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Sterilization of Implantable Polymer-Based Medical Devices: A Review

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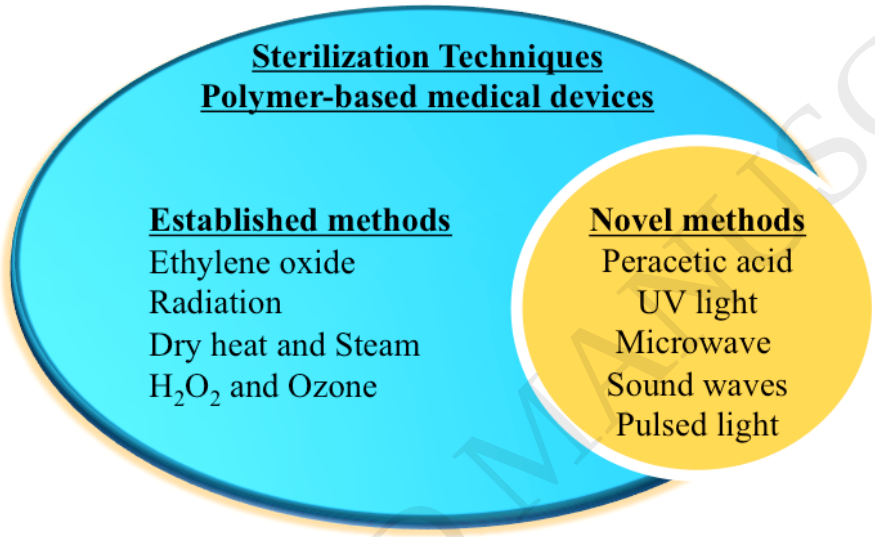
Graphical Abstract:



Abstract:

This review article is focused on the sterilization techniques used for polymer-based implantable medical devices as well as the regulatory aspects governing sterile medical devices. Polymeric materials are increasingly used in implantable devices due to their biodegradable and biocompatible nature. Patients and medical staff often prefer long-term implantable devices and these can be achieved using high molecular weight polymers. Sterilization of polymer-based implantable devices is critical. Since all implantable devices must be sterile, the effect of the sterilization method on the different device components (such as, the polymer, the drug, the electronics, *etc*.) has to be considered. A comprehensive summary of the established sterilization methods is provided along with the possible effects on polymers. In addition, novel sterilization methods are also discussed.

Keywords: polymeric medical devices; implantable devices; sterilization; sterilization techniques for implantable medical devices.