Medtronic, Inc.
8200 Coral Sea Street NE
Mounds View, MN 55112
www.medtronic.com

URGENT FIELD SAFETY NOTICE
CoreValve™ AccuTrak™ Delivery Catheter System
Models DCS-C4-18Fr and DCS-C4-18Fr-23

November 2013

Medtronic Reference: FA600

Dear Physician (Hospital Administrator, OR Manager, and Risk Manager),

This notification is to inform you about practices to avoid nose cone separations from the distal end of the catheter on the CoreValve™ AccuTrak™ Delivery Catheter System (DCS). As of October 31, 2013, Medtronic has received thirty-eight (38) reported nose cone separation events (0.08 percent of implant procedures); five (5) of these reported events (0.01 percent of implant procedures) led to the need for surgical intervention. None of these events resulted in permanent patient harm; however, a nose cone separation could result in additional patient risk.

A thorough review and investigation of the reported events has identified that a majority of these reported events occurred in situations cautioned against in current labeling. In addition, Medtronic has determined that the following situations can lead to nose cone separations:

- Using the CoreValve AccuTrak DCS to retrieve (remove) a partially deployed valve.
- Removing the CoreValve AccuTrak DCS from the patient, after valve deployment, without fully closing the CoreValve AccuTrak DCS capsule.
- Continuing to pull on the CoreValve AccuTrak DCS if increased resistance is felt at the vessel introducer, the introducer's hemostatic valve, or other structure during CoreValve AccuTrak DCS retrieval.

To reduce the occurrence of nose cone separations, Medtronic is modifying the instructions for use (IFU) and training materials for CoreValve AccuTrak DCS models DCS-C4-18Fr and DCS-C4-18Fr-23; however no product returns are necessary:

1. While the DCS is in the patient, ensure the guidewire is extending from the nose cone, and do not remove the guidewire from the catheter while the catheter is inserted in the patient.
2. Once deployment is initiated, retrieval (removal) of the bioprosthesis from the patient is not recommended. Partial repositioning, if needed, should be followed per the IFU guidance.
3. Before DCS removal, ensure the capsule is closed. If the capsule does not close properly, gently rotate the catheter clockwise (<180°) and then counterclockwise (<180°) until the capsule closes.
4. If you encounter increased resistance when removing the DCS through the introducer sheath, do not force passage as increased resistance may indicate a problem and may result in damage to the device and/or harm to the patient. If the cause of resistance cannot be determined or corrected, remove the catheter and introducer sheath as a single unit over the guidewire, and inspect the catheter.

Medtronic, Inc.
8200 Coral Sea Street NE
Mounds View, MN 55112
www.medtronic.com

Medtronic recommends that physicians diligently consider these recommendations to reduce occurrences of nose cone separation events during the CoreValve implant procedure.

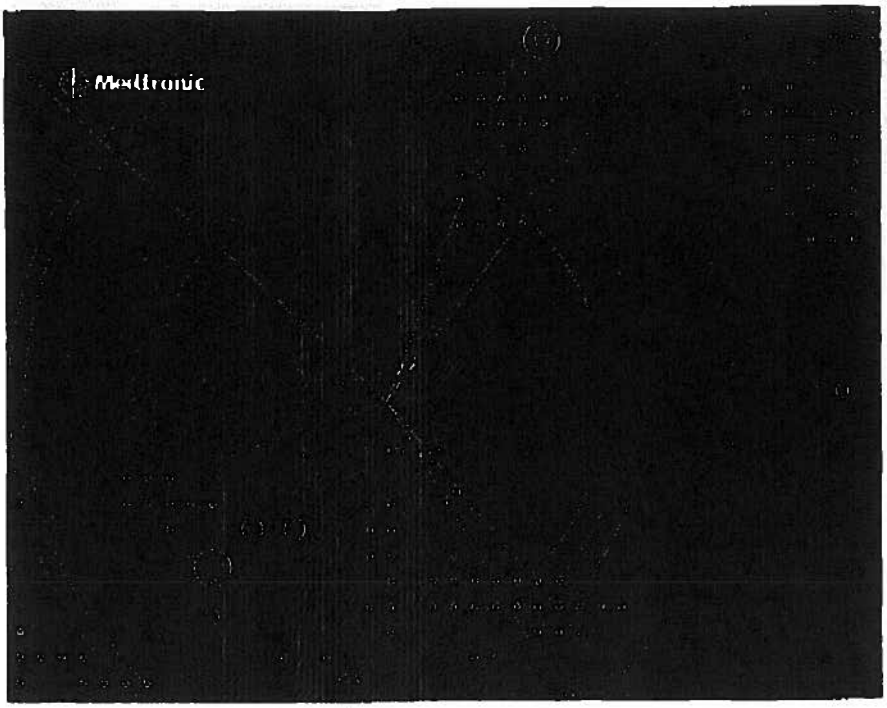
Your Medtronic Field Representative will review the new training materials with you.

The Competent Authority of your country has been informed of this action.

Please share this notification with others in your organization as appropriate. We appreciate your review of this notification and apologize for the inconvenience that it may cause. If you have any questions, please contact your Medtronic sales representative.

Sincerely,

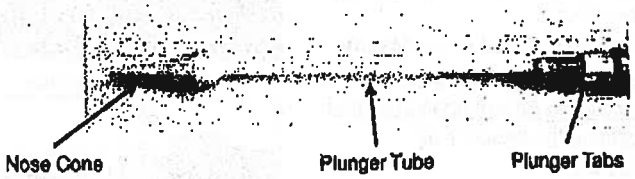
Enclosure: Training materials



Course Objectives

This course summarizes key steps to follow when removing the CoreValve DCS from the patient, including:

1. Methods to prevent nose cone separation from the DCS caused by the nose cone catching on the bioprosthesis or vessel introducer.
2. Possible retrieval techniques that could be employed if the nose cone has been separated from the DCS.



Academia
Medical Education

Medtronic

Nose Cone Separation: Description

- Nose cone separation is a rare event that can occur:
  - During withdraw from a deployed bioprosthesis, the nose cone can catch on the bioprosthesis if the nose cone has not been positioned coaxial to the bioprosthesis with the guidewire.
  - During removal through the vessel introducer, the nose cone can catch on the tip of the introducer or inside of the introducer's hemostatic valve if the capsule is not closed completely.
  - During management of a "pop-out", while using a bailout valve retrieval technique which is not recommended, the nose cone can become trapped inside a partially retrieved bioprosthesis in certain circumstances.
- If additional force is applied to overcome resistance created by a caught nose cone, the nose cone can be separated from the plunger shaft.
- In some cases, the plunger shaft may elongate before nose cone separation occurs.

Nose Cone Separation without Elongation

Nose Cone Separation with Elongation

Academia Medical Education

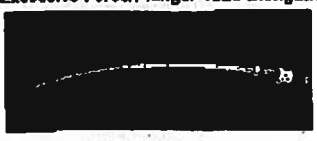
Medtronic

Potential Indicators for Nose Cone Separation

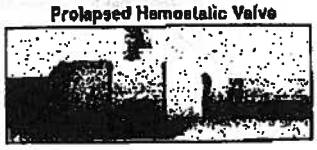
- Potential indicators for separation of the nose cone from the DCS include the following:
  - Fluoroscopic evidence of the nose cone not seated properly within the capsule
  - Increased resistance during withdraw of the DCS with (or without) noticeable elongation of the plunger shaft
  - Prolapsing of the hemostatic valve
- If any of these conditions occurs, stop applying force immediately and investigate the cause of the resistance.

Incomplete Nose Cone Seating

Excessive Force/Plunger Tube Elongation



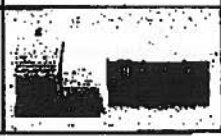
Prolapsed Hemostatic Valve



Academia Medical Education

Medtronic

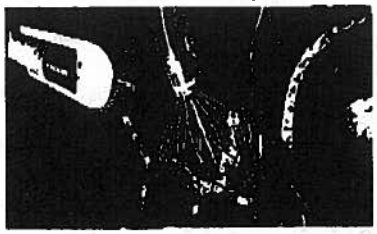
Prevention of Nose Cone Separation

Condition	Looks Like	Resolution
Nose cone not sealed properly		1. Close capsule under fluoroscopic guidance and verify the system is closed before withdrawing. 2. If the capsule does not close properly, gently rotate the catheter clockwise (<180°) and then counterclockwise (<180°) until the capsule closes.
Nose cone caught on introducer sheath		1. Advance DCS slightly forward under fluoroscopy to relieve any tension on the plunger shaft. Then, advance the capsule forward until the nose cone is sealed completely. 2. Withdraw the DCS through the introducer under fluoroscopic guidance.
Nose cone caught on hemostatic valve OR Resistance that cannot be resolved		1. Do not push or pull on the DCS. 2. Remove the DCS and vessel introducer as a single unit over the guidewire and inspect the capsule and nose cone to ensure that the DCS is complete.

Academia
Medical Education

Medtronic

Prevention of Nose Cone Separation: Withdraw DCS

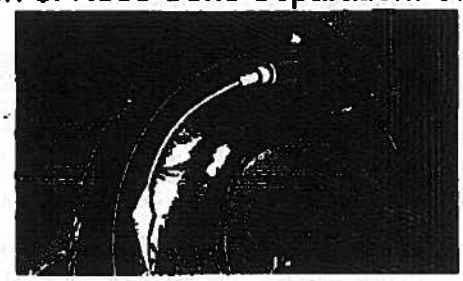


1. Confirm full release of the bioprosthesis using orthogonal fluoroscopic projections.
   - If a frame loop is still attached to a catheter tab, do not pull on the catheter; under fluoroscopy, advance the catheter slightly and, if necessary, gently rotate the handle clockwise (<180°) and counterclockwise (<180°) to disengage the loop from the catheter
2. Confirm that the catheter nose cone is coaxial with the inflow portion of the bioprosthesis.
   - If not coaxial, withdraw the guidewire until the nose cone is coaxial with the inflow portion of the bioprosthesis.
   - While the catheter is inserted in the patient, ensure the guidewire is extending from the nose cone; Do not remove the guidewire from the catheter while the catheter is inserted in the patient
3. Withdraw the capsule and nose cone from the bioprosthesis over the guidewire.

Academia
Medical Education

Medtronic

Prevention of Nose Cone Separation: Close Capsule



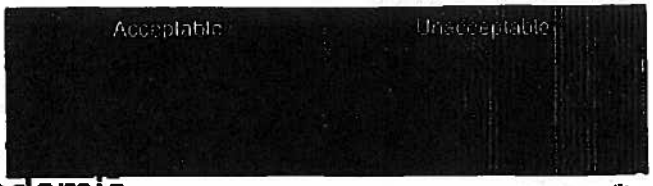
1. Withdraw the capsule and nose cone of the DCS:
   - For transfemoral access, withdraw the catheter until the nose cone is positioned in the descending aorta.
   - For direct aortic access and subclavian access, withdraw the catheter until the nose cone is close to the distal end of the introducer sheath.
2. Close the capsule by advancing the capsule towards the nose cone until it is seated into the end of the capsule.

Academia
Medical Education

Medtronic

Prevention of Nose Cone Separation: Remove DCS

1. Under fluoroscopic guidance ensure the capsule is closed before withdrawal through the introducer sheath.
   - If the capsule does not close properly, gently rotate the catheter clockwise (<180°) and then counterclockwise (<180°) until the capsule closes.
2. If increased resistance is encountered when removing the catheter through the introducer sheath, do not force passage.
   - Increased resistance may indicate a problem and may result in damage to the device and/or harm to the patient if passage is forced.
3. If the cause of resistance cannot be determined or corrected, remove the catheter and introducer sheath as a single unit over the guidewire, and inspect the catheter and confirm that it is complete.



Academia
Medical Education

Medtronic

Retrieval of a Partially Deployed Valve

- Retrieval of a partially deployed bioprosthesis may be used by some to manage a malpositioned bioprosthesis (i.e. a "pop-out");
- However, retrieval (removal) is not recommended according to the CoreValve IFU::

> ***Once deployment is initiated, retrieval of the bioprosthesis (e.g. use of the catheter) is not recommended.***
>
> ***Postdeployment, repositioning of the bioprosthesis (eg, use of a snare and/or forceps) is not recommended***
>
> ***Retrieval or postdeployment repositioning may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery.***

- If an implanter decides to attempt retrieval of a partially deployed bioprosthesis, the decision should be based on the physician's professional medical judgment of the patient's condition and the risks / benefits of attempting the retrieval.

NOTE: Partial repositioning of the valve, if needed, is allowed following IFU guidance.

Warning

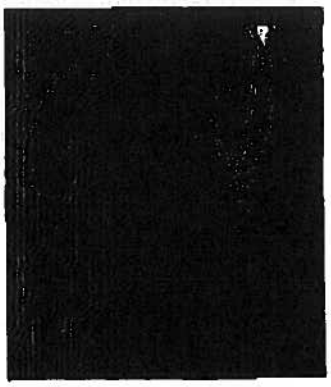
- Do not attempt to retrieve a bioprosthesis if any one of the outflow struts is protruding from the capsule.
- If any one of the outflow struts has deployed from the capsule, the bioprosthesis must be released from the catheter before the catheter can be withdrawn.

Caution

- Do not attempt to "recapture" a partially deployed bioprosthesis at any time by turning the micro-knob until the bioprosthesis has been compressed into the vessel introducer. Turning the micro-knob may damage the capsule or cause inadvertent release of the bioprosthesis – either of which could render successful retrieval impossible.
- When applying traction to the DCS to retrieve a partially deployed bioprosthesis, apply traction directly to the handle of the DCS. Do not pull on the catheter portion of the DCS.

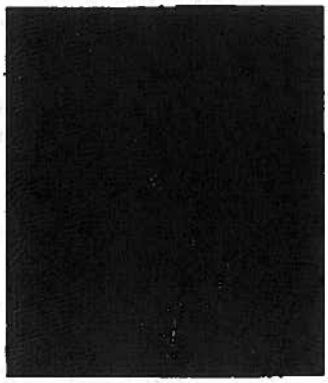
Retrieving a Partially Deployed Valve

1. Lock the DCS by applying firm upward pressure on the macro-slide lever and maintain pressure until the bioprosthesis has been withdrawn completely into the vessel introducer.
   - Do not turn the micro-knob.
2. Under fluoroscopy, withdraw the bioprosthesis to the introducer by applying traction to the handle of the DCS while maintaining position of the introducer.



Retrieving a Partially Deployed Valve

3. As the expanded portion of the bioprosthesis comes into contact with the distal tip of the introducer, apply increasing traction to the handle of the DCS while maintaining introducer position within the access vessel to compress the bioprosthesis into the introducer.
   - For transfemoral access withdraw the bioprosthesis and introducer inferior to the renal arteries before attempting to compress the bioprosthesis into the introducer.
   - It may be necessary to withdraw the bioprosthesis and introducer as a single unit into the iliofemoral vessel to aid compression of the bioprosthesis into the introducer.

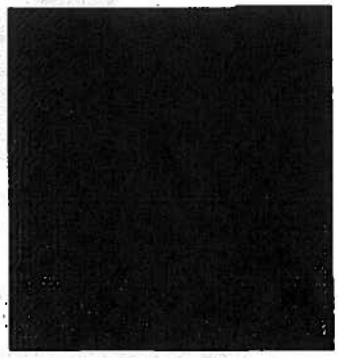


Academia
Medical Education

Medtronic

Retrieving a Partially Deployed Valve

4. Once the entire bioprosthesis is compressed into the introducer, turn the micro-knob counter-clockwise to advance the capsule over the bioprosthesis until the nose cone is seated in the end of the capsule.
   - Use fluoroscopy to verify that the capsule has closed properly and remove the DCS from the introducer.
   - If the capsule is not closed completely:
     - Do not attempt to remove the DCS through the introducer's hemostatic valve.
     - Remove the DCS and vessel introducer as a single unit over the guidewire and replace the introducer with a new one.



Academia
Medical Education

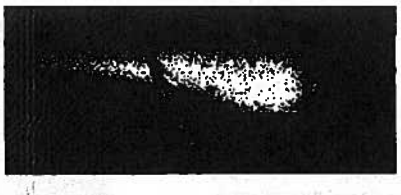
Medtronic

Inadvertent Release of Partially Deployed Valve

If the bioprosthesis is inadvertently released from the DCS while attempting to compress the bioprosthesis into the vessel introducer:

1. Stop applying force to the DCS immediately.
2. Under fluoroscopy, maintain the position of the DCS within the patient's vasculature and withdraw the vessel introducer until the entire bioprosthesis has been released from the introducer,
3. Once the the bioprosthesis has been released from the vessel introducer, carefully withdraw the nose cone into the introducer under fluoroscopy.
4. Advance the capsule to the nose cone and remove the DCS from the introducer sheath,
   - Maintain guidewire position across the released bioprosthesis during removal of the DCS from the vessel introducer.

Retrieving a Separated Nose Cone



1. If the patient's vasculature can accommodate a larger introducer, consider a 22 Fr or larger introducer to snare and retrieve the nose cone.
   - It will not be possible to retrieve the nosecone with a snare through an 18 Fr vessel introducer.
2. After the nose cone has been retrieved inside the larger introducer, remove the nose cone, snare, and introducer as a single unit over a guidewire.

Retrieving a Separated Nose Cone

If it is not feasible to insert a larger vessel introducer because of limited vessel size, or if vascular access was obtained via surgical cut-down:

1. Introduce a snare through the vessel introducer that is distal to the embolized nose cone.
2. Capture the nose cone with the snare.
3. Withdraw the nose cone, snare, and introducer under fluoroscopy as a single unit to the arteriotomy site.
4. Create or extend incision site to remove the nose cone, snare, and introducer as a single unit.
5. Repair the arteriotomy site.

Academia
Medical Education

Medtronic

Summary – Nose Cone Separation

- Nose cone separation is a rare event that can occur when the DCS is withdrawn.
- Signs that a nose cone may be at risk of separating from the DCS include:
  - Fluoroscopic evidence of the nose cone not properly sealed within the capsule
  - Increased resistance when withdrawing the DCS with / without elongation of the plunger shaft
  - Prolapsing of the hemostatic valve
- If any of these conditions occurs and the cause can not be identified or resolved, remove the DCS and introducer sheath as a single unit over the guidewire and inspect the capsule and nose cone for damage.

Incomplete Nose Cone Seating

Excessive Force/Plunger Shaft Elongation

Prolapsed Hemostatic Valve

Academia
Medical Education

Medtronic

Summary -- Retrieving a Separated Nose Cone

If a nose cone does separate from the DCS:

- If the patient's vasculature will safely accommodate a larger introducer, consider using a 22 Fr or larger introducer to snare and retrieve the nose cone.
- If it is not feasible to insert a larger introducer, or if vascular access was obtained via surgical cut-down:
  - Use the vessel introducer distal to the embolized nose cone to introduce a snare, capture the nose cone, and withdraw it into the arteriotomy site.
  - Create or extend the incision and remove the nose cone, snare, and introducer as a single unit.

Academia
Medical Education

Medtronic