URGENT: MEDICAL DEVICE NOTIFICATION

Harmony™ Deliver Catheter System

<table>
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<tr>
<th>Model</th>
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<tr>
<td>HARMONY-DCS</td>
<td>All batches</td>
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March 2022

Dear Implanting Physician,

This letter is regarding the Medtronic Harmony Deliver Catheter System (herein referred to as Harmony DCS). Medtronic is notifying all users of the potential for the capsule bond (see Image 1 below) to break during the procedure and reminding users to follow the Instructions for Use (IFU) should this occur. There are no product retrievals or disposals requested by Medtronic at this time.

As of February 07, 2022, Medtronic has received three (3) complaints, which report that the capsule bond of the Harmony DCS broke during the procedure. In all three complaints, the break in the capsule bond did not result in embolization of any portion of the DCS. In one event, the bond break was observed post successful Transcatheter Pulmonary Valve (TPV) deployment and removal of the
DCS from the patient, with no adverse patient impact. In the two other events, the bond break occurred prior to valve deployment resulting in procedural delay with one event requiring a secondary intervention to remove the DCS. A successful Harmony TPV implantation followed in both these cases using a new Harmony system (TPV and DCS).

This notification has no impact on patients who have a Harmony TPV previously implanted. Since the capsule bond break can only occur during the delivery of the TPV, there are no additional actions required for patients where the Harmony TPV has been successfully implanted. These patients should continue to be monitored per your practice’s normal follow-up procedures.

If a capsule bond break does occur during the procedure, it is necessary to remove the DCS, which may result in procedural delay or a potential secondary intervention. Though not observed to date, and unlikely, potential patient risks such as occlusion, perforation, embolization, dissection, radiation burns, and vascular tissue damage caused by friction may result. The current rate of capsule bond breakage is 0.66%, based on the number of procedures performed using the Harmony DCS since launch in April 2021 through February 23, 2022.

If increased resistance is encountered when advancing or withdrawing the delivery system during the procedure, remove the system as a single unit as advised in the current IFU, specifically the warnings and precautions located in section 4.2.3, including those listed below:

- **Do not advance any portion of the DCS under resistance.** Identify the cause of resistance using fluoroscopy and take appropriate action to remedy the problem before continuing to advance the DCS.
- **Ensure the capsule is closed before DCS removal.** If increased resistance is encountered when removing the DCS through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and harm to the patient. If the cause of resistance cannot be determined or corrected, **remove the DCS and introducer sheath as a single unit over the guidewire**, and inspect the DCS and confirm that it is complete.

Medtronic values patient safety and will continue to closely monitor capsule bond break events; a root cause investigation is on-going. To mitigate potential risk, Medtronic is providing additional instructions consistent with the current IFU to implanting physicians on detecting and resolving a capsule bond break (see Appendix A).

**Customer Instructions:**
Medtronic records indicate that your facility has received one or more of the Harmony DCS. As a result, Medtronic requests that you immediately take the following actions:

- Prior to use, please review the IFU e-manual (https://manuals.medtronic.com/manuals/main), noting the instructions, warnings, and precautions also listed above in this letter.
- Share with all those who need to be aware within your organization or at any organization where the products have been transferred.
- 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,

Eliezer De Jesus
Vice President, Quality
Medtronic Structural Heart & Aortic
APPENDIX A: GUIDANCE ON CAPSULE BOND BREAK

As of February 23, 2022, Possible Indications of a Capsule Bond Break May Include the Following:

- Handle movement that does not correspond to TPV frame movement towards the capsule marker band as seen under fluoroscopy.
  - During initial TPV deployment, if the DCS handles come together and there is no relative movement of the TPV frame to the capsule marker band, as seen under fluoroscopy.
  - It may be helpful to observe handle positions during deployment if there is no relative movement of the TPV toward the DCS capsule marker band.

Advance the inner shaft to launch the distal tip.

Retract the hemostasis valve body to marry the TPV frame to the DCS capsule marker band.

If difficulty is observed (i.e., handle movement is not resulting in movement of the capsule marker band or TPV), this is an indication the capsule bond may be broken.
**Actions to Follow if a Suspected Capsule Bond Break Occurs Prior to TPV Deployment:**

**Note:** Maintain a view of the capsule marker band, distal tip, and TPV frame under fluoroscopy during the entire process of removing the Harmony DCS.

1. Pull the distal tip into the capsule (the distal tip should be nested in the radiopaque marker band on the distal end of the capsule),
2. Lock the proximal handle,
3. Re-advance the hemostasis valve body as far as possible,
4. Lock the hemostasis valve body,
5. Attempt to remove the mated tip and capsule as one unit, as detailed in 4.2.3 of the Harmony IFU.

Additional considerations:

- Do not pull the distal tip through the capsule when removing (i.e., do not over capture the distal tip) to avoid potential capsule embolization.
- If using a separate introducer sheath, attempt to pull the mated tip and capsule as one unit into the sheath. It is recommended to do this step high in the IVC so the system is straight and co-axial.
  - If resistance is encountered and cannot be determined or corrected (i.e., it is not possible to retract the capsule into the introducer sheath), the proximal end of the capsule should be abutted to the distal end of the introducer sheath.
  - The DCS and introducer sheath should be removed as one unit over the guidewire.
- Avoid pulling the proximal handle separately from the guidewire lumen to prevent pulling the TPV out of the capsule.
- Pay close attention to the location of the DCS capsule marker band in relation to the distal tip; the marker band should remain proximal to the distal tip.