A Retrieval Study of the Essure® Micro Insert Female Sterilization Implant

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Introduction: The Essure® implant, premarket approved in 2002, is a permanent female birth control device. It is composed of a Stainless Steel (SS) coil wrapped around polyethylene terephthalate (PET) fibers, tin-silver solder to attach to a Nickel-Titanium (NiTi) outer coil and platinum-iridium (PtIr) radiopaque markers. SS holds the PET fibers in place and NiTi keeps the device in place in the fallopian tube. The PET induces a fibrotic tissue reaction, occluding the tube. It is inserted transcervically through the utero-tubal junction.[1] As part of an FDA-mandated post-market surveillance study, implant retrieval methods are being developed to measure local tissue metal levels and assess the degradation status of the implant. This study developed implant retrieval analysis methods for Essure devices and provided preliminary documentation of the nature and severity of the degradation mechanisms present.

Methods: To develop the tools and approach for device and tissue assessment, devices and tissues removed from six patients were fixed in formalin, then divided into 6 sections, proximal S1 to Distal S6. S1 (the most proximal region), S4 (the region containing PET, solder junction, SS and NiTi), and S6 (Tissue only, distal to the implant) were shipped to our lab. S1, S4 and S6 tissue was used for metal ion analysis, while the S4 portion of the implant was the focus of retrieval analysis. The different locations provide some ability to assess the distribution of ions in proximity to the implant. Tissue was dissected away from the implant remnants and dried under vacuum for at least 24 h, resulting in 21 tissue and 11 implant samples. After weighing, tissue was digested in 70% Nitric Acid overnight at room temperature and heated to about 60 ºC and stirred for 2 h to complete digestion. The solution was diluted using Type 1 Pure Water to 5% Nitric Acid. Tissue and formalin in which it was fixed were then analyzed by Inductively Coupled Mass Spectrometry (ICP-MS, iCAP RQ, Thermo Fisher Scientific, Waltham, MA, USA) for metal ion concentration. Retrieved implant sections were analyzed without additional cleaning steps using Digital Optical Microscopy (DOM, Keyence Model VHZ-ST, Itasca, IL, USA), Scanning Electron Microscopy (SEM, Hitachi, Model S-3700N, Toyko, Japan), and Energy Dispersive Spectroscopy (EDS, Aztec, Oxford Instruments, Abingdon, UK). Implant damage was compared across metal types and between samples. Ion concentration distribution across sections were compared statistically (1-Way ANOVA, $p < 0.05$, with Tukey post-hoc comparisons) by ion type.

Results: Significant differences ($p<0.05$) in Sn ions were seen between S1, S4 (highest), and S6, other ions had consistent levels across sections. Figure 1 shows ion concentration in S4 with low relative levels of Ti, Ni, Cr and Mo, but these were still in the hundreds of ppb.

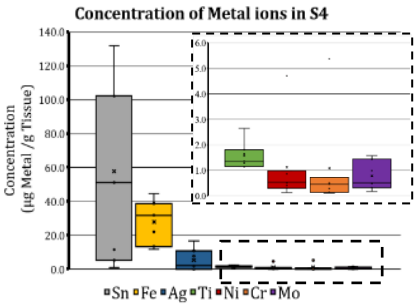

Figure 1: Chart of S4 Sn, Fe, Ag, Ti, Ni Cr and Mo ion concentrations.

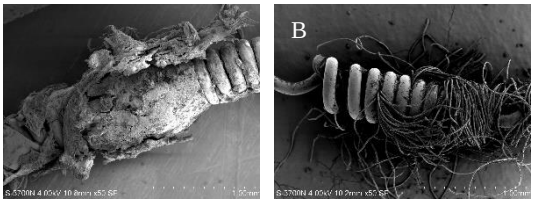

Figure 2: SEM images of a) Tissue attachment to Sn-Ag solder and b) SS coil and PET Fibers with cell attachment

SEM and EDS imaging showed signs of possible fretting corrosion between SS coils, and extensive corrosion of the Sn-Ag solder with a highly fibrous attached tissue (Figure 2a). NiTi and PET fibers appear relatively unaffected. Soft tissue adherence exists between SS coils, on PET fibers and on the Sn-Ag solder (Figure 2). Pieces of corroded solder were found throughout the soft tissue.

Discussion: Sn concentration is significantly higher than all other metals in the local tissue, however, metal ions are observed in all tissue sections. SEM and EDS showed extensive Sn-Ag solder corrosion. Specific patient information was excluded so that an unbiased assessment of implant condition could be made. The ongoing Essure study is descriptive; therefore, it is not designed or powered to detect statistical differences between the Essure and laparoscopic tubal sterilization (LTS) groups. This study is ongoing, and results are interim and subject to change. Final conclusions should not be made until the study is completed and final adjudication of the data is performed. In addition, no clinical correlations between implant status and patient clinical outcome were assessed.

Conclusions: This implant retrieval and analysis methods development study for the Essure implant shows that local tissue metal ion levels can be determined, that there are differences in ion levels at different locations around the device, and that Sn is the highest level metal ion present in the tissue. Imaging analysis shows the oxidized solder.

References :

[1] FDA, Essure Benefits and Risks, Jan. 2021