



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Medtronic Recalls Cardioverter Implantable Defibrillator for Potentially Reduced Shock during High Voltage Therapy**

| Recall Date | Product Description   | Recalling Firm   | Recall Reason  |
|-------------|---|--|--|
| 6/22/2022   | <b>Cobalt Implantable Cardioverter Defibrillators:</b> <ul style="list-style-type: none"> <li>a. Cobalt XT VR ICD Model Numbers: DVPA2D1, DVPA2D4;</li> <li>b. Cobalt XT DR ICD, Model Numbers: DDPA2D1, DDPA2D4</li> </ul>   | <b>Medtronic Inc.,<br/>           Cardiac Rhythm and Heart Failure (CRHF)</b><br>Mounds View,<br>Minnesota | There is the potential for reduced shock energy (~79% of programmed energy) during high-voltage (HV) therapy for Cobalt implantable cardioverter defibrillators (ICDs)             |
| 6/22/2022   | <b>Cobalt Implantable Cardioverter Defibrillators with Cardiac Resynchronization Therapy (CRT-D)</b> <ul style="list-style-type: none"> <li>a. Cobalt XT HF CRT-D, Model Numbers: DTPA2D4, DTPA2D1;</li> <li>b. Cobalt XT HF Quad CRT-D, Model Numbers: DTPA2QQ, DTPA2Q1</li> </ul> | <b>Medtronic Inc.,<br/>           Cardiac Rhythm and Heart Failure (CRHF)</b><br>Mounds View,<br>Minnesota | There is the potential for reduced shock energy (~79% of programmed energy) during high-voltage (HV) therapy for Cobalt cardiac resynchronization therapy defibrillators (CRT-Ds). |
| 6/22/2022   | <b>Cobalt Implantable Cardioverter Defibrillators</b> <ul style="list-style-type: none"> <li>a. Cobalt VR ICD, Model Numbers: DVPB3D1, DVPB3D4;</li> <li>b. Cobalt DR ICD, Model Numbers: DDPB3D1, DDPB3D4</li> </ul>   | <b>Medtronic Inc.,<br/>           Cardiac Rhythm and Heart Failure (CRHF)</b><br>Mounds View,<br>Minnesota | There is the potential for reduced shock energy  |

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| 6/22/2022 | <b>Cobalt Implantable Cardioverter Defibrillators with Cardiac Resynchronization Therapy (CRT-D)</b> <ul style="list-style-type: none"> <li>a. Cobalt HF CRT-D, Model Numbers: DTPB2D4, DTPB2D1;</li> <li>b. Cobalt HF Quad CRT-D, Model Numbers: DTPB2QQ, DTPB2Q1</li> </ul> | <b>Medtronic Inc., Cardiac Rhythm and Heart Failure (CRHF)</b><br>Mounds View, Minnesota | There is the potential for reduced shock energy   |
| 6/22/2022 | <b>Crome Implantable Cardioverter Defibrillators</b> <ul style="list-style-type: none"> <li>a. Crome VR ICD, Model Numbers: DVPC3D1, DVPC3D4;</li> <li>b. Crome DR ICD, Model Numbers: DDPC3D1, DDPC3D4</li> </ul>  | <b>Medtronic Inc., Cardiac Rhythm and Heart Failure (CRHF)</b><br>Mounds View, Minnesota | There is the potential for reduced shock energy (~79% of programmed energy) during high-voltage (HV) therapy for Crome implantable cardioverter defibrillators (ICDs) .           |
| 6/22/2022 | <b>Crome Implantable Cardioverter Defibrillators with Cardiac Resynchronization Therapy (CRT-D)</b> <ul style="list-style-type: none"> <li>a. Crome HF CRT-D, Model Numbers: DTPC2D4, DTPC2D1;</li> <li>b. Crome HF Quad CRT-D, Model Numbers: DTPC2QQ, DTPC2Q1</li> </ul>    | <b>Medtronic Inc., Cardiac Rhythm and Heart Failure (CRHF)</b><br>Mounds View, Minnesota | There is the potential for reduced shock energy (~79% of programmed energy) during high-voltage (HV) therapy for Crome cardiac resynchronization therapy defibrillators (CRT-Ds). |

| Recall Class | Product Identification   | Distribution                           | Affected Dates      |
|--------------|--|--|---------------------|
| I            | <b>Cobalt Implantable Cardioverter Defibrillators</b><br>Model Numbers: DVPA2D1:<br>GTIN 00763000178451, Serial Numbers: RSC600237S - RSM602631S | 6884 Units with Worldwide Distribution | June 2022 and prior |

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|---|---|--|---------------------|
| I | <b>Cobalt Implantable Cardioverter Defibrillators with Cardiac Resynchronization Therapy (CRT-D)</b><br>Model Numbers: DTPA2D4:<br>GTIN 00763000178130, Serial Numbers: RTG600136S - RTC609876S | 8429 Units with Worldwide Distribution | June 2022 and prior |
| I | <b>Cobalt Implantable Cardioverter Defibrillators</b><br>Model Numbers: DVPB3D1:<br>GTIN 00763000178499, Serial Numbers: RSE600212S - RSO606415S  | 2866 Units with Worldwide Distribution | June 2022 and prior |
| I | <b>Cobalt Implantable Cardioverter Defibrillators with Cardiac Resynchronization Therapy (CRT-D)</b><br>Model Numbers: DTPB2D4:<br>GTIN 00763000178215, Serial Numbers: RTO600239S - RTO601549S | 1408 Units with Worldwide Distribution | June 2022 and prior |
| I | <b>Crome Implantable Cardioverter Defibrillators</b><br>Model Numbers: DVPC3D1:<br>GTIN 00763000178543, Serial Numbers: RSG600007S - RSG600025S   | 1657 Units with Worldwide Distribution | June 2022 and prior |
| I | <b>Crome Implantable Cardioverter Defibrillators with Cardiac Resynchronization Therapy (CRT-D)</b><br>Model Numbers: DTPC2D4:<br>GTIN 00763000178291, Serial Numbers: RTW600120S - RTW600034S  | 866 Units with Worldwide Distribution  | June 2022 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)