URGENT MEDICAL DEVICE NOTICE
Medtronic TurboHawk™ Plus Directional Atherectomy Systems Notification

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February 2022

Dear Risk Manager/Health Care Professional,

Please share this notice with your physician users.

There are no product retrievals or disposals requested by Medtronic associated with this issue.

This letter is regarding the Medtronic 6Fr TurboHawk™ Plus Directional Atherectomy System (herein referred to as TurboHawk Plus). Medtronic is reiterating the existing warnings and precautions in the TurboHawk Plus Instructions for Use (IFU) related to the risk associated with tip damage caused by guidewire prolapse. Medtronic has recently communicated IFU warnings and precautions related to instances of guidewire prolapse causing tip damage involving the 6Fr HawkOne Directional Atherectomy System, which resulted in tip detachment and embolization. This communication is for the same issue and the same warnings and precautions applied to TurboHawk Plus and is not a new issue. There are no actions required for patients where TurboHawk Plus was previously used during a procedure.

There have been zero (0) reports of tip damage and zero (0) reports of injury or death on the TurboHawk Plus device. It is being included in this notice because TurboHawk Plus has the same catheter design as HawkOne and is at risk for similar tip damage issues.

Over a three-year period (January 2019-December 2021), Medtronic received reports of tip damage during use of 6Fr HawkOne devices (0.190%), which resulted in instances of tip detachment and embolization. While a majority of the instances related to HawkOne 6 Fr were resolved without patient consequence, 49 events (0.058%) with HawkOne 6FR from January 2019-December 2021 further resulted in tip detachment, requiring endovascular retrieval or open surgical retrieval to resolve. 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.

On the HawkOne Directional Atherectomy System, 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 and TurboHawk Plus (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 TurboHawk Plus catheter is not rotating easily, reposition the catheter or predilate the lesion.
- Warning: Always use direct fluoroscopic observation when manipulating the TurboHawk Plus 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 TurboHawk Plus catheter near the floppy end of the guidewire. If the TurboHawk Plus 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 TurboHawk Plus 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 TurboHawk Plus 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 TurboHawk Plus 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 either device 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 TurboHawk Plus 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.
- Please complete the enclosed Customer Confirmation Form and email to rs.cfqfca@medtronic.com.

Medtronic will notify all applicable regulatory agencies about this matter.

Per your facility’s standard medical device complaint procedures, report to Medtronic any adverse reactions or quality problems if the quality issue described above has been observed. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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 issue or communication, please contact your Medtronic Field Representative.

Sincerely,
Padraic Curran
Vice President of Quality, Peripheral Vascular Health