

Urgent Field Safety Notice

Subset of Medtronic Cobalt™, Cobalt™ XT and Crome™ Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs)

RETRIEVAL OF NON-IMPLANTED DEVICES

November 2020

Medtronic Reference: FA925 Phase II

Dear Risk Manager or Healthcare Provider or Distributor,

On 06 November 2020, Medtronic initiated a medical device retrieval of a subset of Cobalt™, Cobalt™ XT and Crome™ devices. This notice is a follow-up to that initial verbal communication provided to your facility regarding the immediate quarantine of identified devices. The scope of this retrieval includes all model and serial numbers listed in Appendix A.

Medtronic's manufacturing quality processes identified that the Cobalt™, Cobalt™ XT and Crome™ devices listed in Appendix A underwent a specific manufacturing sequence that may have resulted in a cathode component being out of specification. Medtronic took immediate action to quarantine all sold or consigned devices while we complete the investigation.

As of 16 November 2020, Medtronic has received zero (0) complaints related to these identified devices.

Customer Actions:

Medtronic records indicate that your facility has received one or more of the identified devices. As a result, Medtronic requests that you take the following actions:

- Identify and quarantine all non-implanted identified devices.
- Return all non-implanted identified product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return of this product and obtaining replacement product.
- Please share this notification with others in your organization as appropriate.

Please note there are no actions required if a patient were implanted with a device listed in Appendix A. All devices have met final functional testing requirements. These patients should continue to be monitored in accordance with your medical facility's standard care protocols. Medtronic has not identified an immediate incremental risk to the patient if implanted with one of these identified serial numbers. Medtronic continues to investigate this issue and will notify you if there are changes in our recommendations.

The Competent Authority of your country has been notified of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact

your Medtronic Field Representative directly or via Tel No: 01 511 1400.

Sincerely,

A handwritten signature in dark ink, appearing to read 'K. Taverner', is positioned above the printed name.

Keith Taverner
Regulatory Affairs Manager UK & Ireland

Please see Appendix A below.

Appendix A: Cobalt™, Cobalt™ XT and Crome™ devices Affected Serial Numbers

Cobalt™, Cobalt™ XT and Crome™ Affected Model Numbers and Serial Numbers	
Model	DDPA2D4, DTPB2QQ, DVPA2D4, DVPB3D1, DVPB3D4, DVPC3D4, DDPC3D4, DTPA2D4, DTPB2D4
<p>RSM601726S, RTK601865S, RSD600914S, RSD600915S, RSD600916S, RSD600917S, RSD600918S, RSD600919S, RSD600921S, RSD600922S, RSD600923S, RSD600924S, RSD600925S, RSD600926S, RSD600927S, RSD600928S, RSD600930S, RSD600931S, RSD600932S, RSD600933S, RSD600934S, RSD600935S, RSD600936S, RSD600937S, RSD600938S, RSD600939S, RSD600941S, RSD600942S, RSD600944S, RSD600945S, RSD600946S, RSD600947S, RSD600948S, RSD600949S, RSD600950S, RSD600952S, RSD600953S, RSD600955S, RSD600956S, RSD600958S, RSD600959S, RSD600960S, RSD600962S, RSD600963S, RSD600964S, RSD600965S, RSD600966S, RSD600967S, RSD600968S, RSD600969S, RSD600970S, RSD600971S, RSD600972S, RSD600973S, RSD600974S, RSD600975S, RSD600976S, RSD600977S, RSD600978S, RSD600979S, RSD600980S, RSD600981S, RSD600983S, RSD600985S, RSD600988S, RSD600989S, RSD600990S, RSD600991S, RSD600992S, RSD600993S, RSD600994S, RSD600996S, RSD600998S, RSD600999S, RSD601000S, RSD601001S, RSD601002S, RSD601003S, RSD601004S, RSD601005S, RSD601006S, RSD601008S, RSD601009S, RSD601010S, RSD601011S, RSD601012S, RSD601013S, RSD601014S, RSD601015S, RSD601016S, RSD601017S, RSD601018S, RSD601019S, RSD601020S, RSD601021S, RSD601022S, RSE601111S, RSE601112S, RSE601113S, RSE601114S, RSE601116S, RSE601117S, RSE601118S, RSE601119S, RSE601120S, RSE601122S, RSE601123S, RSE601124S, RSE601125S, RSE601126S, RSE601127S, RSE601128S, RSE601129S, RSE601130S, RSE601156S, RSE601157S, RSE601158S, RSF601994S, RSF601996S, RSF601997S, RSF602000S, RSF602001S, RSH600353S, RSH600354S, RSH600355S, RSH600356S, RSH600357S, RSH600358S, RSH600359S, RSH600360S, RSH600361S, RSH600362S, RSH600363S, RSH600364S, RSH600365S, RSH600366S, RSH600368S, RSH600371S, RSH600386S, RSH600387S, RSH600390S, RSM601715S, RSM601716S, RSM601717S, RSM601718S, RSM601720S, RSM601721S, RSM601722S, RSM601723S, RSM601724S, RSM601725S, RSM601727S, RSM601729S, RSM601731S, RSM601732S, RSM601733S, RSM601734S, RSM601736S, RSM601737S, RSM601739S, RSM601742S, RSM601744S, RSM601745S, RSM601746S, RSM601747S, RSM601748S, RSM601749S, RSM601750S, RSM601752S, RSM601754S, RSM601755S, RSM601758S, RSM601759S, RSM601760S, RSM601762S, RSM601763S, RSM601764S, RSM601765S, RSM601766S, RSM601767S, RSM601768S, RSM601770S, RSM601771S, RSM601772S, RSM601773S, RSM601774S, RSM601775S, RSM601776S, RSM601778S, RSM601779S, RSM601780S, RSM601782S, RSM601786S, RSM601787S, RSM601788S, RSM601789S, RSM601790S, RSM601791S, RSM601792S, RSM601794S, RSM601796S, RSM601798S, RSM601799S, RSM601800S, RSM601804S, RSM601805S, RSM601807S, RSM601808S, RSM601809S, RSM601811S, RSM601812S, RSM601815S, RSM601816S, RSM601817S, RSM601818S, RSM601819S, RSM601820S, RSM601822S, RSM601823S, RSM601825S, RSM601826S, RSM601827S, RSM601828S, RSM601829S, RSM601830S, RSM601831S, RSM601832S, RSM601833S, RSM601834S, RSM601835S, RSM601836S, RSM601837S, RSM601839S, RSM601841S, RSM601846S, RSM601850S, RSM601853S, RSQ600326S, RSQ600327S, RSQ600329S, RSQ600330S, RSQ600332S, RSQ600336S, RSQ600337S, RSQ600338S, RSQ600340S, RTG600753S, RTG600754S, RTG600756S, RTG600757S, RTG600758S, RTG600760S, RTG600761S, RTG600762S, RTG600763S, RTG600765S, RTG600768S, RTG600770S, RTK601819S, RTK601821S, RTK601822S, RTK601824S, RTK601825S, RTK601827S, RTK601828S, RTK601829S, RTK601830S, RTK601832S, RTK601834S, RTK601836S, RTK601841S, RTK601844S, RTK601845S, RTK601847S, RTK601850S, RTK601851S, RTK601854S, RTK601855S, RTK601858S, RTK601860S, RTK601861S, RTK601862S, RTK601863S, RTK601864S, RTK601867S, RTK601868S, RTO600958S, RTO600959S, RTO600960S</p>	