

# Medtronic Recalls Rashkind Balloon Septostomy Catheters for Quality Issues

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

## Recalled Product

- Rashkind Balloon Septostomy Catheter
- Lot Numbers: See the Recall database entries below for lot numbers
- Product Numbers: 008764, 007160, and 007161
- Distribution Dates: May 28, 2018 to August 28, 2020
- Devices Recalled in the U.S.: 142
- Date Initiated by Firm: August 25, 2020

## Device Use

The Rashkind Balloon Septostomy Catheters are used to create an atrial septal defect (<https://www.mayoclinic.org/diseases-conditions/atrial-septal-defect/symptoms-causes/syc-20369715>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) or to enlarge an existing atrial septal defect as a treatment option for patients with Cyanotic Congenital heart defects (<https://medlineplus.gov/ency/article/001104.htm>).

## Reason for Recall

Medtronic Inc. is recalling Rashkind Balloon Septostomy Catheters because of device quality issues that may lead to the device breaking, separating or failing during use. If this occurs, use of the affected product may cause serious adverse health consequences such as damage to blood vessels (vascular injury) and death.

There have been two reported injuries and one death.

Additionally, Medtronic has stopped the manufacturing and distribution of Rashkind Balloon Septostomy Catheters due to reasons unrelated to this recall.

## Who May be Affected

- Health care providers using the affected Rashkind Balloon Septostomy Catheters
- Patients undergoing procedures using the affected catheters

## What to Do

On September 9, 2020 Medtronic sent an Urgent Medical Device letter to all affected customers with the following instructions:

- Identify and quarantine all unused Rashkind Balloon Catheters affected by the recall.
- Return all unused affected product in your inventory to Medtronic. Contact Medtronic Customer Service at 1-888-283-7868<sup>5</sup> to initiate a product return. Your local Medtronic Representative can assist you in the return of this product.
- Complete the Customer Confirmation Form attached to the notice and email it to [RS.CFQFCA@medtronic.com](mailto:RS.CFQFCA@medtronic.com) (<mailto:RS.CFQFCA@medtronic.com>).
- Forward this notice to all those who need to be aware within your organization.

## Contact Information

Customers who have questions about this recall may contact Medtronic Customer Service by phone at (888)-283-7868<sup>5</sup>.

## Additional Resources:

- Medical Device Recall Database Entry Rashkind Balloon Septostomy Catheter, 6f (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=183535>)
- Medical Device Recall Database Entry Rashkind Balloon Septostomy Catheter, 5f (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=183685>)
- Medical Device Recall Database Entry Rashkind Balloon Septostomy Catheter, 4f (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=183686>)

## How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.