FSN Ref: FSN-1 Rev 02 FSCA Ref: FSCA-1

Date: Update 2024/06/10; Initial 2024/03/01

Field Safety Notice
Hintermann Series H3 Total Ankle Replacement System
Communication of Recommendations

For Attention of: Patients, Caregivers, and Health Care Providers

Field Safety Notice
Hintermann Series H3 Total Ankle Replacement System
Communication of Recommendations

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Hintermann Series H3 Total Ankle Replacement System consists of sterile packaged implants and are indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis, or arthritis secondary to inflammatory disease. The device system is for prescription use.
1.	2. Commercial name(s)*
	Hintermann Series H3 Total Ankle Replacement System
1.	3. Unique Device Identifier(s) (UDI-DI)
	Refer to list attached at the end of this document.
1.	4. Primary clinical purpose of device(s)*
	For ankle replacement surgeries.
1.	5. Device Model/Catalogue/part number(s)*
	Refer to the list attached at the end of this document.
1.	6. Affected serial or lot number range
	All lots are affected by the FSN. THIS IS NOT A RECALL.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	FDA issued a safety communication related to PMA P16036: Hintermann Series H3 Total Ankle Replacement Has a Higher-Than-Expected Risk of Device Failure. See weblink https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety. Results summarized are interim data only. The study is a continued follow-up of the premarket cohort with the intent to follow subjects for 10 years post implantation, but only a minimum of 5 years of follow-up data is currently available. All subjects were enrolled at a single center located outside the US with approximately 80% of implantations performed by the same surgeon, which limits the generalizability of the study results to US patients and US clinical practice. Additional analyses are planned in the final report to assess the risk of revision.
2.	2. Hazard giving rise to the FSCA*
	There is no product problem. FDA safety communication related to PMA P160036 post approval study requires notification of recommendations to patient, caregivers and healthcare professionals.

2.	3. Safety Communication/Recommendations

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 appropriate Competent Authority and DT MedTech at quality@dtmedtech.com. 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 appropriate Competent Authority and DT MedTech at quality@dtmedtech.com.

3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☒ Follow patient management recommendations (see 2.3 above) ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	None
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Refer to the FDA Communication https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher- expected-risk-device-failure-fda-safety	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☒ None There is no recall of devices. The FSN is to provide recommendations to patients, caregivers and healthcare professionals.	
3.	6. By when should the action be completed?	None
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*		
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN-1 dated 2024/03/01
4.	3. For Updated FSN, key new information as follows:	
	FSN-1 was updated as the initial FSN-1 indicated that this was not a FSCA. While a recall is not being performed, this is a FSCA as advice is being given by the manufacturer regarding the use of the device (recommendations listed above).	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	None	
4.	6. Anticipated timescale for follow-up FSN	None
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	DT MedTech, LLC, A Vilex Company
	b. Address	111 Moffitt Street, McMinnville, Tennessee37110 USA
	c. Website address	www.dtmedtech.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	None with updated FSN-1
4.	10. Name/Signature	Lauren Pryor Quality Manager

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

REF	Product name Hintermann Series H3	Primary DI 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
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

REF	Product name Hintermann Series H3	Primary DI
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 RIGHT SIZE 3	B095301123
301124	FC TALAR COMPONENT RIGHT SIZE 4	B095301124
301125	FC TALAR COMPONENT RIGHT SIZE 5	B095301125
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

REF	Product name Hintermann Series H3	Primary DI
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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Field Safety Notice Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-1
FSN Date*	10 June 2024
Product/ Device name*	Hintermann Series H3 Total Ankle Replacement System
Product Code(s)	See attached

2. Distributor/Importer Details	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	lauren.pryor@vilex.com; quality@dtmedtech.com
Distributor/Importer Helpline	1-800-521-5002 Ext. 100
Postal Address	111 Moffitt Street McMinnville, TN 37110 USA
Web Portal	https://www.dtmedtech.com/
Deadline for returning the Distributor/Importer reply form*	26/07/2024

4. Distributors/Importers (Tick all that apply)	
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	I have identified customers that received or may have received this device
☐	I have attached customer list
☐	I have informed the identified customers of this FSN
☐	I have received confirmation of reply from all identified customers
Print Name	
Signature	
Date	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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302206	H3 TIBIAL COMPONENT LEFT SIZE 6	B095302206