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Class 2 Device Recall BOBBY Balloon Guide Catheter



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Class 2 Device Recall BOBBY Balloon Guide Catheter



Date Initiated by Firm	April 30, 2026
Date Posted	August 07, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2912-2026
Recall Event ID	98909 ²³
510(K)Number	K193607 ²⁴
Product Classification	Catheter, percutaneous ²⁵ - Product Code DQY ²⁶
Product	BOBBY Balloon Guide Catheter REF: BOB-895-CN BOB-895-EMEA BOB-895-EMEA-AL BOB-895-US MV-BGA01095

For use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems.

Code Information	Catalog Number: BOB-895-CN UDI codes: (01)00842429111062(11)250819(17)280731(10)0001218734 (01)00842429111062(11)250822(17)280731(10)0001222844 (01)00842429111062(11)250825(17)280731(10)0001224137 (01)00842429111062(11)250828(17)280731(10)0001226522 (01)00842429111062(11)250910(17)280831(10)0001264372 (01)00842429111062(11)250911(17)280831(10)0001281308 (01)00842429111062(11)250917(17)280831(10)0001283704 Lot Numbers: 0001218734 0001222844 0001224137 0001226522 0001264372 0001281308 0001283704 Catalog Number: BOB-895-EMEA UDI code: (01)00842429108550(11)241108(17)271031(10)0000756596 (01)00842429108550(11)241109(17)271031(10)0000757384 (01)00842429108550(11)241118(17)271031(10)0000758945 (01)00842429108550(11)241120(17)271031(10)0000765270 (01)00842429108550(11)241121(17)271031(10)0000767660 (01)00842429108550(11)241126(17)271031(10)0000772588 (01)00842429108550(11)241202(17)271130(10)0000774885 (01)00842429108550(11)241128(17)271031(10)0000778089 (01)00842429108550(11)241204(17)271130(10)0000779647 (01)00842429108550(11)241207(17)271130(10)0000781240 (01)00842429108550(11)241210(17)271130(10)0000784041 (01)00842429108550(11)241210(17)271130(10)0000799436 (01)00842429108550(11)241213(17)271130(10)0000802183 (01)00842429108550(11)241210(17)271130(10)0000802619 (01)00842429108550(11)241214(17)271130(10)0000809792 (01)00842429108550(11)241217(17)271130(10)0000812812
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Catalog Number: BOB-895-EMEA-AL

UDI codes:

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Catalog Number: BOB-895-US

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Catalog Number: MV-BGA01095

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FEI Number 3013556777

**Recalling Firm/
Manufacturer** MICROVENTION INC.
35 Enterprise
Aliso Viejo CA 92656

**For Additional
Information Contact** Terrence Callahan
949-899-7194

**Manufacturer Reason
for Recall** Due to an increase rate of balloon pinhole defects.

**FDA Determined
Cause ²** Under Investigation by firm

Action On 04/30/2026, an "URGENT MEDICAL DEVICE RECALL" Letter was mailed to customers informing them that due to an increased rate of balloon pinhole defects (inflation-related issues).

Customers are instructed to:

1. Immediately stop using and quarantine the affected BOBBY Balloon Guide Catheters
2. Reconcile, complete and return the "CUSTOMER ACKNOWLEDGEMENT FORM" via email to Terumo4118@sedgwick.com or FAX +1 877-650-7688 and return affected products.
3. Provide Recall Letter to any/all medical facilities to your organization has distributed recalled products to.
4. Return Product
-Return product through provided Ground Return Service or Return Service Label receipt provided in this recall notification and ship the products to Processing Center through the below contact.
Ship to Address
2670 Executive Drive Suite A
Indianapolis, IN 46241 USA
-Credit will be issued for customer purchased products upon return and verification of recall unit(s).

For Questions or further assistance - contact Sedgwick at +1 877-650-7686 or direct any questions to Terumo Neuro Sr. Director of Post Market Surveillance at +1 949-899-7194 Monday -Friday 8:00 a.m. to 5:00 p.m. (PST) or email recalls@microvention.com

Quantity in Commerce 5500 devices

Distribution Worldwide - U.S. Nationwide distribution in the states of AL, AR, AZ, CA, FL, GA, IA, IL, KS, KY, LA, MI, MN, MO, MT, NC, NH, NM, NY, OH, PA, SD, TN, TX, WA, and WI.

The countries of Europe - Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Romania, Slovenia, South Africa, Spain, Sweden, Switzerland, Ukraine, and United Kingdom.

Asia - China, Japan, Jordan, New Zealand, South Korea, and United Arab Emirates.

Total Product Life Cycle [TPLC Device Report](#)²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

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22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
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27. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=DQY>
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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ph. 1-888-INFO-FDA (1-888-463-6332)

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U.S. Department of **Health & Human Services**

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12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=98909
24. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K193607>
25. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DQY>
26. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DQY>
27. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=DQY>
28. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DQY&knumber=&applicant=MicroVention%2C%20Inc%2E