

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

#### Bard Peripheral Vascular Inc EVSRF catheter

| Recall Date | Product Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Recalling Firm               | Recall Reason                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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| 11/13/2024  | The EVSRF catheter is a sterile, single-use disposable medical device for endovenous radiofrequency ablation, a procedure in which a refluxing vein is thermally coagulated to permanently eliminate the vein from blood circulation. The catheter has a long shaft for insertion into a vein, a handle with start/stop button, and a connector cable. The catheter shaft has a heating element that is energized by the digiRF radiofrequency generator, which is a multi-voltage energy delivery system with touchscreen control that automatically sets the non-adjustable treatment parameters for the catheter. A button on the catheter (or a foot pedal attached to the generator) begins an automated treatment cycle of 20 seconds long at a set temperature of 120°C, and the treatment stops automatically when complete. The catheter is used within a sterile operative field, while the generator remains outside the sterile | Bard Peripheral Vascular Inc | The Venclose" RF Ablation Catheters may have been manufactured with internal wiring error. The red and yellow signal wires were soldered on swapped ports of the catheter PCB. This error in wire configuration would lead to power being applied through the proximal 3/4th of the heating coil, bypassing the thermocouple, which will then cause the generator to overdrive the catheter in an attempt to reach desired temperature set point. The wire attachment error causes the device to reach temperatures exceeding the levels intended for therapeutic efficacy, while the console is falsely indicating that temperature has not |

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|  | operative field at all times. |  | yet been reached, thus increasing the risk of harm due to excessive temperature. |
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| Recall Class | Product Identification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Distribution                 | Affected Dates       |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| II           | <p>Catalog Number: VC-10A2.5-6F-100</p> <p>UDI codes:</p> <p>(01)00858254006015(17)241009<br/> (10)65497423<br/> (01)00858254006015(17)241006<br/> (10)66030181<br/> (01)00858254006015(17)241011<br/> (10)66599182<br/> (01)00858254006015(17)241017<br/> (10)66634308<br/> (01)00858254006015(17)241020<br/> (10)66784768<br/> (01)00858254006015(17)241026<br/> (10)66793709<br/> (01)00858254006015(17)241028<br/> (10)66793710<br/> (01)00858254006015(17)241103<br/> (10)66897727<br/> (01)00858254006015(17)241113<br/> (10)66947733<br/> (01)00858254006015(17)241117<br/> (10)67054619<br/> (01)00858254006015(17)241130<br/> (10)67308611<br/> (01)00858254006015(17)250322<br/> (10)69548248<br/> (01)00858254006015(17)250419<br/> (10)69548249<br/> (01)00858254006015(17)250423<br/> (10)69548250<br/> (01)00858254006015(17)250427<br/> (10)69567357<br/> (01)00858254006015(17)250511<br/> (10)69567358<br/> (01)00858254006015(17)250515<br/> (10)70322501</p> | 222,373 catheters nationwide | September and prior. |

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|  | (01)00858254006015(17)250607<br>(10)70523716<br>(01)00858254006015(17)250523<br>(10)70597994<br>(01)00858254006015(17)250525<br>(10)70751594<br>(01)00858254006015(17)250606<br>(10)70791660<br>(01)00858254006015(17)250613<br>(10)71054985<br>(01)00858254006015(17)250620<br>(10)71197454<br>(01)00858254006015(17)250703<br>(10)71197455<br>(01)00858254006015(17)250801<br>(10)71197574<br>(01)00858254006015(17)250622<br>(10)71319092<br>(01)00858254006015(17)250630<br>(10)71361455<br>(01)00858254006015(17)250712<br>(10)71589682<br>(01)00858254006015(17)250721<br>(10)71780480<br>(01)00858254006015(17)250724<br>(10)71780481<br>(01)00858254006015(17)250821<br>(10)71974718<br>(01)00858254006015(17)250803<br>(10)72167973<br>(01)00858254006015(17)250821<br>(10)72216631<br>(01)00858254006015(17)250809<br>(10)72216758<br>(01)00858254006015(17)250810<br>(10)72282293<br>(01)00858254006015(17)250828<br>(10)72440542<br>(01)00858254006015(17)250914<br>(10)72491306<br>(01)00858254006015(17)250905<br>(10)72609982<br>(01)00858254006015(17)250912<br>(10)72735944<br>(01)00858254006015(17)250920<br>(10)72845915<br>(01)00858254006015(17)250927<br>(10)73024457 |  |  |
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|  | (01)00858254006015(17)250929<br>(10)73184835<br>(01)00858254006015(17)251005<br>(10)73218082<br>(01)00858254006015(17)251011<br>(10)73319890<br>(01)00858254006015(17)251012<br>(10)73424182<br>(01)00858254006015(17)251102<br>(10)73441733<br>(01)00858254006015(17)251121<br>(10)73808592<br>(01)00858254006015(17)251125<br>(10)74103378<br>(01)00858254006015(17)251127<br>(10)74171115<br>(01)00858254006015(17)251129<br>(10)74219123<br>(01)00858254006015(17)260112<br>(10)74355356<br>(01)00858254006015(17)241108<br>(10)V67114001<br>(01)00858254006015(17)241108<br>(10)V67114002<br>(01)00858254006015(17)241108<br>(10)V67114003<br><br>Lot Numbers: 65497423<br>66030181 66599182 66634308<br>66784768 66793709 66793710<br>66897727 66947733 67054619<br>67308611 69548248 69548249<br>69548250 69567357 69567358<br>70322501 70523716 70597994<br>70751594 70791660 71054985<br>71197454 71197455 71197574<br>71319092 71361455 71589682<br>71780480 71780481 71974718<br>72167973 72216631 72216758<br>72282293 72440542 72491306<br>72609982 72735944 72845915<br>73024457 73184835 73218082<br>73319890 73424182 73441733<br>73808592 74103378 74171115<br>74219123 74355356 V67114001<br>V67114002 V67114003 |  |  |
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|  | <p>Catalog Number: VC-10A2.5-6F-60</p> <p>UDI codes:</p> <p>(01)00858254006008(17)241013<br/>(10)66186400<br/>(01)00858254006008(17)241024<br/>(10)66793696<br/>(01)00858254006008(17)241102<br/>(10)66793697<br/>(01)00858254006008(17)241107<br/>(10)66793698<br/>(01)00858254006008(17)241021<br/>(10)66802218<br/>(01)00858254006008(17)241031<br/>(10)66863470<br/>(01)00858254006008(17)241110<br/>(10)66981017<br/>(01)00858254006008(17)241120<br/>(10)67017611<br/>(01)00858254006008(17)241125<br/>(10)67105253<br/>(01)00858254006008(17)241115<br/>(10)67190839<br/>(01)00858254006008(17)241123<br/>(10)67241133<br/>(01)00858254006008(17)241128<br/>(10)67429950<br/>(01)00858254006008(17)241204<br/>(10)67429951<br/>(01)00858254006008(17)241204<br/>(10)67429952<br/>(01)00858254006008(17)250410<br/>(10)69548196<br/>(01)00858254006008(17)250327<br/>(10)69548197<br/>(01)00858254006008(17)250416<br/>(10)69548198<br/>(01)00858254006008(17)250331<br/>(10)69659895<br/>(01)00858254006008(17)250502<br/>(10)69659896<br/>(01)00858254006008(17)250505<br/>(10)69748757<br/>(01)00858254006008(17)250509<br/>(10)69928277<br/>(01)00858254006008(17)250601<br/>(10)70414634</p> |  |  |
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|  | (01)00858254006008(17)250517<br>(10)70487066<br>(01)00858254006008(17)250519<br>(10)70634659<br>(01)00858254006008(17)250529<br>(10)70673130<br>(01)00858254006008(17)250604<br>(10)70868426<br>(01)00858254006008(17)250608<br>(10)70933358<br>(01)00858254006008(17)250612<br>(10)70994254<br>(01)00858254006008(17)250614<br>(10)71075353<br>(01)00858254006008(17)250618<br>(10)71197363<br>(01)00858254006008(17)250704<br>(10)71197364<br>(01)00858254006008(17)250705<br>(10)71197365<br>(01)00858254006008(17)250806<br>(10)71197533<br>(01)00858254006008(17)250625<br>(10)71278440<br>(01)00858254006008(17)250628<br>(10)71278441<br>(01)00858254006008(17)250707<br>(10)71609707<br>(01)00858254006008(17)250727<br>(10)71629666<br>(01)00858254006008(17)250714<br>(10)71650328<br>(01)00858254006008(17)250710<br>(10)71650329<br>(01)00858254006008(17)250717<br>(10)71818971<br>(01)00858254006008(17)250719<br>(10)71818972<br>(01)00858254006008(17)250731<br>(10)71913951<br>(01)00858254006008(17)250814<br>(10)72151238<br>(01)00858254006008(17)250816<br>(10)72216513<br>(01)00858254006008(17)250807<br>(10)72248924<br>(01)00858254006008(17)250825<br>(10)72405570 |  |  |
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|  | <p> (01)00858254006008(17)250823<br/> (10)72475111<br/> (01)00858254006008(17)250903<br/> (10)72524414<br/> (01)00858254006008(17)250831<br/> (10)72576947<br/> (01)00858254006008(17)250907<br/> (10)72640519<br/> (01)00858254006008(17)250910<br/> (10)72768920<br/> (01)00858254006008(17)250918<br/> (10)72812308<br/> (01)00858254006008(17)250922<br/> (10)72978442<br/> (01)00858254006008(17)250925<br/> (10)73048080<br/> (01)00858254006008(17)250927<br/> (10)73141510<br/> (01)00858254006008(17)251008<br/> (10)73184825<br/> (01)00858254006008(17)251015<br/> (10)73441652<br/> (01)00858254006008(17)251017<br/> (10)73493157<br/> (01)00858254006008(17)251025<br/> (10)73542584<br/> (01)00858254006008(17)251029<br/> (10)73656671<br/> (01)00858254006008(17)251123<br/> (10)73656672<br/> (01)00858254006008(17)251201<br/> (10)74137006<br/> (01)00858254006008(17)251204<br/> (10)74137007<br/> (01)00858254006008(17)251206<br/> (10)74288518<br/> (01)00858254006008(17)260114<br/> (10)74355347<br/> (01)00858254006008(17)260121<br/> (10)74989575<br/> <br/> Lot Numbers: 66186400<br/> 66793696 66793697 66793698<br/> 66802218 66863470 66981017<br/> 67017611 67105253 67190839<br/> 67241133 67429950 67429951<br/> 67429952 69548196 69548197<br/> 69548198 69659895 69659896 </p> |  |  |
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|  | <p>69748757 69928277 70414634<br/> 70487066 70634659 70673130<br/> 70868426 70933358 70994254<br/> 71075353 71197363 71197364<br/> 71197365 71197533 71278440<br/> 71278441 71609707 71629666<br/> 71650328 71650329 71818971<br/> 71818972 71913951 72151238<br/> 72216513 72248924 72405570<br/> 72475111 72524414 72576947<br/> 72640519 72768920 72812308<br/> 72978442 73048080 73141510<br/> 73184825 73441652 73493157<br/> 73542584 73656671 73656672<br/> 74137006 74137007 74288518<br/> 74355347 74989575</p> <p>Catalog Number: VC10A256F100</p> <p>UDI codes:<br/> (01)00858254006015(17)260222<br/> (10)74959653<br/> (01)00858254006015(17)260227<br/> (10)75563807<br/> (01)00858254006015(17)260402<br/> (10)76413778<br/> (01)00858254006015(17)260524<br/> (10)77536423<br/> (01)00858254006015(17)260529<br/> (10)77750390</p> <p>Lot Numbers: 74959653<br/> 75563807 76413778 77536423<br/> 77750390</p> <p>Catalog Number: VC10A256F60</p> <p>UDI codes:<br/> (01)00858254006008(17)260215<br/> (10)75087737<br/> (01)00858254006008(17)260304<br/> (10)75439758<br/> (01)00858254006008(17)260306<br/> (10)75784764<br/> (01)00858254006008(17)260311<br/> (10)75828822<br/> (01)00858254006008(17)260314<br/> (10)75940087</p> |  |  |
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|  | <p>(01)00858254006008(17)260326<br/> (10)76272657<br/> (01)00858254006008(17)260412<br/> (10)76413711<br/> (01)00858254006008(17)260422<br/> (10)76960626<br/> (01)00858254006008(17)260424<br/> (10)77048331<br/> (01)00858254006008(17)260425<br/> (10)77093851<br/> (01)00858254006008(17)260502<br/> (10)77115614<br/> (01)00858254006008(17)260603<br/> (10)77272719<br/> (01)00858254006008(17)260605<br/> (10)77948128<br/> (01)00858254006008(17)260611<br/> (10)77984934<br/> (01)00858254006008(17)260617<br/> (10)78094204<br/> (01)00858254006008(17)260621<br/> (10)78220237<br/> (01)00858254006008(17)260626<br/> (10)78295294<br/> (01)00858254006008(17)260701<br/> (10)78387756</p> <p>Lot Numbers: 75087737<br/> 75439758 75784764 75828822<br/> 75940087 76272657 76413711<br/> 76960626 77048331 77093851<br/> 77115614 77272719 77948128<br/> 77984934 78094204 78220237<br/> 78295294 78387756</p> <p>Catalog Number: VCOUS6F100</p> <p>UDI codes:<br/> (01)00858254006244(17)251005<br/> (10)73310842<br/> (01)00858254006244(17)251009<br/> (10)73319925<br/> (01)00858254006244(17)251214<br/> (10)73319926<br/> (01)00858254006244(17)251023<br/> (10)73388088<br/> (01)00858254006244(17)251109<br/> (10)73623196</p> |  |  |
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|  | <p> (01)00858254006244(17)251112<br/> (10)73923359<br/> (01)00858254006244(17)251114<br/> (10)73954408<br/> (01)00858254006244(17)251116<br/> (10)73987507<br/> (01)00858254006244(17)251214<br/> (10)74020834<br/> (01)00858254006244(17)260107<br/> (10)74507761<br/> (01)00858254006244(17)260110<br/> (10)74889457<br/> (01)00858254006244(17)260116<br/> (10)74933204<br/> (01)00858254006244(17)260124<br/> (10)75016007<br/> (01)00858254006244(17)260130<br/> (10)75127795<br/> (01)00858254006244(17)260204<br/> (10)75204432<br/> (01)00858254006244(17)260206<br/> (10)75276852<br/> (01)00858254006244(17)260214<br/> (10)75305699<br/> (01)00858254006244(17)260404<br/> (10)76413837<br/> (01)00858254006244(17)260406<br/> (10)76480490<br/> (01)00858254006244(17)260506<br/> (10)76526332<br/> (01)00858254006244(17)260507<br/> (10)77379776<br/> (01)00858254006244(17)260507<br/> (10)77379777 </p> <p> Lot Numbers: 73310842<br/> 73319925 73319926 73388088<br/> 73623196 73923359 73954408<br/> 73987507 74020834 74507761<br/> 74889457 74933204 75016007<br/> 75127795 75204432 75276852<br/> 75305699 76413837 76480490<br/> 76526332 77379776 77379777 </p> <p> Catalog Number: VCOUS6F60 </p> <p> UDI codes:<br/> (01)00858254006251(17)251020 </p> |  |  |
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|  | (10)73319896<br>(01)00858254006251(17)251107<br>(10)73573950<br>(01)00858254006251(17)251119<br>(10)73890876<br>(01)00858254006251(17)251214<br>(10)74070677<br>(01)00858254006251(17)260208<br>(10)74507759<br>(01)00858254006251(17)260409<br>(10)76413830<br>(01)00858254006251(17)260507<br>(10)76593887<br><br>Lot Numbers: 73319896<br>73573950 73890876 74070677<br>74507759 76413830 76593887 |  |  |
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