



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

Urgent Medical Device Customer Notification

Symplicity™ Catheters Model RDN006

January 22, 2013

Dear Health Care Provider , Risk Manager or Hospital Administrator:

In response to reports of issues with the connector for the Symplicity™ Catheter (Model RDN006) , Medtronic is distributing this notification to inform you of methods to detect the failure and guidance to minimize inconveniences to you and your patients.

Please note, there have been no reported patient injuries resulting from these connection failures, nor are there any expected. The result of these connection failures is the potential need during the procedure to replace the catheter to successfully complete the renal denervation procedure.

Our investigation has determined that all lots of Symplicity Model RDN006 manufactured prior to November 30, 2012, are potentially affected. Medtronic has observed a connection issue complaint rate of approximately 5% of devices provided since enrollment of the Symplicity™ HTN3 trial began. These connection issues cause unstable temperature readings or lack of signal to the generator. In events where a connection failure leads to unstable temperature reading, the generator's safety algorithm is triggered and energy delivery is terminated, or if there is a lack of signal to the generator, it will not initiate treatment, thus in either situation protecting the patient from unsafe treatment.

These connection issues manifest in one of the following ways:

- a flickering generator display screen upon initial catheter connection
- generator status display of "check connection"
- rapid fluctuations in the temperature reading
- multiple early termination of energy delivery accompanied by "check status" safety codes 22, 23 and/or 32 despite confirming electrode placement as defined by the IFU.

Medtronic recommends the following actions:

Per the IFU, connect the catheter into the generator prior to inserting into the patient. If you observe any of the conditions above, follow the steps below:

1. Assure the catheter connector plug is fully seated into the generator by unplugging and re-plugging the catheter. If this resolves the issue, continue with treatment.
2. Gently wiggle the connector plug. If this resolves the issue, continue with treatment.
3. If the issue remains, replace the catheter. Complete the applicable product return form(s) and return the catheter to Medtronic for investigation in accordance with normal complaint handling procedures.

Medtronic has determined the main cause of the poor connection is related to variation in the catheter's connector plug assembly and is not specific to any catheter lots. To address this issue, Medtronic has developed a new catheter connector. No connection issues specific to the generator have been identified, thus Medtronic does not recommend changing generators.

We apologize for any inconvenience this issue may cause you or your institution and do appreciate your prompt attention to the requested actions. Please contact your Medtronic RDN representative Gulf Medical Co. Ltd. Tel : 96626512828

to provide information regarding availability of Symplicity catheters with the new cable connector and to answer any other questions you may have concerning this issue.

Sincerely,

Moussa Srour
Senior Director CardioVascular