

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Bard Access Systems, Inc. Recalls BD 4 Fr Single-Lumen PowerPICC Catheters

Recall Date	Product Description	Recalling Firm	Recall Reason
04/16/2025	BD 4 Fr Single-Lumen PowerPICC Catheters, REF: 2194108, 3194118, 3194335, 3194355, 6194355, 2174108, 1194108D1NS, 1194108D2NS, CK000375, CK000501ANS, CK000882NS, CK000959NS, 3174118, 6174118, CK000930NS, CK000937ANS, CK001027NS, 3174355, 3174335J, CK000524ANS, CK000955, 3174335, 6174108, 8174118, CK000540, 4174118, 6174335, 8174355, CK000660NS, CK000839, 3174135, 3174155, 6174355, 8194118, 22184118, CK000483, 8174335, CK000196	Bard Access Systems, Inc.	Catheters indicated for short-or-long term access to the central venous system have tubing that exceeded melt flow index specification (higher), which could lead to increased material fatigue leaks, which could lead to infiltration, extravasation, discomfort, phlebitis, bleeding, air embolism, foreign body embolism, infection and interruption to therapy.

Recall Class	Product Identification	Distribution	Affected Dates
I	REF/UDI-DI/Lot(Expiration): 2194108/00889989030587/REHR0118(28-Feb-2025), REHQ3587(28-Feb-2025), REHQ3551(28-Feb-2025), REHR1437(28-Feb-2025), REHQ3513(28-Feb-2025), REHQ3599(28-Feb-2025), REHT2240(31-May-2025), REHY2816 (31-Oct-2025);	183,670 Worldwide - US Nationwide distribution including in the states of WI, NC, TX, NY, CA, MN, MT, RI, MA, OH, CT, SC, IL, CO, VA, NJ, GA, UT, FL, PA, IN, MD, KY, AZ, MI, WA, HI, MO, VT, AL, NM, TN, DE, LA,	March 2025 and Prior

3194118/00801741027741/REHR1 546(28-Feb-2025); 3194335/00801741027772/REHR0 025(28-Feb-2025); 3194355/00801741027789/REHQ3 050(28-Feb-2025), REHR0007(28-Feb-2025); 6194355/00801741139079/REHR0 007(28-Feb-2025), REHR0080(28-Feb-2025), REHU3309(30-Jun-2025); 2174108/00801741138966/REGV1 296 (31-Mar-2025), REGX0239(31-Mar-2025), REGT6082 (31-May-2025), REGU1733(30-Jun-2025), REGU1669(30-Jun-2025), REGV0410(31-Jul-2025), REGX0214(31-Aug-2025), REGW3741(31-Aug-2025), REGX0215(30-Sep-2025), REHN2402(30-Sep-2025), REHS1080(30-Sep-2025), REGY0240(31-Oct-2025), REGZ0212 (31-Oct-2025), REHN2423(31-Oct-2025), REGZ1010(30-Nov-2025), REGZ2094(30-Nov-2025), REGZ1023 (30-Nov-2025), REHN1419(31-Dec-2025), REHP1751(31-Jan-2026), REHR1459(31-Mar-2026); 1194108D1NS/00801741154782/R EHX1947(31-Mar-2025); 1194108D2NS/00801741154881/R EHX1125(31-Mar-2025); CK000375/00801741102660/REHY 0131(31-Mar-2025); CK000501ANS/00801741140815/R EHZ1466(31-Mar-2025); CK000882NS/00801741188794/RE HX3598(31-Mar-2025); CK000959NS/00801741200960/RE HX0561(31-Mar-2025); 3174118/00801741027598/REGT43 12(31-May-2025), REGT4200(31-May-2025), REGT4250(31-May-2025),	IA, NH, ID, DC, WV, KS, NE, SD, ND, WY, AK, OK, OR, AR and the countries of Andorra, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Colombia, Costa Rica, Czech Republic, Denmark, Finland, France, French Polynesia, French Guayana, Germany, Greece, Guadeloupe, Guatemala, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Jordan, Kuwait, Luxembourg, Martinique, Mexico, Netherlands, New Caledonia, New Zealand, Norway, Pakistan, Poland, Portugal, Qatar, Republic of Korea, Reunion, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Turkey, United Arab Emirates, United Kingdom, Viet Nam.	
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REGT1920(31-May-2025), REGT2997(31-May-2025), REGT3368(31-May-2025), REGT3115(31-May-2025), REGT3443(31-May-2025), REGT4436(31-May-2025), REGU1639(30-Jun-2025), REGU1739(30-Jun-2025), REGV1884(31-Jul-2025), REGV3348(31-Jul-2025), REGV3288(31-Jul-2025), REGW2589(31-Aug-2025), REGW3675(31-Aug-2025), REGW1602(31-Aug-2025), REGX2231(30-Sep-2025), REGX1037(30-Sep-2025), REHP1759(31-Oct-2025), REGZ2508(30-Nov-2025), REGZ1397(30-Nov-2025), REHQ1848(30-Nov-2025), REHN1706(31-Dec-2025), REHN3907(31-Dec-2025), REHP0859(31-Jan-2026); 6174118/00801741139017/REGS27 86(31-Mar-2025), REGS3903(30-Apr-2025), REGU1649(30-Jun-2025), REGV1890(31-Jul-2025), REGW0829(31-Aug-2025), REGX2261(30-Sep-2025), REGX1063(30-Sep-2025), REGZ1416(31-Oct-2025), REHR0058(31-Dec-2025), REHS1902(30-Apr-2026); CK000930NS/00801741188091/RE HY3377(30-Apr-2025); CK000937ANS/00801741224003/R EHY3360(30-Apr-2025); CK001027NS/00801741223921/RE HY0886(30-Apr-2025); 3174355/00801741027635/REGT0 477(31-May-2025), REGT1747(31-May-2025), REGT4224(31-May-2025), REGV3363(31-Jul-2025), REGW3676(31-Aug-2025), REGX2205(30-Sep-2025), REGZ1398(31-Oct-2025),		
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REGZ2513(30-Nov-2025), REHP0870(31-Jan-2026), REHR0110(31-Mar-2026); 3174335J/00801741111716/REGV1 895(30-Jun-2025), REGZ0465(30-Jun-2025); CK000524ANS/00801741124068/R EJN2419(30-Jun-2025); CK000955/00801741200922/REG W3501(30-Jun-2025); 3174335/00801741027628/REGV0 199(31-Jul-2025), REGV3423(31-Jul-2025), REGW1603(31-Aug-2025), REGZ0428(31-Oct-2025), REHS1930(30-Apr-2026); 6174108/00801741139000/REGV3 345(31-Jul-2025), REGX1802(30-Sep-2025), REGX2978(30-Sep-2025), REGX0250(30-Sep-2025), REGY0747(31-Oct-2025), REGZ0061(31-Oct-2025), REHR1412(31-Dec-2025), REHR1507(31-Jan-2026), REHR0101(31-Mar-2026); 8174118/00801741139093/REGV33 01(31-Jul-2025), REGV0574(31-Jul-2025), REGW0758(31-Aug-2025), REHP1795(30-Nov-2025), REGZ1462(30-Nov-2025), REHN3916(31-Dec-2025), REHR0014(28-Feb-2026); CK000540/00801741105142/REGV 3241(31-Jul-2025); 4174118/00801741138980/REGZ04 75(31-Aug-2025), REGW1608(31-Aug-2025), REHS4176(31-Oct-2025), REHS2807(31-Oct-2025), REHR1444(31-Oct-2025), REHV1385(31-Jan-2026), REHV1739(31-Jul-2026); 6174335/00801741139024/REGW3 468(31-Aug-2025), REGZ1452(30-Nov-2025), REHR1518(31-Mar-2026),		
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REHT3429(31-May-2026); 8174355/00801741139116/REGW2 667(31-Aug-2025), REHR1520(30-Nov-2025); CK000660NS/00801741129650/RE JQ1520(31-Aug-2025); CK000839/00801741154393/REG W2674(31-Aug-2025); 3174135/00801741027604/REGV3 422(31-Oct-2025), REGX1057(31-Oct-2025), REGZ0464(31-Oct-2025), REGW1574(30-Nov-2025); 3174155/00801741027611/REGX1 038(31-Oct-2025), REGV0609(31-Oct-2025), REGW0737(31-Oct-2025), REGW3615(31-Oct-2025), REGV3362(31-Oct-2025), REHS1900(31-Jul-2026); 6174355/00801741139031/REGX2 134(31-Oct-2025), REGW0830(31-Oct-2025), REGV1927(31-Oct-2025), REGV3426(31-Oct-2025), REGW0745(31-Oct-2025), REHR1446(31-Jul-2026), REHS1932(31-Jul-2026); 8194118/00801741139123/REHY15 84(31-Oct-2025); 22184118/00801741121579/REGX1 035(31-Oct-2025), REGZ1436(30-Nov-2025), REGX2200(31-Dec-2025), REHS1034(31-Dec-2025); CK000483/00801741099397/REG W2673(31-Oct-2025); 8174335/00801741139109/REHR1 519(30-Nov-2025); CK000196/00801741028847/REGZ 0456(31-Mar-2026), REHS1895(30-Jun-2026)		
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For additional information, please visit the [FDA Website](#).