

Urgent Field Safety Notice

Medtronic HawkOne™ Directional Atherectomy System

System Notification

Product Name	Model Numbers
HawkOne™ Directional Atherectomy System	6Fr: <ul style="list-style-type: none">• H1-M-INT• H1-S-INT

December 2021

Medtronic reference: FA1203

Dear Risk Manager or Health Care Professional,

Please share this notice with your physician users.

This letter is regarding the Medtronic 6Fr HawkOne™ Directional Atherectomy System (herein referred to as HawkOne). Medtronic is reiterating the existing warnings and precautions in the HawkOne Instructions for Use (IFU) related to the risk associated with tip damage caused by guidewire prolapse.

Medtronic has received reports of tip damage during use of 6Fr HawkOne devices, which has resulted in some instances of tip detachment and embolization. Over a three-year (36 month) period, the overall observed rate of tip damage is 0.168%. While most instances were resolved without patient consequence, some events further resulted in tip detachment, requiring endovascular retrieval or open surgical retrieval to resolve. The overall observed rate of in vivo tip detachment is 0.061%. These rates are based on the number of events reported to Medtronic, compared with the number of distributed devices and as such, these rates may underestimate the actual occurrence rate of the issue. No deaths have been reported related to this issue. Risks to the patient resulting from tip detachment are identified in the IFU, and may include arterial dissection, arterial perforation, arterial rupture, ischemia, and/or vascular complications that could require surgical repair.

Guidewire prolapse is the predominate cause of tip damage as evident by returned device investigation and engineering testing. The presence of guidewire prolapse can cause the guidewire to buckle into a loop and develop a kink during retraction of the catheter. The potential risk for guidewire prolapse is inherent in all Rapid Exchange (RX) vascular devices such as HawkOne (see image 1 for illustration).

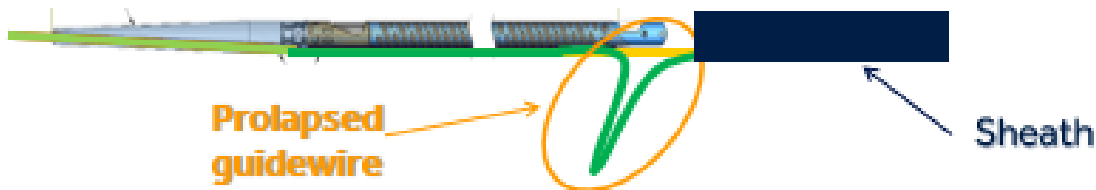


Image 1. Prolapsed guidewire illustrated example

Please adhere to the existing IFU instructions, and warnings and precautions listed below to reduce the risk of guidewire prolapse:

Directions for Use

- **Carefully remove the catheter from the patient under fluoroscopic guidance.**
- **Caution: Do not torque the catheter shaft more than 360° in one direction. Torquing the catheter shaft more than 360° in one direction could result in tip fracture or other device failure. If the HawkOne catheter is not rotating easily, reposition the catheter or predilate the lesion.**
- **Warning: Always use direct fluoroscopic observation when manipulating the HawkOne Catheter in the peripheral vessels. If resistance is met during manipulation, determine the cause of the resistance before proceeding**
- **Warning: Never advance the distal tip of the HawkOne catheter near the floppy end of the guidewire. If the HawkOne catheter is advanced to this position, it can cause the guidewire to buckle into a loop when retracting the catheter. If buckling occurs, remove the catheter and guidewire together to prevent potential damage to vessel walls. If resistance is still felt, remove the sheath together with the guidewire and catheter.**
- **Warning: Avoid excessive movement of the HawkOne catheter within the vessel at all times. Excess movement could result in embolization or vessel damage. In addition, excessive catheter manipulation while the cutter window is open could result in the embolization of previously excised tissue fragments.**
- **Warning: Do not use HawkOne catheter in bends in excess of 90°. Using in bends in excess of 90° can result in device failure.**

No updates will be applied to the current HawkOne IFU at this time. Patients should continue to be monitored per your practice's normal follow-up procedures.

There are no actions required for patients where HawkOne was previously used during a procedure. **There are no product retrievals or disposals requested by Medtronic.**

Customer Instructions:

Medtronic records indicate that your facility has received one or more of the 6Fr HawkOne devices. As a result, Medtronic requests that you immediately take the following actions:

- Share with all those who need to be aware within your organization or to any organization where the products have been transferred.
- Prior to use please review the IFU included with your product, noting the warnings and precautions listed in this letter

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative at <XXXX>.

Sincerely,

Local / BU Manager