Task Force “Avarie e Complicanze”

Nota di chiarimento relativa all’avviso di sicurezza del 3 giugno 2019 inerente un sottogruppo di pacemaker della ditta Medtronic (Azure, Astra, Percepta, Serena, Solara)

Come auspicato da AIAC nelle raccomandazioni del 3 giugno 2019 relative all’avviso di sicurezza di Medtronic su un sottogruppo di pacemaker a rischio di malfunzionamento (**Azure™, Astra™, Percepta™, Serena™ e Solara™**) dovuto a un danno a carico di un condensatore ceramico multistrato del dispositivo, in cui si richiedeva alla ditta un periodico aggiornamento sull’incidenza delle malfunzioni e sui provvedimenti adottati per minimizzare i rischi, Medtronic ha inviato ad AIAC una nota di chiarimento che alleghiamo.

15 luglio 2019

Ezio Soldati
Chairman della Task Force
“Avarie e Complicanze”

Renato Pietro Ricci
Presidente AIAC
a nome del Consiglio Direttivo

Medtronic
Further, Together

June 26, 2019

Esteemed AIAC Scientific Society

This letter is being sent at your request for information from Medtronic to provide assurance that hospital inventory, sold and/or distributed product for Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ cardiac resynchronization therapy pacemakers (CRT-P), manufactured with a specific multilayer ceramic capacitor are meeting performance reliability predictions, continue to meet the Essential Requirements and are appropriate for use.

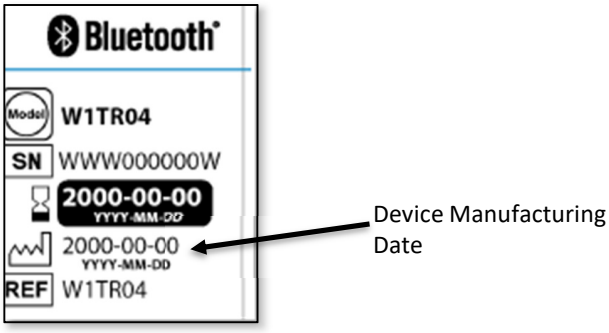
Specifically, you requested information regarding the manufacturing date after which Medtronic implemented a new capacitor component as described in the FDA Safety Communication from May 2019. Below please find information for your records.

Medtronic May 2019 Performance Note Summary
All product released into distribution (since their original market-release date) continue to perform within our reliability projections as established as part of the product development process. A series of enhancements to further reduce the potential for the capacitor to develop a leakage pathway was implemented beginning in February 2019. Given the low predicted rate of failure in the devices manufactured prior to these enhancements, we are not segregating existing inventory into “pre-“, “intra-“ or “post-“ enhancement categories.

Manufacturing Enhancement Update
Beginning June 1, 2019, all newly manufactured product released into distribution has been implemented with a new low voltage capacitor.

Important! Product with a manufacture date earlier than June 1, 2019 is considered safe to implant for the reasons noted above. No action on your part is required. This date is being provided per your request for information.

Note: June 1, 2019 reflects the manufacturing date of the device and can be found on the outside of the device box as noted below. Please be aware that product in inventory and/or distribution may continue to show manufacturing dates prior to June 1, 2019 for many months -- as existing device inventory works its way through our distribution networks.



Sincerely,

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