Executive Summary

This Issue Impact Assessment (IIA) was initiated due to product complaints received from the field for the DxTerity diagnostic catheter. A total of 6 complaints for mislabeled 5F product as 6F were received on February 7th, 2018. No other complaints have been received as of March 5th, 2018.

All 6 complaints were received from Germany. All 6 complaint devices are being returned. A root cause investigation is in the process of being completed. Based on the root cause investigation performed so far, it is likely that an operator issued the correct label stock (5F) in the ERP but physically used the incorrect stock (6F) during manufacturing of DxTerity lot 60074805. CAPA PR 379804 has been opened to further investigate the root cause and document corrective actions.

There has been no patient safety impact due to any of the six "mislabeled" complaints. The most likely harm expected from this failure mode is further delay in procedure time, however this delay would be clinically insignificant and therefore patient harm is unlikely to occur. The clinically insignificant delay in procedure time is likely to result in customer dissatisfaction (user annoyance). Swapping of catheters during an intravascular procedure is a common occurrence in a catheterization laboratory. It does not pose any additional safety risk to the patient. However, based on the compliance risk of having mislabeled/misbranded product in the field, FCA number CVG-18-Q4-17 will be initiated to retrieve the impacted product lot 60074805 from the field.

Assessment Information

Location:	Medtronic, Inc. Design Site: Santa Rosa, CA Contract Manufacturer: Flex Medical, Tijuana Baja California, Mexico
Author:	Refugio Ortiz
Date:	February 7, 2018
Issue Title:	DxTerity™ Mislabel Issue
Issue Source(s):	The issue was found from field complaints. Appendix 1 lists all the complaints received to date for this issue.

Product Information

Brand Name:	DxTerity™ Diagnostic Catheter
Model Number(s)/ Catalog Number(s):	DXT5JL40
Regulatory Classification	FDA Regulatory Status: MDD Regulatory Class: Class III 510(k)/PMA Number: 510K- K161287 FDA Product Code: DQO
Product Description & Usage:	The DxTerity diagnostic catheter is indicated for cardiac and vascular procedures. It is designed to deliver radiopaque media, guidewires, and therapeutic agents to selected sites in the vascular system. The different configurations of the

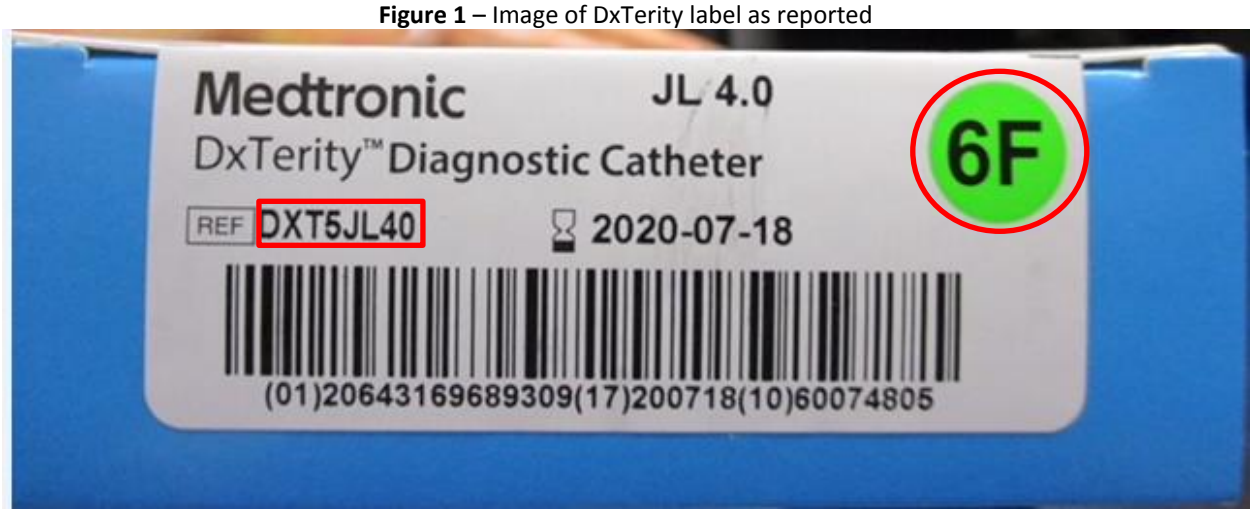
	diagnostic catheter are designed to be used in arteries from access sites such as the radial, brachial, and femoral arteries.

Section 1: Issue Identification

Issue Description:

On February 7, 2018, Medtronic was notified by two accounts of a 5F DxTerity catheter (item DXT5JL40 – 5F Judkins Left 4.0 curve) with a green 6F indicator on the carton label (see figure 1). As a 5F item, the French size indicator should be a grey 5F indicator. Complaints PE 0702353420 and PE 0702355495 were initiated.

Figure 1 – Image of DxTerity label as reported



- The catheters inside in the carton are the correct DXT5JL40 item and all other information and configuration details are correct.

Medtronic CAPA PR 378122 has been opened to further investigate the issue and to document any additional corrective actions.

Field Complaints (US and International):

As of March 5, 2018, a total of 6 DxTerity "mislabeled" complaints have been received since commercial launch.

As of Date: March 5, 2018	**Total Number of Complaints Related to Issue**: 6	
	Number of Complaints	**Number of FDA MDRs/Vigilance Reports**
US	0	0
International	6	0

Reference Appendix 1 for additional information on the complaints received to date. No adverse event has been reported with any of the complaints received. The devices were not used upon realization of the fault condition.

Issue Scope and Rationale

The scope of the issue is confined to all devices manufactured prior to August 23, 2017 which is the implementation date for the corrective actions per Flex CAPA CA-TQ000020. In order to better understand the scope of the issue Medtronic performed sampling and inspection activities of product under Medtronic control at distribution centers in the United States.

- **Time-Based Sampling/Inspection:**
  To increase certainty that this specific defect was not time-based (specific operator/shift related, specific period of time, etc.), material on-hand at Medtronic's Memphis, TN Distribution Center manufactured within one (1) week of lot # 60074805 was 100% visually inspected for carton label mislabeling defects/issues. The activity consisted of reviewing all on-hand 5-pack carton labels from 4 lots before and 4 lots after the subject lot to ensure that the information contained on the label stock matches the variable, printed CFN on the label the inspection confirmed the French size within the CFN aligns to the French size printed on the label stock.

- **Additional Sampling/Inspection:**
  According to Process FMECA for Diagnostic Catheter Products (DxTerity) 10181990DOC, the potential failure mode of "Missing or Incorrect Information on Label" may result in Zone 1 clinical effects/risks. Per statistical sampling guidance contained in Design Characterization and Verification Procedure (CVSOP013), Attribute Agreement Test Method Validation (10082327DOC) and Purchased Product Sampling Plan Determination (10196035DOC) procedures, Zone 1 risks require sampling plans utilizing 90% confidence and 90% reliability minimum. To provide additional confidence, a c=0 attribute sampling approach was selected using 95% confidence and 95% reliability (n=59 lots) at 100% frequency.

  Specifically, 59 lots were selected from a higher risk sub-population of 160 lots provided by Flex Medical. This sub-population included lots which were determined (via a review of in-process scanning/manufacturing data) to have had a manufacturing stoppage of >3 minutes. While this does not indicate the label stock was changed, it presents an opportunity (Flex confirmed minimum time required to change label stock was >3 min). The inspection was conducted using the same method indicated above.

- **Results:**
  Additional sampling and inspection activity has been completed. A total of 5,425 carton labels were inspected in accordance with the method indicated above – 870 reviewed during time-based inspection and 4,555 during additional "at-risk" sun-population inspection. There were zero discrepancies/failures detected during either inspection.

Total number of Impacted Devices:

Based on the results of the inspection above, the implementation of corrective actions performed by Flex Medical, and no complaints received to date for any other DxTerity lot for either a carton label or pouch label issue, the scope of the issue is deemed limited to DxTerity lot 60074805. There is a total of 1495 units in this lot (299 5-packs).

Are any subpopulations of devices at higher risk?

☐ **Yes. Subpopulations:**

☒ **No**

Rationale: Based on the investigation performed to date, no subpopulations of devices within the bounded scope of one impacted DxTerity lot 60074805 are at greater risk.

Predicted rate of occurrence of this issue and number of occurrences

Sampling of units within Medtronic control of DxTerity lot 60074805 has shown that out of 115 5-packs inspected, 60 5-packs were labeled as 6F and 55 were labeled as 5F. applying this percentage of 52.17% mislabeled 5F 5-packs as 6F 5-packs, the total number of mislabeled 5-packs is (299 * 0.5217) = 156 5-packs.

The occurrence rete of the issue within lot 60074805 would be (156/299) * 1000,000 = 521,739 CPM

Section 2: HHA Section: Hazard / Harm / Other Factors

Hazard and Hazardous situation:

The hazardous situation associated with this issue is:

- The physician intends to use a 6F device, but the actual device is a 5F catheter that was mislabeled as being 6F.

The resulting hazard would be that the wrong product or size was selected:

- Actual diameter is smaller than labeled.

Harm(s):

No harms or patient injury has been reported as a result of the mislabeling complaints.

Dr. Sidney Cohen, Sr. Clinical Medical Advisor, Coronary/RDN was consulted to review these potential harms and determine which of the harms would be related to the specific clinical scenario resulting from the mislabeling. For this scenario where the actual device is smaller than intended, Dr. Cohen stated that it was unlikely that the physician would notice that a smaller catheter was being used, as there would be no dimensional interference resulting in an inability to cross the sheath and the performance of the 5F and 6F DxTerity catheters are very similar. At most, if the physician were to notice, they would have to make the decision to continue using the 5F catheter or exchange for a 6F, resulting in the potential harms of Physician Annoyance and Longer Procedure Time.

It should be noted that the further delay in procedure time referenced above, would be clinically insignificant and therefore patient harm is unlikely to occur. The clinically insignificant delay in procedure time is likely to result in customer dissatisfaction (user annoyance). Swapping of catheters during an intravascular procedure is a common occurrence in a catheterization laboratory. It does not pose any additional safety risk to the patient.

The only device that would be passed through the lumen of the diagnostic catheter would be when the physician

is conducting a fractional flow reserve (FFR) measurement in conjunction with the diagnostic catherization. As the FFR devices are guide-wire based, there is no issue presented when using a 5F diagnostic catheter.

Are any subpopulations of patients at higher risk?

☐ **Yes. Subpopulations:**

☒ **No/ Unknown**

Rationale: Per the information available to date, no subpopulations of patients are at a higher risk.

Exacerbating Factors:

Per the information to date, there are no conditions or factors which may contribute to, or exacerbate, the Hazard/Risk.

Mitigating Factors:

- Section 4.1, M052478T001 (DxTerity Diagnostic Catheter IFU):
  - "Carefully inspect the diagnostic catheter before use to verify that the size, shape, and condition of the catheter are suitable for the intended procedures."
  - "Select a diagnostic catheter with optimal tip shape and optimal size, taking into account the access site, the target site, and the patient's anatomy."
- Section 6 Step 3, M052478T001 (DxTerity Diagnostic Catheter IFU):
  - "The diagnostic catheter may be introduced into the selected vessel by cutdown technique, Seldinger technique, or introducer methods. When using an introducer, ensure that it is a French size greater than or equal to the selected diagnostic catheter."
- The hub of the DxTerity catheters are color-coded for each French size: 5F catheters have a grey hub, and 6F catheters have a green hub.
- For this complaint, the carton label stock was incorrect, while the pouch labels were correct. Frequently, the diagnostic catheters are removed from their shelf carton and stored as individual pouches, which are correctly labeled.

Severity of Harm:

The following is a list of the harms and corresponding severities that may potentially occur resulting from the two hazardous situations described in the Harms section.

Table 3 - Severity of Harm

Potential Clinical Effect	Predicted Severity per DFMECA 10165393DOC	Predicted Severity per PFMECA 10165393DOC	Severity per Review with Dr. Rothman
Physician Annoyance	4	4	4
Prolonged Procedure	6	6	5

Occurrence of Harm:

Per 10191345DOC, the occurrence of harm is the product of two probabilities:
P1= Probability that the hazardous situation occurs
P2 = Probability that the hazardous situation will result in harm

P1
As of March 5, 2018, 6 complaints have been received for mislabeled product. No specific hazardous situations were reported as part of these complaints. As explained above the probability of the hazardous situation occurring within the impacted lot is estimated to be 521,739 CPM.

P2
To date none of the 6 complaints received for this issue have resulted in a harm. In all complaints filed so far, the issue has been identified prior to the product being used. It is possible that mislabeled devices have been used in the field without the user detecting the issue. A total of 825 units (165 5-packs) have been sold from lot 60074805. Assuming that a third of the units have been used in the field (275 units), based on the estimated 52.17% mislabeled product rate, it is expected that a total of 143 mislabeled units have been used in the field.

In order for the hazardous situation of having a mislabeled product lead to a harm of Physician annoyance or prolongation of procedure the issue must be detected by the user during use. Out of the estimated 143 mislabeled units that have been used in the field, a total of 6 units have been detected prior to use. As a conservative measure it will be assumed that the 6 units were identified during use. As a result P2 = (6/143) * 1000,000 = 41,958 CPM.

It should be noted that for a mislabeled product to be used, the following must occur:

- The user does not detect the discrepancy of the carton label having contradictory variable print vs pre-printed information (5F vs 6F or vice versa).
- The user does not take the product out of the 5-pack carton and places it in their shelves prior to use.
- The user does not notice that product information on the pouch label correctly identifies the product as 5F when selecting what device to use.
- The user does not notice the color of the hub being grey (5F) and not green (6F).

Summary of risk(s) considering all harms and occurrences in above sections:

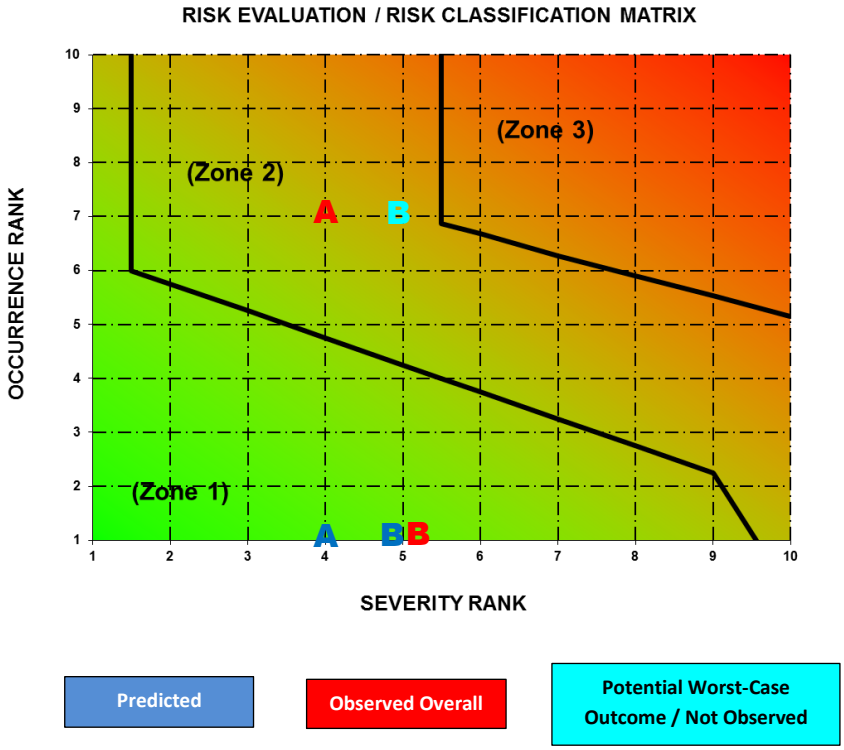
Patient Populations	Hazard	Probability of Hazardous Situation (p1)	Harm *(As defined by Master list of harms)*	Probability of Hazardous Situation Leading to Harm (p2)	Probability of Harm (p1xp2)	Harm Occurrence Category *(As defined by the BU)*	Severity Rank of Harm *(per Policy 034)*	Risk Zone *(per BU risk matrix)*
General	Actual diameter is smaller than labeled.	0.5217391	Physician Annoyance	0.0419580	0.0218911	7	4	2
		0.5217391	Prolonged Procedure	0.0419580 (worst case / not observed)	0.0218911	7	5	2
				0 (actual / observed)	0	1	5	1

Other Factors

Not applicable

Section 2.2: HHA Summary Section

Patient Safety Risk:



A **Physician Annoyance (No patient Safety Risk)**

B **Prolongation of procedure time**

Patient Safety Risk:

No Risk ☐	Low / Risk Zone 1 ☐	Medium / Risk Zone 2 ☒	High / Risk Zone 3 ☐

Overall Risk Summary and Acceptability

The overall patient risk associated with DxTerity lot 60074805 has not been impacted by this issue due to the following:

- The contents of the pouch label are correct and frequently the diagnostic catheters are removed from their shelf cartons and stored as individual pouches at the accounts.
- The hub of the DxTerity catheters are color-coded for each French size: 5F catheters have a grey hub, and 6F catheters have a green hub.
- There are instructions in the IFU to inspect the diagnostic catheter before use to verify the size.
- No harms or patient injury has been reported because of the mislabeling complaints.
- There is no impact on the performance of a 5F DxTerity diagnostic catheter when used instead of the intended 6F size DxTerity diagnostic catheter.
- The issue is only expected to result in “physician annoyance” and “longer procedure time”; however,

Section 2.2: HHA Summary Section
the delay in procedure time would be clinically insignificant and would not pose any additional safety risk to the patient. The issue results in an increased quality/regulatory compliance risk associated with DxTerity lot 60074805 as mislabeled product from this lot has been distributed to the field.

Section 3: Actions and Conclusions	
CAPA Initiated?	☒ Yes, PR 378122 ☐ No,
PHO Initiated?[1]	☒ Yes, 2082-PHO ☐ No Rationale: ☐ To be determined by the BU review board process.
Initiate Actions to Manage issue/mitigate risk in the field?	☒ Yes[2] FCA number CVG-18-Q4-17 will be initiated to retrieve the impacted product lot 60074805 from the field. ☐ No, Rationale: ☐ Insufficient Data to Make a Decision(s). A new IIA revision is required to finalize document. ☐ To be determined by the BU review board process
IIA Reassess Threshold	This IIA will be reassessed if further investigation performed per CAPA PR 378122 or complaint data significantly changes the scope of the population impacted by this issue. This action will be tracked in the CAPA and Danvers Product Evaluation Committee meetings.

[1] Refer to Policy 006, *Product Hold Orders (PHO)*
[2] If action is taken consider Policy 004, *Field Corrective Actions* and Policy 115, *Corrections and Removal*.

Update of Risk Management Files (if applicable) recommended?	The risk management documentation predicts this issue. Reference DFMECA 10165393DOC and PFMECA 10165393DOC. No updates are required for these documents based on this issue. **System that will contain evidence of completion**: N/A

Section 4: Approval Requirements

	HHA summary		Actions to manage issue/mitigate risk in the field		
Function/Roles **Note**: one individual may potentially fulfill multiple approver functions. **Column 1**	**Zone 1, 2 and 3 Patient Risk** **Column 2**	**No Patient Risk** **Column 3**	**Yes** **Column 4**	**No/ Insufficient data** **Column 5**	**To be determined by the BU review board process[3]** **Column 6**
Author	**Required**	**Required**	**Required**	Follow Approval requirements based on HHA summary- (Columns 2 and 3)	Follow Approval requirements based on actions to be taken in the field (Columns 4 and 5)
Immediate Manager	**Required**	**Required**	**Required**		
Dir. Of Quality (Post Market Quality for BU)	**Required**	**Required**	**Required**		
VP of Quality/ BU Quality Leader	**Required**	**Required**	**Required**		
Regulatory Management Representative [Ex: VP, Director]	**Required**	**Required**	**Required**		
BU Medical Safety representative / Personnel with Clinical Knowledge	**Required**	**Required**	**Required**		
Subject Matter Expert (If different from Author) *[ex: CAPA Owner]*	**Required**	**Required**	**Required**		
Medical Director or Medical Safety Designee	**Required**	Not Required	**Required**		
Legal Counsel	Not Required	Not Required	**Required**		
Dept. Mgmt. Marketing	Not Required	Not Required	**Required**		
Global SVP – Quality and Strategic Scientific Operations	**Notification required for Zone 3 with no**	Not required	Not required	**Notification required for Zone 3 and no**	

[3] Applicable only for those BU's that have a review board process.

Section 4: Approval Requirements

	FCA			**FCA**	
Group-Level Chief Safety Officer	**Notification required for IIAs with observed severity 3 or higher (5 point scale) with no FCA.**	Not required	Not required	**Notification required for IIAs with observed severity 3 or higher (5 point scale) with no FCA.**	

Each BU may include additional approvers as deemed appropriate (e.g., Legal Counsel or qualified representative, Post-Market Quality representative, etc.).
For administrative updates, only the Author and Immediate Manager are required approvers.

Appendix 1: Complaints

PE - PLI #	Country	Lot Number	Product Quantity	Primary Code
0702353420-10	Germany	60074805	1	Mislabeled
0702353420-20	Germany	60074805	1	Mislabeled
0702353420-30	Germany	60074805	1	Mislabeled
0702353420-40	Germany	60074805	1	Mislabeled

0702353420-50	Germany	60074805	1	Mislabeled
0702355495-10	Germany	60074805	1	Mislabeled