

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**

| <b>1. Information on Affected Devices*</b> |                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.                                         | <b>1. Device Type(s)*</b><br><p>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.</p> |
| 1.                                         | <b>2. Commercial name(s)*</b><br>Hintermann Series H3 Total Ankle Replacement System                                                                                                                                                                                                                                                                                                      |
| 1.                                         | <b>3. Unique Device Identifier(s) (UDI-DI)</b><br>Refer to list attached at the end of this document.                                                                                                                                                                                                                                                                                     |
| 1.                                         | <b>4. Primary clinical purpose of device(s)*</b><br>For ankle replacement surgeries.                                                                                                                                                                                                                                                                                                      |
| 1.                                         | <b>5. Device Model/Catalogue/part number(s)*</b><br>Refer to the list attached at the end of this document.                                                                                                                                                                                                                                                                               |
| 1.                                         | <b>6. Affected serial or lot number range</b><br>All lots are affected by the FSN. THIS IS NOT A RECALL.                                                                                                                                                                                                                                                                                  |

| <b>2. Reason for Field Safety Corrective Action (FSCA)*</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.                                                          | <b>1. Description of the product problem*</b><br><p>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 <a href="https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety">https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety</a>. 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.</p> |
| 2.                                                          | <b>2. Hazard giving rise to the FSCA*</b><br><p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

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| 2. | 3. Safety Communication/Recommendations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|    | <p data-bbox="316 291 1081 327"><b>Recommendations for Patients and Caregivers</b></p> <ul style="list-style-type: none"> <li data-bbox="363 365 1370 506"> <p>• <b>Patients who are considering a Hintermann Series H3 TAR system:</b></p> <ul style="list-style-type: none"> <li>○ Discuss all available treatment options for painful arthritic ankle joints with your health care provider.</li> <li>○ Know there are benefits and risks associated with all joint replacement medical devices and procedures.</li> </ul> </li> <li data-bbox="363 512 1386 968"> <p>• <b>Patients who have a Hintermann Series H3 TAR system:</b></p> <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ Contact your health care provider if you are experiencing any of the following: <ul style="list-style-type: none"> <li>▪ any new or worsening pain or swelling,</li> <li>▪ inability to use your ankle or bear weight,</li> <li>▪ grinding or other noise, or</li> <li>▪ weakness around your implanted device.</li> </ul> </li> <li>○ 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.</li> <li>○ <u>Report any problems or complications</u> experienced with your TAR system to the appropriate Competent Authority and DT MedTech at <a href="mailto:quality@dtmedtech.com">quality@dtmedtech.com</a>. Your report, along with information from other sources, can provide information that helps improve patient safety.</li> </ul> </li> </ul> <p data-bbox="316 995 1049 1031"><b>Recommendations for Health Care Providers</b></p> <ul style="list-style-type: none"> <li>• Review and discuss the <b>Recommendations for Patients and Caregivers</b> above with your patients.</li> <li>• As part of shared decision-making, discuss the benefits and risks of all relevant treatment options for painful arthritic ankle joints with your patients.</li> <li>• 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.</li> <li>• Read and carefully follow the Instructions for Use for the Hintermann Series H3 TAR system.</li> <li>• Monitor patients with the Hintermann Series H3 TAR system for device problems such as loosening and fractures of the implant components of the device.</li> <li>• For suspected device problems, such as a fractured plastic (polyethylene) component, consider performing X-rays to further evaluate the device integrity. <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ 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.</li> </ul> </li> <li>• <u>Report any problems or complications</u> experienced by patients with Hintermann Series H3 TAR systems to the appropriate Competent Authority and DT MedTech at <a href="mailto:quality@dtmedtech.com">quality@dtmedtech.com</a>.</li> </ul> |

| 3. Type of Action to mitigate the risk* |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |      |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| 3.                                      | <b>1. Action To Be Taken by the User*</b><br><br><input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device<br><br><input type="checkbox"/> On-site device modification / inspection<br><br><input checked="" type="checkbox"/> Follow patient management recommendations (see 2.3 above)<br><br><input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU)<br><br><input type="checkbox"/> Other <input type="checkbox"/> None                                   |      |
| 3.                                      | 2. By when should the action be completed?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | None |
| 3.                                      | 3. Particular considerations for:                      Implantable device<br><br>Is follow-up of patients or review of patients' previous results recommended?<br>No<br><br>Refer to the FDA Communication <a href="https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety">https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety</a>                                                                 |      |
| 3.                                      | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Yes  |
| 3.                                      | <b>5. Action Being Taken by the Manufacturer*</b><br><br><div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Product Removal<br/> <input type="checkbox"/> Software upgrade<br/> <input type="checkbox"/> Other             </div> <div> <input type="checkbox"/> On-site device modification/inspection<br/> <input type="checkbox"/> IFU or labelling change<br/> <input checked="" type="checkbox"/> None             </div> </div><br>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<br>(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, Tennessee 37110 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<br>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.\*

FSN Ref: FSN-1 Rev 02

FSCA Ref: FSCA-1

| 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 |