Managing Obsolescence and Replacement of "Endangered and Extinct" Medical Engineered Materials

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Material obsolescence may occur for many reasons, and Medtronic's current approach to these obsolescence events is reactive rather than proactive—an especially difficult approach to sustain due to the time and effort required to test and receive approval for new designs in the medical device industry. Our team developed a prototype rating system for determining the obsolescence risk of materials used by Medtronic and urgency of response necessary. Additionally, we examined a specific material of interest to Medtronic—SAC305, a lead-free solder (96.5% Sn, 3% Ag, 0.5% Cu)—and compare its efficacy to a leaded solder (63% Sn, 37% Pb) at pin interfaces on PCBs with SEM.

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Medtronic

Background

Materials in Medtronic's medical devices may become endangered and extinct for a variety of reasons, whether from government regulation, changes by suppliers, or other factors. Medtronic's current approach to this is generally reactive, with little attempt to predict which materials may soon become obsolete and proactively respond. Such an approach ultimately costs Medtronic time, money, and resources as the amount of time to properly respond to impending obsolescence is often greater than the amount of time Medtronic has. A proactive response will allow Medtronic to better manage material obsolescence and give Medtronic time to properly select and test replacement materials before obsolescence occurs.

The present task is to develop a system of managing endangered and extinct materials for Medtronic for present and future use. Inspiration for the approach is drawn from a case study by the United States Navy on managing technological obsolescence in naval submarines [1], where the Navy implemented a six-step approach to obsolescence management. From 2001 to 2010, this approach prevented over 1,000 obsolescence issues and avoided $96 million in costs.

The focus of this project falls especially on the first two steps of that approach: proactively identifying the issue and communicating it to relevant stakeholders. To address Medtronic's problem, a rating system was created, which outputs an obsolescence rating and an urgency factor for a given material. The obsolescence rating informs how likely the material is to be obsolete in the future, while the urgency factor informs how much priority it deserves in the present.

Factors

To manage obsolete materials well, Medtronic must move from a reactive strategy to a proactive strategy, which involves the prediction of obsolescence. Various factors – such as regulation, health risks, and public perception – can be used to predict when a material could become obsolete.

Obsolescence Factors	Description
Government	The likelihood of regulation and time (years) to regulation.
Environmental Risk	Modified NFPA 704 safety diamond guidelines.
Health Risk	Modified NFPA 704 safety diamond guidelines.
Public Perception (Use)	The public perception on using a material in a product.
Public Perception (Obtain)	The public perception on obtaining a material for production.
Raw Material	The availability of the raw materials used to manufacture a material.
Ethics of Manufacturing	Ethical concerns present anywhere in the manufacturing process.
Supplier Updates	The likelihood of supplier changing or discontinuing a product and time (years) to the update.
Economics	The economic viability of the material/supplier.

Ratings from these obsolescence factors communicate the degree of material obsolescence; however, an urgency factor is also needed to inform Medtronic how important the material is to their product, and how quickly they need to find a replacement material.

Urgency Factors	Description
Timescale Factor	Time for a replacement to be approved – including testing and regulation.
Importance to Product	Importance of the specific material for the product itself.
Importance to Performance	Importance of the material for the performance of the product – including the quality, reliability, and longevity.
Difficulty of Material Access	The level of difficulty in accessing the material.

Rating System

Obsolescence Rating

After each obsolescence factor is scored, the table below is used to determine the overall obsolescence rating. The total score is the sum of the points contributed by each factor, on a scale of 0-10. Any score 10 or above is functionally equal to 10—the total score should not be used to compare different materials above 10 to each other; only to conclude both are extinct. It is also possible to have negative scores, but these are functionally equal to 0.

Score	Government*	Health Risk	Environmental Risk	Public Perception (use)**	Public Perception (obtain)**	Raw Material	Ethics of Manufacturing	Supplier Updates*	Economic
0	**10**	0	0	-0.55	-0.55	0	0	**10**	0
1	**10**	0.50	0.50	-0.43	-0.43	0	0	**10**	0
2	**10**	0.75	0.75	-0.30	-0.30	0	0	**10**	0
3	6.00	1.00	1.00	-0.17	-0.17	0.04	0	6.00	0
4	4.29	1.50	1.50	-0.04	-0.04	0.37	0.04	4.29	0.04
5	3.33			0	0	0.42	0.37	3.33	0.04
6	2.73			0.04	0.04	0.48	0.55	2.73	0.37
7	2.31			0.37	0.18	0.55	0.80	2.31	0.55
8	2.00			0.55	0.37	0.80	1.15	2.00	0.55
9	1.76			1.50	0.55	1.50	1.50	1.76	1.50
10	1.58			**10**	**10**	**10**	**10**	1.58	**10**

**Government and Supplier Updates first follow a Yes / Maybe / No scale. "Yes" goes to the table with the score being time in years, "Maybe" adds a flat +1 to the score, and "No" does nothing to the score.*
***A score of 5 reflects an indifferent attitude; lower than a 5 a positive attitude; higher than a 5 a negative attitude.*

Score Ranges
The total score on a scale of 0-10 is then used to determine the obsolescence rating based on the ranges below.

>8.98	4.83-8.97	3.19-4.82	<3.18
Extinct: Material is no longer able to be obtained or used.	**Endangered:** Material will no longer be obtained/used in the near future.	**Emerging:** Material can be obtained or used, but this is likely to change in the future.	**Little/No Threat:** Material can be obtained/used.

Urgency Factor

While the obsolescence rating combines scores for factors into a quantitative value to determine a final rating, the urgency factor does not. Instead, four factors are considered, which are useful for cursory understanding and communication of priority level for each material.

Timescale Factor	Importance to Product	Importance to Performance	Difficulty of Material Access
	High	High	High
Time (Years)	Medium	Medium	Medium
	Low	Low	Low

Example Case

Related to obsolescence, Medtronic had a need to examine the differences between leaded and lead-free solder. Using the Obsolescence Rating, leaded solder was found to have a score of 3.34, giving it an emerging rating. The Urgency Factor has a timescale of 0 years, medium importance to product, high importance to performance, and low difficulty of material access. This means leaded solder can still be obtained and used by Medtronic and this is unlikely to change in the future. Given the scores from the rating system, leaded solder is a good example case to use in the selection and testing of replacement materials.

The replacement material being examined for the leaded solder (63% Sn, 37% Pb) is SAC305 solder, a lead-free solder alloy (96.5% Sn, 3% Ag, 0.5% Cu). Using Scanning Electron Microscopy (SEM), both the leaded solder and lead-free solder were compared to note any differences in structure that may result in differing properties.

Results and Discussion

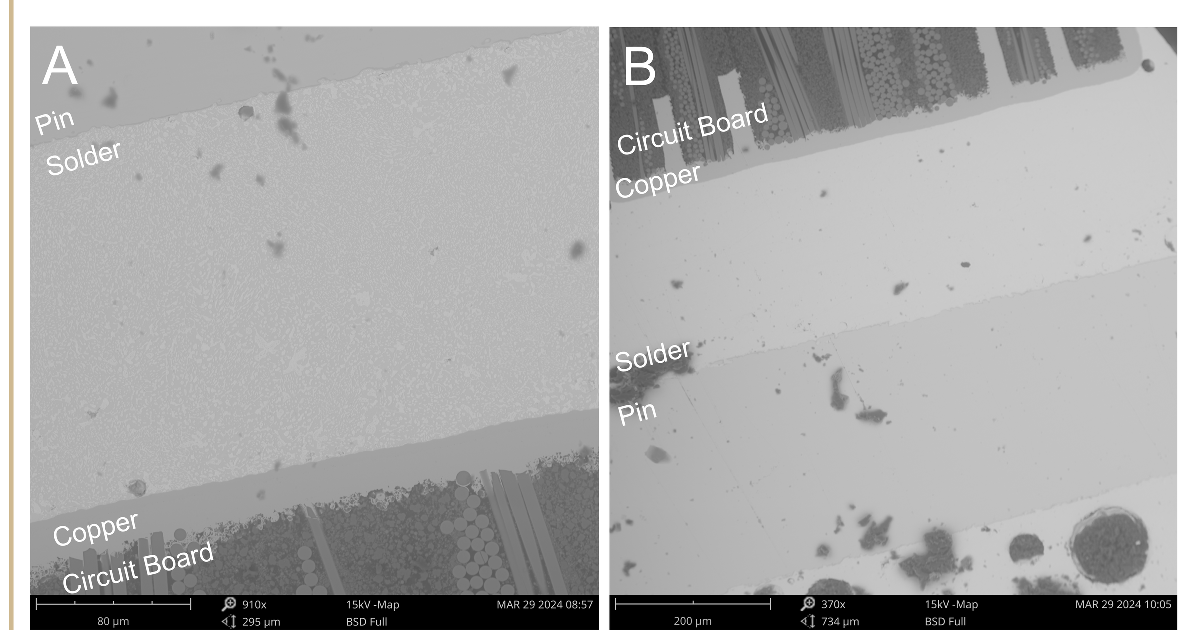

Figure 1: SEM images of solders. Figure 1A shows the leaded solder and Figure 1B shows the SAC305 solder.

The leaded solder contained a eutectic microstructure of lead and tin, which is to be expected given the makeup of the leaded solder material being at the eutectic point. The SAC305 solder was primarily the tin phase, which also is to be expected given that the solder material is 96.5% tin.

When observing the interface between the solder material and the copper circuit board connectors and the interface between the solder material and the pin, both interfaces appeared similar. The interface between the copper circuit board connectors and the leaded solder appeared slightly smoother than the SAC305 solder interface, whereas the interface between the pin and the leaded solder appeared slightly rougher than the SAC305 solder interface.

It should be noted that an error occurred between SEM sessions which resulted in focusing issues; therefore, later images were considerably out of focus. However, observations were still able to be made.

Future Work

While the factors for the rating system are fairly robust, their aggregation into a single obsolescence rating is less so. Many of the factors will need additional description and standardization into what qualifies for different scores, so that multiple people using the system could obtain consistent results. The scoring for Ethics of Manufacturing and Economics are especially deferred to Medtronic's judgment and will necessitate further examination. Additionally, once a standard is established for how scores are arrived at for individual factors, how those factors then contribute to the overall rating needs refinement. What numbers should be added for different scores, or if the formula should be addition-based, merits research, and further testing should be done on materials with well-known obsolescence conditions to see if they land where would be expected.

For future work on the SAC305 solder, mechanical and fatigue testing should be researched further, for the purpose of long-term implants. This would determine if SAC305 could be a viable replacement material for the leaded solder currently used in Medtronic's medical devices. Other future work on SAC305 solder would be the production requirements of the solder. Since SAC305 has a higher melting point and different compositional makeup than the leaded solder currently used, SAC305 solder might have different processing requirements to produce similar end products to the leaded solder. These additional processing requirements could eliminate SAC305 as a viable replacement for leaded solder.

Acknowledgements & References

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References:

1. Defense Standardization Program Office, Obsolescence management for Virginia-class submarines: Case study 1–8 (2010). Ft. Belvoir, VA; Defense Standardization Program Office.