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Urgent: Medical Device Correction

EverFlex™ Self-Expanding Peripheral Stent with Entrust ™ Delivery System

Instructions for Use Updates

Product Name	Model Numbers	Lot Identification
EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System	All Models	All Lots

15 July 2022

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Risk Manager/Health Care Professional,

Please share this notice with your physician users.

Medtronic is writing to inform you of an update to the Instructions for Use (IFU) for the EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System (herein referred to as EverFlex Entrust). This update provides a validated manual deployment workaround method to help mitigate potential harms related to the low risk of partial stent deployment.

Note: There are no product retrievals or disposals requested by Medtronic.

In a 3-year period between 01-May-2019 and 30-Apr-2022 there were eighty-seven (87) reported occurrences of partial stent deployments (0.049% occurrence rate). This occurrence rate is below the rate predicted in product risk management documentation. Fifty-seven (57) of these events resulted in no or negligible patient harm (0.032% rate). Nine (9) of these events resulted in minor harm (0.005% rate) such as secondary endovascular procedure and twenty-one (21) of these events resulted in major harm (0.012% rate) such as surgical conversion. Potential major harms associated with partial deployment include embolism, occlusion/ischemia, vessel perforation, rupture, blood loss, and secondary intervention such as an additional endovascular procedure or

surgical conversion. Higher friction forces may occur in longer stent lengths and Medtronic has observed the rate of partial stent deployment is higher for longer stent lengths, such as the 150mm length stent.

There were no patient deaths, and no permanent impairment harms associated with this issue.

No complaints received have been determined to be related to manufacturing.

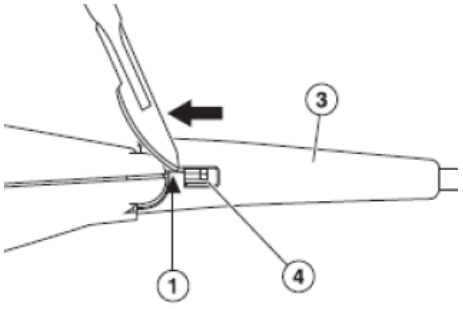
Medtronic has completed validation testing for the manual deployment workaround method update being added to the EverFlex Entrust IFU and included in this letter. These instructions should **only** be followed in the event a partial stent deployment occurs. Medtronic is taking this action to reduce the severity of potential patient harms. The steps provided below are intended to reduce or avoid the need for secondary or surgical intervention– in the event of partial stent deployment.

Please Note: in a no deployment situation, the device should be removed per the instructions for use (IFU) recommendations and disassembly should not be attempted.

EverFlex Entrust IFU Updates for Manual Deployment Workaround Method:

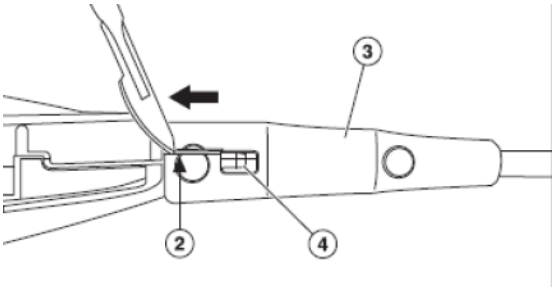
In the unlikely event of a delivery system failure, where the stent is partially deployed and the thumbwheel is unable to rotate, the following steps may solve the issue to successfully deploy the stent:

1. *Ensure that the safety locking pin is completely removed from the delivery system, and there is no slack in the system.*
2. *Separate the gray strain relief from the handle using an 11-blade scalpel to cut the gray strain relief on the top and bottom of the handle. Cut from the white tabs toward the handle. See Figure 1and Figure 2.*
   ***Note:** Do not cut beyond the white tabs. Cutting beyond the white tabs may cut into the catheter, causing damage to the catheter.*
3. *Use a hemostat to slide the strain relief down the catheter and away from the handle. See Figure 1and Figure 2.*
   ***Caution:** Failure to hold the delivery system in a fixed position may cause the stent to foreshorten or lengthen.*



1. Top cut line
3. Grey Strain relief
4. White tabs

Figure 1. Strain Relief cut location (top of device)



5. Bottom cut line
6. Grey Strain relief
7. White tabs

Figure 2. Strain Relief cut location (bottom of device)

4. *Locate the seam that runs along the length of the handle. Open the two halves of the handle by separating the halves at the open safety locking pin location. Use a hemostat if necessary.*
5. *Set aside the two halves of the handle.*

6. *Keep the inner shaft and delivery system stable.*
7. *Hold the gold isolation sheath with one hand, and use the other hand or a hemostat, to grip the cable that is attached to the outer sheath.*
8. *Pull back the cable, moving the outer sheath until the stent is fully deployed. If resistance is encountered, stop this workaround.*
9. *Once the stent is fully deployed, remove the delivery system from the patient.*

There are no actions required for patients where EverFlex Entrust was previously used during a procedure. **There are no product retrievals or disposals requested by Medtronic and product can continue to be used in accordance with the IFU and the above instructions.**

Customer Instructions:

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

- Please review the upcoming updates to the IFU in this letter
- Please share this notice with all those who need to be aware within your organization or to any organization where the products have been transferred
- Please complete the enclosed Customer Confirmation Form and hand back or scan then email back to your local Medtronic field representative.

Medtronic will notify all applicable regulatory agencies about this matter. This letter serves as a notification for your records regarding the upcoming updates to the EverFlex Entrust IFU; no further actions are needed.

Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic field representative.

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 local Medtronic field representative.

Sincerely,

DocuSigned by:

Signer Name: Diana Teo
Signing Reason: I approve this document
Signing Time: 13 July 2022 | 18:46 SGT
05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead

Singapore & Malaysia

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 14 July 2022 | 14:58 SGT
90D0724C9B1C402A99B286449A1644B8

Medtronic QRA Lead

Indochina & Frontier Markets Plus

DocuSigned by:

Signer Name: Parichart Bunjobchokchai
Signing Reason: I approve this document
Signing Time: 15 กรกฎาคม 2022 | 15:27 SEAST
1EE8203B3B0D401EAAC8FA853EBB987A

Medtronic QRA Lead

Thailand

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Customer Confirmation Form

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Instructions for Use Updates

For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately

Medtronic is asking that you sign and date this form to acknowledge receipt of the enclosed letter.
Note: The addressee may continue to receive reminders of this notice until a response is received.

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

By signing this form, I confirm that I have read the Urgent Medical Device Correction Notification Letter, dated 15 June 2022, from Medtronic regarding the EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System Instructions for Use updates listed above and will take appropriate action.

Name (print): _____ Signature: _____ Stamp: _____ Date: ☐☐ DD ☐☐☐ MMM ☐☐☐☐ YYYY