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Micra® Transcatheter Pacing System

End of Service/Postmortem Considerations

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The Medtronic Micra Transcatheter Pacing System (TPS) is a leadless pacing system implanted directly into the heart (Medtronic Micra® TPS Clinician Manual). Leadless pacing systems have advantages over traditional transvenous pacing systems including the ability to leave the device implanted (indefinitely) once it has reached end-of-service due to battery depletion. Specifically, Micra TPS can remain safely implanted in the heart, even after patient death.

However, because the Micra TPS is delivered intravenously and implantation is directly into the patient's heart, physical evidence of a pacemaker may no longer be apparent to medical examiners or morticians during examination of a deceased patient.

Country Regulations

Some countries regulate the removal of implantable cardiac devices prior to burial in order to avoid crematory damage, crematory operator injury or environmental pollution (Galey & Mulley, 2002). Some countries also regulate the removal of implantable cardiac devices prior to burial in order to prevent possible environmental contamination to ground water sources (Smith, Gitsham, Donell, Rose, & Hing, 2012).

Final Disposition without Removing the Micra TPS

In countries where explanation of an implanted device is not required, the Micra TPS device may be safely buried or cremated along with the remains of the deceased. In addition, even in countries where explant postmortem is required, a device may be unintentionally cremated. Regardless of the intent, extensive testing conducted by Medtronic and the Southwest Research Institute has proven the Micra TPS can be safely cremated both inside and outside of the deceased body.
Several tests were performed to analyze the explosion and toxicity risks of the Micra TPS device in both controlled and uncontrolled testing environments.

Smoke density testing of the Micra TPS device was performed by the Southwest Research Institute. The Micra TPS device results were well within the limits established by the US Environmental Protection Agency (Southwest Research Institute, 2014).

Ballistic and explosive event analysis of the Micra TPS device was performed, also by the Southwest Research Institute. The results concluded that the devices did not have enough weight or velocity at the point of explosion (roughly 1600 degrees Fahrenheit) to penetrate skin or damage the refractory tile wall of a crematory (Medtronic Report, MDT2185829). Testing has also confirmed the Micra TPS device does not pose an explosion risk to the health of a crematory operator, fire fighters responding to an emergency, or people attending an open cremation ceremony.
An experiment to evaluate the explosion damage potential of the Micra TPS in an actual crematory setting did not demonstrate any major explosion potential or potential for crematory damage. The device batteries did not rupture in 33% of the samples. The cremation methods used were consistent with cremation industry standards and therefore generalizable to other scenarios.

An environmental device composition matrix analysis determined that the amount of pollutants attributable to the Micra TPS device was negligible compared to the amount of pollutants generated by other sources during the cremation process (Medtronic Report, MDT2185829).

In summary, the Micra TPS can be cremated in standard crematory settings without causing disturbing noises, occupational injury risk or damage to the crematory retort (Medtronic Report MDT2172498).

There is a blood borne pathogen risk to the health care provider or mortician removing the device, taking this into consideration, along with the required resources, and device removal authorization from the deceased's legal representative, it is recommended that the Micra TPS device is not removed prior to cremation or burial.

Two postmortem removal recommendations have resulted from comprehensive testing and analysis of the Micra Transcatheter Pacing System (TPS):

- The design of the Micra TPS does not require it to be explanted in preparation for cremation or burial. The Micra TPS is not a risk to the wellbeing of employees, equipment or the environment.
- If removal of the device is mandatory, postmortem device removal instructions have been created and are available in written format; Medtronic White Paper CQES-WP20150102rev1.

Citations

Galey, C., & Mulley, G. (2002). Pacemaker explosions in crematoria: problems and possible solutions. *Journal of the Royal Society of Medicine, 95,* 353-355.

Micra® MC1VR01 Single chamber transcatheter pacing system (VVIR) Clinician Manual; http://manuals.medtronic.com/manuals/main/region

Medtronic Data on File: MDT2172498-Micra Human Cadaver Cremation Test Report, July 2014

Southwest Research Institute, (2014).. Optical Smoke Density Evaluation of Pacemaker with Lithium Battery Tested In Accordance with ATSM E 662-09, Standard Test Method for Specific Optical Density of Smoke Generated By Solid Materials, and Supplemented With Toxicity Evaluation Tested in General Accordance with ASTM E 800-07, Standard Guide for Measurement of Gases Present or Generated During Fires.(Report) . Medtronic Data of File: MDT2185829-Micra Cremation Evaluation Test Report, Sept 2014

Smith, T., Gitsham, P., Donell, S., Rose, D., & Hing, C. (2012). The potential dangers of medical devices with current cremation practices. *European Geriatric Medicine, 3,* 97-102.