Inspections, Compliance, Enforcement, and Criminal **Investigations**

Tin Wiskers Problems, Causes, and Solutions

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DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB*

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Recently, a little-known phenomenon called tin whiskering caused the recall of several models of a pacemaker. This incident revealed tin whiskers to be a general threat to all users and manufacturers of medical devices that incorporate electronic circuitry. To prevent future problems, field personnel will need to educate themselves and manufacturers. This guide is intended to help in this endeavor by describing the problems, causes, and solutions associated with tin whiskers.

TIN WHISKERS

Tin whiskers are metal filaments which grow from tin. They are extremely thin, 1-2uM typically, and grow as straight, kinked, or spiraled single crystals of tin. They can reach a length of 9mm (3/8") and carry 10mA of current before burning up. The electrical resistance of a tin whisker 3mm (1/8") long is about 50 ohms. Because of their current carrying ability and low electrical resistance, whiskers are a threat to electronic circuits.

The ability of tin whiskers to cause electronic circuit problems was established in 1951. Many sudden failures and intermittent problems were associated with tin whiskers because of their ability to short closely spaced electronic circuits. Whiskers were found to grow across circuit connections and, because of their thin, brittle nature, would break free and lodge across circuits. Investigation into preventive measures was started, but

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solutions developed slowly due to the complex nature of tin whisker growth.

The exact cause of tin whisker growth is still not fully understood. It is known that a whisker grows from its base and that the tin around the base does not thin as the whisker grows. It seems that the energy for growth comes from microstrains present in the tin or from externally applied pressure. Tin atoms appear to diffuse along screw dislocations within the tin and are pushed outwards by stresses. Growth rate varies tremendously, and it may be unsteady. Whiskers can fully develop in minutes or take decades to form. Spurts of growth may occur.

The growth of tin whiskers is not directly related to the surrounding medium. Whiskers will grow in sealed components, under high vacuum, and in low or high humidity. Temperature has some effect on the rate of growth, and the thickness of tin deposits affects whisker density. An obvious factor affecting whisker growth is pressure. High-compression pressure from bolts or screws will always produce whiskers in tin deposits.

It was 1974, two decades after the problem was recognized, that scientifically valid methods were established for controlling whisker growth. Two methods are currently used. The most common is to avoid using tin. Other metals or alloys of tin are used instead with solder (tin/lead) being the most popular. The other method is known as "reflow." After the tin is in place, the tin coated part is heated to a temperature above tin's melting point. This heating releases any stress that exists within the tin deposit.

The FDA became interested in tin whiskers as the result of pacemaker failures. A group of pacemakers from a single manufacturer were found to have a high rate of failure due to tin whiskers growing from the tin-plated case of the pacemaker crystal component. An electrical bridge between the crystal and its case disabled the crystal component, resulting in the total loss of pacemaker output. The FDA issued a Class I recall for the affected devices and initiated a follow-up investigation.

Examination of the manufacturing process revealed that the manufacturer's specification for the crystal component should have prevented tin-whisker growth. The crystal component specification called for gold, nickel, or solder plating. Any one of these case coatings would have prevented the tin whisker problem. The manufacturer, however, failed to test the crystal components for proper material composition. It relied on its vendor to deliver proper components. Unfortunately, a bad batch of crystal components resulted in 80 percent of the affected devices having tin-plated crystal components.

PROBLEM PREVENTION

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Testing is the key to preventing tin whiskers. Testing for material composition and/or material structure should be part of any critical device manufacturing.

Testing must be performed independent of the vendor. As the pacemaker case illustrates, a manufacturer cannot absolutely rely on the vendor to meet composition specifications. Errors will occur which make independent testing of critical components mandatory.

Manufacturers must test for the appropriate problem. Knowledge of tin whiskers is relatively new in industry and problems of understanding will arise. In the follow-up investigation, a manufacturer questioned by FDA confused tin dendritic growth with whisker growth. Both of these phenomena occur in tin but they are very different. Dendrites result from a voltage induced plating phenomenon which requires both voltage and high humidity. Whiskers grow spontaneously. The manufacturer erroneously claimed that his pacemakers were resistant to tin whiskers because his circuitry was protected from voltage and high humidity. He even used dendrite as a synonym for whisker. Obviously, this manufacturer was confused about the causes and prevention of tin whiskers.

Some knowledge of tin whiskers, its causes and consequences, should be available at the manufacturing site. Asking about component composition testing will quickly reveal a manufacture's understanding of the tin whisker problem. If a manufacturer specifies whisker resistant parts and uses component composition testing to verify his specifications, then tin whiskers will not cause problems.

CONCLUSIONS

Untreated tin coating should never be used in conjunction with electronic circuitry.

Device manufacturers should verify the material composition and/or the material structure of all critical electronic components independent of the component supplier.

The investigator can help prevent tin whisker problems by enquiring into material testing of critical electronic components. However, knowledge of tin whiskers is new in the industry. The investigator may first have to educate manufacturers about tin whisker problems before looking into material testing.

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Manufacturers should attempt to control the problem for the most part by specification with subsequent assurance of vendor conformance to the specification. Every manufacturer of electronic devices would not be expected to do material analyses of all incoming components. It would, however, be expected of every pacemaker manufacturer.

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