Medtronic Ireland Ltd,
Unit G
Swords Business Campus
Balheary Road
Swords
Co.Dublin
Tel 01 511 1400
Fax 01 807 7220
www.medtronic.com
vat IE 9513488W

URGENT FIELD SAFETY NOTICE

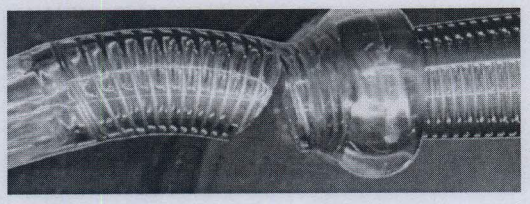
Medtronic® Select 3D™ and Select CAP™ Arterial Cannula
Model Numbers (All Lots)
78618, 78620, 78622, 78624, 78718, 78720, 78722, CB78722, 78724, 78818, 78820, 78822, 78920, 78922, 78924, 3Y90R3, C300901B
Recall

Medtronic Reference: FA604

31 January 2014

Dear Healthcare Professional,

Medtronic is initiating a voluntary Urgent Medical Device Recall for all models of its Select 3D™ and Select CAP™ Arterial Cannula product families due to reports of the cannula body splitting near the suture collar similar to that shown in the photo below. Since January, 2012, Medtronic has received nine (9) such reported events which represent a 0.06% occurrence rate. **Of these, one (1) was associated with a patient death and one (1) other was associated with serious injury.**



Potential patient harms resulting from this type of splitting may include:

- The delivery of inadequate blood flow, possibly resulting in ischemia or inadequate perfusion.
- Difficulty in inserting/removing the cannula tip, possibly resulting in a procedural delay, vessel damage, dissection or other complications that may contribute to patient death.

Our records indicate that your facility has received affected product. As a result, Medtronic is asking that you take the following actions:

1. Immediately identify and quarantine all affected product in your inventory.
2. Return all affected product in your inventory to Medtronic. Your Medtronic Sales Representative will assist you with the return of this product.

Select 3D and Select CAP Arterial Cannula are not available for purchase at this time. Please contact your Medtronic Sales Representative at 01 511 1400 to assist with alternative cannula selection and any additional questions you may have related to this notification.

Medtronic has notified the Irish Medicines Board of this recall.

Please share this notification with others in your organisation as appropriate. We appreciate your cooperation with this matter and apologise for the inconvenience that it may cause.

Yours sincerely,

LJ Bridge

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager – UK & Ireland