

Urgent Field Safety Notice
Bio-Medicus™ Insertion Kits
 Incorrect Labeling - Recall

Product Description	Model #	Lot #
Bio-Medicus™ Insertion Kit	96551	220641720
Bio-Medicus™ Insertion Kit	96553	220719040

September 2021



Medtronic Reference: FA1193

Dear Risk Manager, Health Care Professional,

Medtronic is writing to inform you of incorrect labeling for two manufactured lots of the Bio-Medicus™ Insertion Kits for the models and lot numbers listed above. Medtronic records indicate you have received at least one of the listed products. No other product model or lot numbers are affected by this issue.

During manufacturing of the two listed lot numbers, product for model 96551 was labeled as model 96553 and product for model 96553 was labeled as model 96551. See figure 1 below for correct product model descriptions.

Figure 1: Differences in Bio-Medicus™ Insertion Kits models 96551 and 96553

Model #	Image of Product	Visual (Naked Eye) differences	Actual differences
96551		3 dilators	3 dilators Guidewire is 0.038" OD and 180 cm (70") in length
96553		2 dilators	2 dilators Guidewire is 0.025" OD and 60 cm (23") in length

As of August 25, 2021, Medtronic has received twelve (12) customer reports where the Bio-Medicus™ Insertion Kits have the incorrect guidewire. In ten (10) of the twelve (12) field reports, the incorrect guidewire was found prior to use and the guidewire was subsequently replaced prior to the procedures. In two (2) of the twelve (12) events reported, the incorrect guidewire was found during the procedure, and similarly, the guidewire was replaced for completion of the procedure. One (1) of these two (2) events resulted in a surgical repair of the initial guidewire insertion site with no additional patient harms reported. The potential harm when the mislabeling is identified prior to use is procedure delay while an appropriate Insertion Kit is located. If the mislabeling is not identified prior to use, and the clinician uses the incorrect guidewire or incorrect dilator from the mislabeled kit, there is potential for harm due to blood loss during the procedure. There have been no reported adverse patient consequences associated with this issue.

For affected product that has been used, no action is necessary, and patients should continue to be managed in accordance with your standard patient management protocol.

Customer Actions:

To mitigate risks associated with this issue, Medtronic is requesting that you carry out the actions below:

- Please review your inventory for listed product.
- Immediately identify and quarantine all unused, listed product in your inventory.
- Return the impacted products to Medtronic. Your Medtronic representative can assist in facilitating the return of product as necessary. If alternative product is needed, your Medtronic representative can assist you with identifying suitable replacement product.

Please share this notification with others in your organization as appropriate. If product within scope has been forwarded to another facility, please notify the facility of the Urgent Field Safety Notice.

Please maintain a copy of this communication in your records. Medtronic has notified the Competent Authority of your country of this action.

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, please contact your Medtronic Representative.

Sincerely,