-year follow-up of the cohort of 298 patients who were enrolled in the premarket clinical studies and
- a new enrollment study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=601967&c_id=5491) with five-year follow-up.

The FDA has approved a total of two mobile-bearing TARs – the Scandinavian Total Ankle Replacement devices (STAR Ankle) in 2009, and the Hintermann Series H3 TAR system.

The FDA previously issued a Safety Communication (<https://public4.pagefreezer.com/browse/FDA/20-02-2024T15:13/https://www.fda.gov/medical-devices/safety-communications/risk-device-component-breaking-patients-strykers-star-ankle-fda-safety-communication>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) in 2021 about the higher risk of device failure related to breakage of the polyethylene (plastic) component of the STAR Ankle system.

FDA Actions

The FDA is working with the manufacturer to evaluate all available information about the performance of Hintermann Series H3 TAR systems and the risk of device failure.

The FDA will continue to work with mobile-bearing TAR manufacturers to better understand the factors that contribute to device failures.

The FDA is also collaborating with international regulatory agencies to review data from registries for mobile-bearing TARs and further evaluate device failure rates.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with Your Device

If you think you had 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>).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Unique Device Identifier

The unique device identifier (UDI) helps identify individual medical devices sold in the United States from manufacturing through distribution to patient use. The UDI allows for more accurate reporting, reviewing, and analyzing of adverse event reports so that devices can be identified, and problems potentially corrected more quickly.

- [How do I recognize a UDI on a label? \(/medical-devices/unique-device-identification-system-udi-system/udi-basics\)](/medical-devices/unique-device-identification-system-udi-system/udi-basics)
- [AccessGUDID database - Identify Your Medical Device \(https://accessgudid.nlm.nih.gov/\)](https://accessgudid.nlm.nih.gov/)
- [Benefits of a UDI System \(/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system\)](/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system)

You can find the UDI provided by DT MedTech LLC for Hintermann Series H3 TAR systems by checking the table below.

Search:

Export Excel

Version or Model Number ▲	Device Description ◆	Device Identifier Number ◆
300105	H3 PE INLAY SIZE 1 - 5MM	B095300105
300106	H3 PE INLAY SIZE 1 - 6MM	B095300106
300107	H3 PE INLAY SIZE 1 - 7MM	B095300107
300109	H3 PE INLAY SIZE 1 - 9MM	B095300109

Version or Model Number ▲	Device Description ◆	Device Identifier Number ◆
300205	H3 PE INLAY SIZE 2 - 5MM	B095300205
300206	H3 PE INLAY SIZE 2 - 6MM	B095300206
300207	H3 PE INLAY SIZE 2 - 7MM	B095300207
300209	H3 PE INLAY SIZE 2 - 9MM	B095300209
300305	H3 PE INLAY SIZE 3 - 5MM	B095300305
300306	H3 PE INLAY SIZE 3 - 6MM	B095300306
300307	H3 PE INLAY SIZE 3 - 7MM	B095300307
300309	H3 PE INLAY SIZE 3 - 9MM	B095300309
300405	H3 PE INLAY SIZE 4 - 5MM	B095300405
300406	H3 PE INLAY SIZE 4 - 6MM	B095300406
300407	H3 PE INLAY SIZE 4 - 7MM	B095300407
300409	H3 PE INLAY SIZE 4 - 9MM	B095300409
300505	H3 PE INLAY SIZE 5 - 5MM	B095300505
300506	H3 PE INLAY SIZE 5 - 6MM	B095300506
300507	H3 PE INLAY SIZE 5 - 7MM	B095300507
300509	H3 PE INLAY SIZE 5 - 9MM	B095300509
300605	H3 PE INLAY SIZE 6 - 5MM	B095300605
300606	H3 PE INLAY SIZE 6 - 6MM	B095300606
300607	H3 PE INLAY SIZE 6 - 7MM	B095300607
300609	H3 PE INLAY SIZE 6 - 9MM	B095300609
301111	TALAR COMPONENT RIGHT SIZE 1	B095301111
301112	TALAR COMPONENT RIGHT SIZE 2	B095301112
301113	TALAR COMPONENT RIGHT SIZE 3	B095301113
301114	TALAR COMPONENT RIGHT SIZE 4	B095301114
301115	TALAR COMPONENT RIGHT SIZE 5	B095301115
301116	TALAR COMPONENT RIGHT SIZE 6	B095301116
301121	FC TALAR COMPONENT RIGHT SIZE 1	B095301121
301122	FC TALAR COMPONENT RIGHT SIZE 2	B095301122
301123	FC TALAR COMPONENT RIGHTSIZE 3	B095301123
301124	FC TALAR COMPONENT RIGHT SIZE 4	B095301124
301125	FC TALAR COMPONENT RIGHT SIZE 5	B095301125

Version or Model Number ▲	Device Description ◆	Device Identifier Number ◆
301201	H3 TIBIAL COMPONENT RIGHT SIZE 1	B095301201
301202	H3 TIBIAL COMPONENT RIGHT SIZE 2	B095301202
301203	H3 TIBIAL COMPONENT RIGHT SIZE 3	B095301203
301204	H3 TIBIAL COMPONENT RIGHT SIZE 4	B095301204
301205	H3 TIBIAL COMPONENT RIGHT SIZE 5	B095301205
301206	H3 TIBIAL COMPONENT RIGHT SIZE 6	B095301206
302111	TALAR COMPONENT LEFT SIZE 1	B095302111
302112	TALAR COMPONENT LEFT SIZE 2	B095302112
302113	TALAR COMPONENT LEFT SIZE 3	B095302113
302114	TALAR COMPONENT LEFT SIZE 4	B095302114
302115	TALAR COMPONENT LEFT SIZE 5	B095302115
302116	TALAR COMPONENT LEFT SIZE 6	B095302116
302121	FC TALAR COMPONENT LEFT SIZE 1	B095302121
302122	FC TALAR COMPONENT LEFT SIZE 2	B095302122
302123	FC TALAR COMPONENT LEFT SIZE 3	B095302123
302124	FC TALAR COMPONENT LEFT SIZE 4	B095302124
302125	FC TALAR COMPONENT LEFT SIZE 5	B095302125
302201	H3 TIBIAL COMPONENT LEFT SIZE 1	B095302201
302202	H3 TIBIAL COMPONENT LEFT SIZE 2	B095302202
302203	H3 TIBIAL COMPONENT LEFT SIZE 3	B095302203
302204	H3 TIBIAL COMPONENT LEFT SIZE 4	B095302204
302205	H3 TIBIAL COMPONENT LEFT SIZE 5	B095302205
302206	H3 TIBIAL COMPONENT LEFT SIZE 6	B095302206

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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.

Was this helpful?