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Risk of Tin Whiskers in Medical Devices

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Abstract

The reliability problem of tin whiskers in lead-free electronics has been studied for the past several decades. However, due to tin whiskers have not received sufficient attention and require further study especially because more lead-free products are being implemented in advanced medical equipment such as surgical instruments, medical implants, and life-sustaining devices. In an effort to raise awareness among the medical community about the risks of tin whiskers, this paper presents a brief introduction to tin whiskers, followed by the cases reported to date on whiskers in medical devices. Recommendations for mitigation practices are then presented.

Keywords: Tin whiskers; Lead-free electronics; Reliability risks; Medical industry; Electronic packaging; Tin whisker mitigation

Introduction

Tin-based coatings have been extensively used in the medical electronics industry, particularly in safety-critical devices such as pacemakers, defibrillators, and infusion pumps. Unfortunately, these coatings are susceptible to electrically conductive tin whiskers (i.e., thin crystalline filaments formed as surface eruptions on the tin-metal finishes), which can lead to short circuits [1] and malfunction. In life-supporting devices, tin whiskers can actually cause patient injury or death.

Tin whiskers were first reported by Bell Labs in the 1940s, on their channel filters used for multichannel transmission lines. Much research has been conducted on the growth mechanisms of tin whiskers and methods to mitigate them [2-4].

Until recently, lead has been used as an alloying element with tin to suppress tin whisker growth. However in 2003, the European Union passed the Reduction of Hazardous Substances (RoHS) directive, mandating lead-free electronics in electrical and electronic equipment sold or used in the EU after July 1, 2006 [5]. Other nations such as Japan, China, Korea, and the United States also have laws that restrict the use of environmentally hazardous substances in electronic products [6]. The electronics industry has migrated to lead-free electronics, mainly driven by government legislation and market forces. A large number of electronic parts manufacturers have adopted pure tin or high-tin lead-free alloy finishes as a replacement for lead-alloyed finishes. Pure tin or high-tin lead-free alloys are preferred as a low-cost drop-in replacement for existing tin-lead plating processes. However, not all U.S. industries have made a complete and risk-free transition to lead-free electronics.

Because the major drawback of lead-free finishes in electronics is the potential formation of tin whiskers, the medical device industry must focus on understanding the risks associated with tin whiskers.

For instance, a NASA website lists reports of many losses due to tin whisker growth, resulting in over $1B in damages [1]. A common issue is that the medical equipment and systems will suddenly stop working without notice or alert and in some cases during surgery or patient monitoring. Specific cases of medical device failures due to tin whiskers are reported in pacemaker recalls, failure of defibrillators and infusion pumps [1,7].

This study addresses the risks associated with the new generation of RoHS-compatible materials and components and raises awareness within the medical community about the issues of using lead-free assemblies. Mitigation strategies are proposed for tackling the reliability risks in lead-free medical devices during the design, development, and manufacturing stages.

Tin Whiskers and the Medical Device Industry?

Tin whiskers were first reported in medical devices in 1986 when pacemakers from one manufacturer failed. Tin whiskers were found growing from the tin-plated case of the pacemaker's crystal component. An electrical bridge between the crystal and its case disabled the crystal component, resulting in the total loss of pacemaker output. The U.S. Food and Drug Administration (FDA) issued a Class I recall for the affected devices and initiated a follow-up investigation. The results of the investigation revealed that the problem originated in the manufacturing process. The manufacturer had not tested the crystal components to confirm the correct material content but had solely relied on the vendor to deliver the right components [8].

Since medical devices are considered high-reliability products, they were originally exempt from RoHS compliance for lead-free electronics in 2003. However, after 2014, the recast version of the RoHS directive required the majority of electronic devices to fully comply with the lead-free practices. The exceptions are mobile electro-medical devices and imaging systems, which are currently exempted for using lead-free solders; portable emergency defibrillators, which do not have an expiration date; and implantable devices, which are excluded from the RoHS directive.

As part of this study, FDA's Manufacturer and User Facility Design Experience (MAUDE) database was searched for tin whisker-related issues reported in medical devices between January 2006 and December 2016. A total of 77 entries were found [9]. The database shows that in the past 10 years, tin whisker shorting caused malfunction of two types of medical devices: one infusion pump model and three automated external defibrillator models.

In these malfunction reports, the manufacturer identified tin whiskers in the electronics of the medical devices. One report mentioned that a patient noticed the insulin infusion pump suddenly began ringing, the display turned blank, and the keypad was unresponsive. The root cause was tin whiskers on the force sensor connector, which led to a short circuit. The remaining 76 reports mentioned that tin whiskers were found in the electronic components of three external defibrillator models.

In all the reports, the affected device could not be powered on due to premature battery depletion. The root cause was depletion of the device's internal hybrid layer capacitor batteries, which prevented the device from powering on and delivering shock defibrillation energy. In 4 reports (out of 76), the device did not provide any voice prompts or early warning signs as well. In about 21% of the reports (16 out of 76), the manufacturer found non-shorting tin whiskers within the connector assembly and claimed these whiskers did not contribute to device malfunction and could not result in short circuit. However, in about 79% of the reports (61 out of 74), the root cause of the malfunction was short circuit due to tin whiskers. In 50 out of 61 reports, which involved two defibrillator models, tin whiskers shorted the pins of the switch flex cable assembly connector, which resulted in battery depletion while the device was powered off. The remaining 9 reports (out of 61) involved a different defibrillator model, and the manufacturer observed tin whiskers growing on the inside surface of the electromagnetic interference shield. The shield fell onto the printed circuit board and shorted several components, causing premature depletion of the battery.

Two reports of defibrillator malfunction, in 2006 and 2008, explicitly mentioned that the RoHS-compliant tin-plated material for the flex cable assembly was the main root cause of the tin whisker issues. These two reports claimed the problem was resolved by reverting to non-RoHS-compliant materials. However, analysis of the MAUDE database for 10 years after these two reports showed numerous reports of tin whisker shorting for the same devices. As mentioned earlier, tin whiskers can melt when they short, so not finding visual proof of their existence does not mean that they are not the root cause of the device malfunction. Figure 1 shows the distribution of adverse events as a result of tin whisker growth per year during the 2006-2016 time frame retrieved from the MAUDE database.

These reports prove that tin whiskers must be considered a serious reliability risk in high-reliability products such as medical devices. Because medical devices have to last for a long time, their manufacturers need to have highly reliable, clean processes in place as the medical industry moves toward lead-free electronics.

Tin whiskers are not merely a supply-chain issue as originally accepted but rather an overall manufacturing concern. When transitioning to lead-free, medical manufacturers need to be aware that there is no single drop-in replacement for the reliable Sn-Pb alloy solders. In many cases, a combination of several lead-free solutions needs to be integrated into a single medical system. Solder chemistries such as tin-silver-bismuth (Sn-Ag-Bi) or tin-silver-bismuth-copper (Sn-Ag-Bi-Cu), which have been recommended for high-reliability applications such as military and aerospace, could be considered for medical devices. Bi can lower the melting temperature of the solder which, in addition to mitigating tin whisker growth, can eliminate pad cratering (i.e., mechanical cracking of a PCB laminate). Although Bi is an effective element, it is not readily available, it tends to oxidize, which causes the Sn-Ag-Cu (SAC) solder to become brittle, and when it is applied on components or board finishes that contain Pb, it can result in poor fatigue resistance [10].

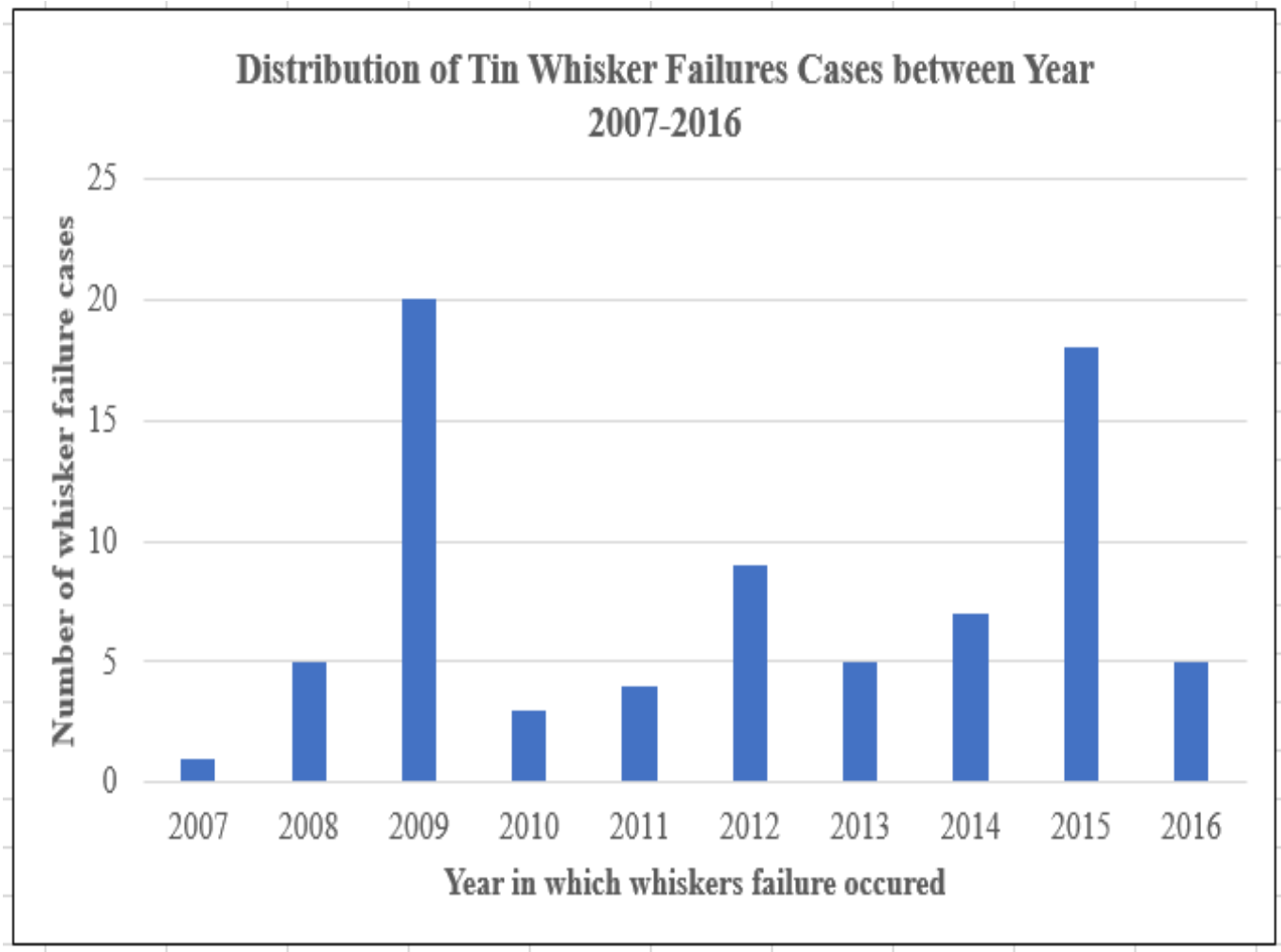

Figure 1: Distribution of adverse events due to tin whisker growth from the FDA MAUDE database, 2007–2016.

Depending on the type of soldering operation, solder joint configuration, component level, and field conditions, the actual implementation of lead-free electronics will be unique to the application, and the specific conditions and risks will need to be examined. In addition to electronic circuit board processing materials, possible reliability risks should be monitored on the composition and physical properties of the interconnection alloy, surface finish of the printed wiring board (PWB), quality of the component lead termination finish, and ionic cleanliness levels. Variability in the assembly process and electronics miniaturization can introduce additional product reliability issues that need to be carefully examined before lead-free implementation in medical devices.

Tin Whisker Characteristics and Growth Theories

Whiskers tend to grow from the base of tin surfaces; they can be straight, kinked, bent, or a combination of straight and bent; and they have a diameter of up to 10 μm and length of up to 500 μm. Although whiskers are generally short, their lengths follow a lognormal distribution that can lead to very long whiskers. Whiskers with lengths of 10 mm and greater have been reported [1,3]. Due to their unpredictable nature and ability in grow in different shapes, they tend to form at random locations on the metal surface (Figure 2).

The rate of whisker growth is non-linear and depends significantly on the coating thickness and circumstances. Whiskers have an average growth rate up to 1–2 μm/month but can grow much slower or faster. Therefore, depending on the circumstances, the incubation period for whisker growth can vary from hours to years [3,11,12]. Whiskers are electrically conductive and carry a current from 20 to 30 mA under a 15 V voltage. This current can cause short circuits in closely packed electronic components due to bridging of adjacent conductor and can lead to failures such as current leakage, metal vapor arcing or plasma at low pressure, and flash-over voltage. Sometimes the current can cause audible noise and other damages due to debris [1]. Although research on tin whiskers has been conducted in many industries over the past 60 years, there is no complete understanding or evidences explaining their growth mechanisms and the factors that accelerates their growth [3,4,13]. The scientific community has accepted the presence of compressive stress gradients in tin films as the underlying cause for tin whisker formation. Compressive stress gradients can develop as a result of multiple material processes that interact with each other, such as interdiffusion, phase transformation, and stress relaxation [4]. Additionally, many processing factors, such as plating parameters and conditions [14-18];

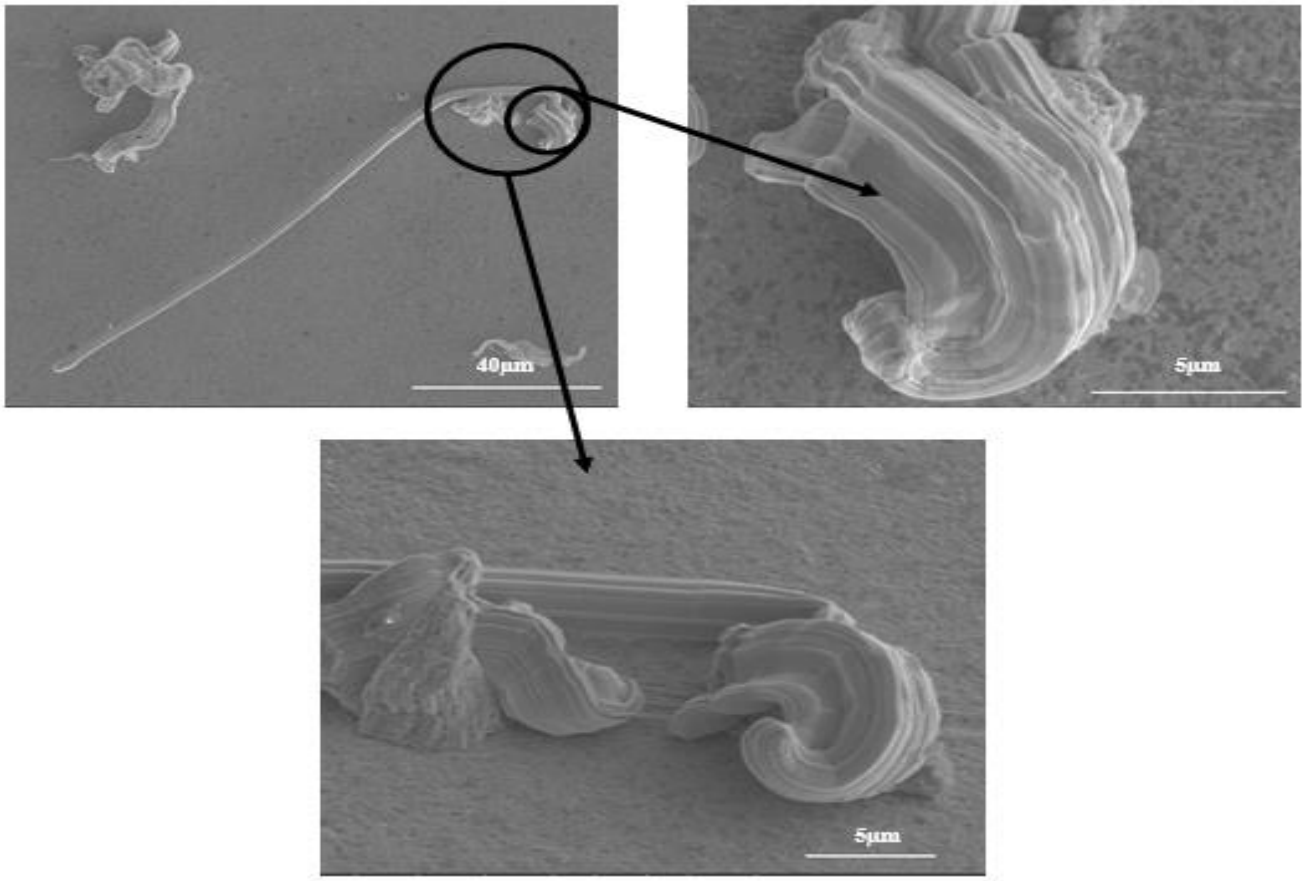

Figure 2: Tin whisker profiles with various geometries shown at different magnifications.

grain size and orientation (i.e., film texture) [19-21]; film microstructure [22-27]; film composition [24,25,28-30]; film thickness [14,19,20,22,31,32]; and thermal cycling, corrosion, and mechanical deformation [33-47] can enhance the formation of stress gradients in the films and contribute to tin whisker growth.

A summary of the most recent experimental studies in combination with finite element modeling demonstrates that the formation of Cu6Sn5 intermetallic compounds (IMCs) at the film-substrate interface is the major contributing factor to stress gradients in tin films [4]. Cu6Sn5 IMCs are a result of Cu's tendency to diffuse from the substrate into the tin film preferentially along the tin columnar grain boundaries intersecting the Cu/Sn interface with a wedge-shaped IMC. The IMC grows in volume over time, leading to the development of a compressive stress gradient in the tin film [46,48,49]. It is reported that tin whiskers are stress-relieving phenomena that in fact form at grains with lower stress (i.e., weak grains) than at neighboring grains, further confirming the existace of a stress gradient in the tin film. Studies have confirmed that weak grains, which are most susceptible to tin whisker growth, have different grain orientation (210) in the hkl plane and lower stress state than the neighboring grains with a (321) grain orientation. The weak grains are present at the time of deposition and do not form by a later re-nucleation process [50; 51]. This leads to a belief that the chemistry and quality of tin-based deposition is very important.

With the development of ever smaller electronics for medical devices, the potential for short circuiting due to whiskers increases. Since whiskers are difficult to observe even under a microscope and may melt or vaporize after short circuiting, the possibility of whisker-induced failure in commercial electronic components is actually higher than what engineers have reported to date [1,3].

Current Mitigation Methods for Tin Whisker Growth

Many studies have been dedicated to mitigation strategies that can eliminate or temporarily postpone tin whisker growth. Following is an overview of various mitigation techniques currently used by industry [3,52,53,54]:

Sn alloy – the use of a Sn alloy was one of the earliest proposed solutions. The addition of a small amount of lead into the Sn bath has a significant impact on the mitigation of Sn whiskers growth [55, 56, 57]. With the new RoHS directive, the application of lead is no longer allowed. Some "out of scope" products are exempted and allowed to use Sn-Pb alloy finishes [52]. Other effective Sn alloys for the mitigation of Sn whiskers such as Sn-Bi, Sn-Sb, Sn-Ag, and Sn-Ni are reported in the literature [58, 59]. All of them have shown a temporary retardation effect on the growth of Sn whiskers. It is also recommended that a modified plating procedure could produce a variety of Sn alloy coatings with properties very similar to those of a Sn-Pb alloy [59].

Matte Sn – Matte Sn or low-stress Sn is proposed as a solution to mitigate the growth of Sn whiskers with respect to bright Sn, because of the larger grain size and the ability to withstand high temperature conditions [3].

Post-plating bake at 150oC for 1-2 hours – Post-plating bake is a process usually completed within one day of plating and is believed to produce more uniform IMCs at the substrate/coating interface [60,61].

Underlayer – An underlayer is an application of metal coating on a substrate prior to the final tin finish. The most common metal used as an underlayer is nickel [3]. Other metals such as copper and silver are also used as underlayers in some applications, but they are not as common as nickel [3, 52].

Plating thickness –According to International Electronics Manufacturing Initiative (iNEMI) guidelines, the minimum thickness of the plating should not be less than 8μm if pure tin plating is applied [52]. iNEMI contends that a larger thickness increases the incubation period of the growth of Sn whiskers.

Solder dipping – Solder dipping is done in a hot tin bath and is a less common mitigation practice. This method also might not work for a pure Sn or Sn-Cu alloy, but it is proven to work for Sn-Ag or Sn-Ag-Cu [52].

Application of Heat Treatment – Heat treatment is the process in which Sn plated components are dipped in a hot oil bath. This process is proven effective in the mitigation of Sn whiskers [58, 62]. The theory behind this application is that any internal stresses formed in the film are relieved. After the heat treatment the components need to be very carefully handled so that the stresses do not develop again.

Application of Conformal Coating – A conformal coating increases the corrosion resistance in the tin coatings and can add an insulation barrier that could prevent failures caused by Sn whisker growth. When utilizing this procedure, it is important to consider also the material properties of the applied coating [52, 63].

Risk Assessment Methodology

To quantify the failure risk due to tin whiskers, Pinsky et al. [64] proposed a metric based on risk factors created for different applications. The metric uses empirical knowledge of whisker formation, which provides a relative (comparative) risk prediction but not a quantified risk probability. Another approach to assess risk is Okada et al.'s [65] reliability estimation, whereby an Eyring model was used to estimate the acceleration factors and predict tin whisker growth in terms of average length for temperature cycling. However, whisker growth can occur without temperature cycling, so this estimation has limited applicability. Fang et al.'s approach [66] was to quantify tin whisker risk as the probability of a conductive whisker growing across adjacent electrically isolated conductors, resulting in unintended electrical leakage. The risk assessment algorithm is based on whisker growth characteristics, the geometry of the product at risk, failure criteria, and time. Tin whisker growth parameters include density, length, and growth angle, which refers to the angle between a whisker and its orthotropic projection against the finished surface from which the whisker develops (Figure 3) [67].

All of the growth parameters are considered functions of time. The growth parameters are modeled in terms of probabilistic time-dependent distributions [49,68] and quantified based on experimental data. The geometry parameters include spacing between adjacent conductors and available conductor area. A bridging short is assumed to occur if a whisker has sufficient length and the proper angle to span the space between a defined pair of conductors as shown in Figure 3.

The whisker length and angle can also be expressed with a mathematical algorithm as follows:

$$l_w.sin\,(\theta) \geq l_s \quad \text{Eq:(1)}$$

Where θ is the whisker growth angle, lw is the length of the whisker, and ls is the pitch spacing between the two adjacent conductors (as shown in Figure 3) [67]. This definition can also be applied to any surface shapes and is not limited to leaded conductor. Bridging risk can also be computed following the steps in Figure 4 flowchart.

In Figure 4 f represents the number of failures, mc is the sample size for Monte Carlo simulation, w is the length of a simulated whisker, min is the minimum spacing of two adjacent exposed conductors of a part, and w is the number of whiskers in a simulation. The symbols n and m are the iteration control numbers for Monte Carlo simulation and simulated whiskers, respectively. The risk of failure due to tin whiskers, Ri, is defined as the ratio of the number of failures per number of potential failure opportunities at a particular time. The final risk at a particular time is:

$$P_{Ri}=N_f/N_{mc} \quad \text{Eq:(2)}$$

If a failure occurs during a run of the simulation, the simulation will go to the next run in order to avoid double counting a failure. It is assumed that the product will fail immediately once a tin whisker bridge occurs, so it is not necessary to examine the other whiskers in the simulation as the product has already failed. If there is more than one part of a particular type in a product, the risk for that part type is estimated as follows:

$$P^i_{Risk}=1-(1-P_{Ri})^{ni} \quad \text{Eq: (3)}$$

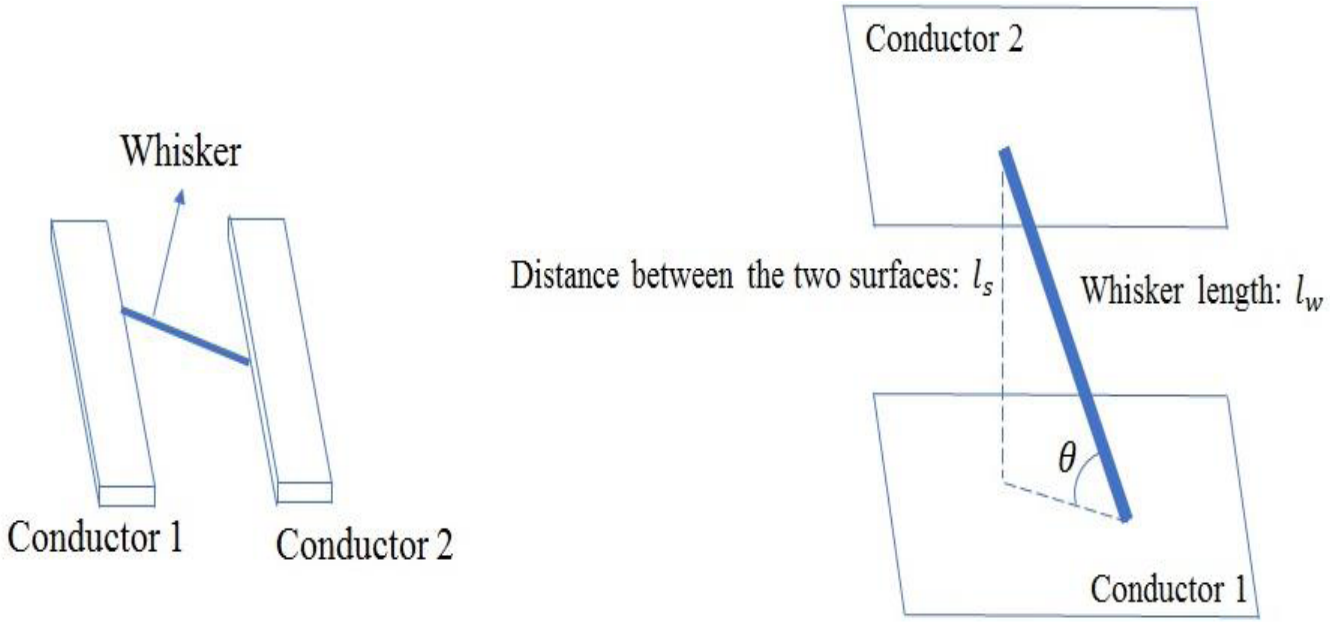

Figure 3: Schematic of whisker growth parameters [67].

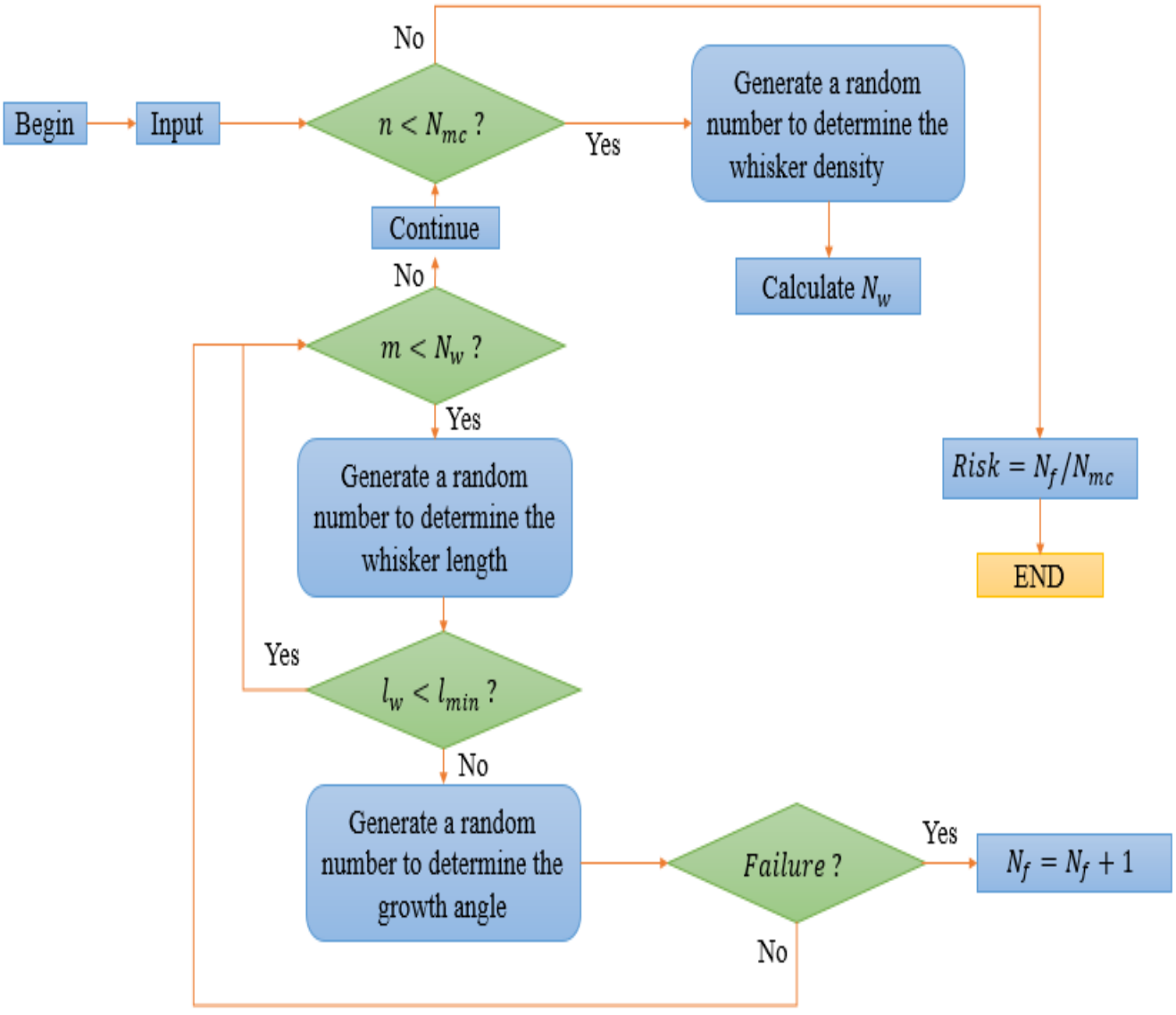

Figure 4: Tin whisker bridging risk assessment flowchart [67].

where i is the part type, n_i is the number of parts of the i^{th} type, and P^i_{Risk} is the total risk for all the parts of the i^{th} type. If there is more than one type of part in a product, assuming no redundancy, the total risk from tin whiskers for the product is shown in Eq. 4:

$$P_{Product}=1-\Pi^{m}_{j=1}(1-P^{j}_{Risk}) \quad \text{Eq: (4)}$$

where P product is the part type, m is the number of the part type and P risk is the total failure risk posed by tin whiskers to the product. The number of whiskers in a simulation is the product of sampled whisker density and the application conductor areas. The procedure for a Monte Carlo simulation is at a particular time (usually the mission life). If the tin whisker risks for varying periods are required, the whisker growth data can be input into the algorithm as arrays or the growth rates of mean of length and density can be input such that the mean of length and density can be calculated at each desired time.

Managing Tin Whisker Risk

In addition to relying on their suppliers, medical device manufacturers should themselves ensure that parts meets lead-free standards and are selected based on the specific field conditions. Strategic partnerships should be formed to ensure that the manufacturers select reliable suppliers who provide parts without the potential risk of tin whiskers. Even before the medical device is manufactured, original equipment manufacturers (OEMs) need to evaluate the threat that tin whiskers could pose for the final product's functionality and implement a comprehensive risk reduction program to mitigate those risks. This program can be based on proven environmental tests, a database for tin whisker risks examined from other critical applications on modeling, evaluation of the extent of conformal coating coverage at the whisker scale, and, if necessary, the development of improved coating application methods. An overall risk assessment and reduction plan, supply chain assessment, and manufacturing best practices for avoidance are other necessary aspects of the program, as is current and in-depth knowledge of the findings of ongoing research and standards development projects. The program culminates in validation of the selected mitigation techniques from custom-designed laboratory assessments.

Medical device manufacturers and suppliers need to understand and address the different types of tin whisker risks that can occur at the different levels/stages of the system assembly. Because tin finishes and solders are prone to tin whiskers, if lead-free solder is implemented, then the terminal finishes of package electronic devices and printed circuit boards will need to be optimized and compatible with the lead-free solder.

A typical lead-free implementation approach needs to be realized in several stages that might have some overlap. Stage 1 will introduce the lead-free solder type (both reflow and wave solder) while everything else, such as components and board finishes, will remain lead-based at this initial stage for testing. Multiple alloy systems will be selected at this stage to satisfy the needs and requirements of each system component. Stage 2 will focus on eliminating lead from board finishes that contain lead for corrosion and oxidation protection and ensuring finishes are compatible with the lead-free solder selection in stage 1. Stage 3, which will take the longest time and poses the greatest concerns, involves lead elimination from components in which lead is part of the component structure and function. Many decisions and alterations need to be completed in stages 1 and 2 before stage 3 can be fully accomplished [69].

Standards Related to Tin Whiskers

To address the issues related to tin whiskers and to provide a common guidance, standards have been framed. The Joint Electron Device Engineering Council (JEDEC) provides two standards related to tin whiskers: JESD22A121A [70] and JESD201 [71]. The two standards highlight the environmental conditions under which tin whiskers are suspected to grow the most and also detail the acceptable length of tin whisker growth. The Japan Electronics and Information Technology Industries Association (JEITA) provides standards for testing tin whiskers. The International Electrotechnical Commission (IEC) provides an environmental testing standard. The Government Electronics Information Technology Association (GEIA) of the USA provides a standard to address whisker mitigation [69].

Issues with Current Tin Whisker Standards and Recommendations

Because the growth mechanisms for tin whiskers are not thoroughly understood, several issues and inconsistencies prevail in the standards as described earlier, especially as high-risk medical device manufacturers fully implement lead-free electronics in their systems. The following measures are recommended: caution should be practiced when measuring tin whiskers length as whiskers tend to grow in various shapes and sizes, case-specific conditions need to be developed for environmental testing since ambient conditions differ from field conditions, setting up acceptance criteria is a must and also case-specific since whisker length and density should be considered, and more studies can be conducted on the shorting properties of tin whisker growth since shorts are unpredictable events that can cause the most equipment damage.

Conclusions

Product reliability and regulation plays a significant role in the design, development and commercialization of medical devices. A comprehensive understanding of tin whiskers and their role in device failure along with effective strategies to mitigate their growth are thus essential for successful and long-term medical device operation.

This paper reviewed tin whisker characteristics, growth theories, the effect on medical devices, and current standards and regulations, and provided recommendations for a more effective and robust transition and implementation of lead-free medical devices. Because tin whiskers can cause serious reliability issues and fatal medical product failures, the main goal of this paper is to increase tin whiskers awareness among the medical community. Further, we aim to educate manufacturers, suppliers, and end users involved in any aspect of the medical device development and usage process about best practices to prevent device failure due to tin whiskers.

There is no one lead-free solution that fits all situations, and as the medical device industry moves towards RoHS compliance, they will be dealing with the possibility of tin whisker growth when new lead-free materials are used to assemble electronic circuitry. Managing the reliability risks presented by tin whisker formation is a critical challenge for the medical device industry.

Development of medical devices is highly regulated. The FDA provides a guidance stating that reliability should be part of device performance requirements. Yet the role of reliability testing and analysis varies significantly from one manufacturer to another.

As a result, in order to ensure high reliability in medical devices, OEMs must ensure their strategic partners can assess the risks of tin whiskers and implement risk mitigation tactics. They should also ensure that their contract manufacturers have expertise in handling the risks associated with tin whiskers and are familiar with RoHS compliance best practices on a global level. Tin whisker risk mitigation should be part of every compliance plan, starting at the design and prototyping phase. Tin whisker growth is affected by component plating quality and ionic cleanliness levels in addition to electronic circuit board processing materials.

Avoiding tin whiskers is not feasible through component selection alone. Whiskers can grow from the tin-rich solder alloys used to assemble RoHS-compliant electronic products as well as from solderable parts coated with tin finishes. The medical device industry should be aware that tin whisker formation and growth is not only a supply chain issue, but also an overall manufacturing concern, because of the extended life cycle of medical devices and the potential safety threat to patients. Because these devices are often critical for hospitals and healthcare centers, the manufacturers must learn best mitigation practices and put processes in place to protect against tin whiskers. Extensive case studies, and regulations need to be in place before robust, fully lead-free medical devices are considered risk-free from growth of whiskers.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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