

Boston Scientific Corporation Recalls VICI VENOUS STENT System and VICI RDS VENOUS STENT System for Potential of Stent Migration

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

- VICI VENOUS STENT System (VICI SDS) and VICI RDS VENOUS STENT System
- Models and Serial Numbers: [See Medical Device Recall Database Entry](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186851) (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186851>).
- Distribution Dates: September 21, 2018 to April 9, 2021
- Devices Recalled in the U.S.: 31,798
- Date Initiated by Firm: April 12, 2021

Device Use

The VICI SDS and VICI RDS VENOUS STENT Systems are intended for the treatment of obstructions and occlusions in the narrowed or blocked venous veins.

Reason for Recall

Boston Scientific is recalling the VICI SDS and RDS VENOUS STENT Systems after reports indicate that the stents may migrate or move from where they are initially implanted.

A migrated stent may require another surgery or catheter procedure to retrieve it, which increases risks to the patient, including possible damage to the blood vessel, heart walls or other organs. If the stent migrates to the heart, it could cause life-threatening injury.

There have been 17 complaints and reported injuries related to this issue. No deaths have been reported.

Who May be Affected

- Health care providers using the VICI VENOUS STENT System and VICI RDS VENOUS STENT System

- Patients who have a procedure using the VICI VENOUS STENT System or VICI RDS VENOUS STENT System

What to Do

On April 12, 2021, Boston Scientific Corporation sent an Urgent Medical Device Recall Notification to customers asking them to:

- Immediately discontinue use of the device
- Remove all affected units from inventory and secure them
- Complete the company's Verification Form to acknowledge receipt and report products that will be returned
- Package affected products for shipping and contact the local Boston Scientific representative to arrange for their return

Contact Information

Customers with questions should contact their Boston Scientific sales representative.

Additional Resources

- [Medical Device Recall Database Entry](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186851)
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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.