Protection of Electronics for Reprocessable Surgical Devices

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INTRODUCTION: Electronics destined to be placed in a reusable surgical device will likely have to go through reprocessing (commonly machine cleaning followed by steam sterilization) prior to a subsequent surgical procedure. Reprocessing is known to be very aggressive on electronics (even when protected) because of the temperature, pressure and chemicals involved. Protection of electronics through overmolding can be done by polymeric materials (despite their lower barrier effect properties compared with metals) as a result of the quasi absence of gaps, i.e. no microclimate inside of the housing. The risk of condensing of unwanted chemicals (mostly water after sterilization) is drastically reduced. Unlike the involved chemicals in gaseous phases that are relatively harmless for an overmolded electronic device, the chemicals in liquid phase (cleaning products, typically solutions of very strong bases, pH 11 and more) are chemically very aggressive and are to be reliably kept off of the electronics even after several reprocessing cycles. This article discusses this specific topic in the case of an overmolded electronic device.

METHODS: Overmolding allows to build a housing in one block and in one-step process around an electronic device. Except from the interface between the connection elements (typically fluor-polymer isolated conductors or golden pins) and the overmolding material, there aren't any potential ingress paths for a liquid. It is commonly known that interfaces are prone to ageing and to a delamination throughout the repeated reprocessing cycles.

In this study, we tested the sealing quality of an overmolded electronic device equipped with PTFE conductors. The PTFE conductors had been pre-treated in order to improve their adherence potential with the overmolding material. The testing method was to perform a dielectric test after an IP67 immersion in water at different ageing stages.

Ageing is performed in the air, inside a thermal shock chamber from 0 °C to 150 °C. The sterilization temperature range is typically from 20 °C to 135 °C. The extended temperature range for the ageing is meant to compensate for the higher thermal conduction coefficient of steam compared to air. Alternatively, another group of parts was aged inside of a tabletop sterilizer running in a loop. The sterilizer used for the test didn't completely cool down to room temperature at the end of each cycle, leading to a degraded test.

To test the sealing against the IP 67 standard, the samples have to be immersed for 30 minutes in water over-pressurized with 0.1 bar. The method for detecting potential water ingress into the housing is a dielectric test at 1500 volt performed in water. If the leakage current stays underneath the limit of 0.350 mA, the test is successful (see IEC 60947-1, §8.3.3.4)

RESULTS: Figure 1 shows the values of the dielectric test after an IP 67 immersion and after different ageing stages. The two different groups of parts tested (up to 556 sterilizations at 134 °C and aged up to 800 thermal shocks from 0 to 150 °C) are represented in black and grey. Both values are at least ten times below the acceptance criteria for this test. The outliner (part N°2) was defective from the beginning. After analysis, the root cause was a damaged conductor, outside of the overmolding area.

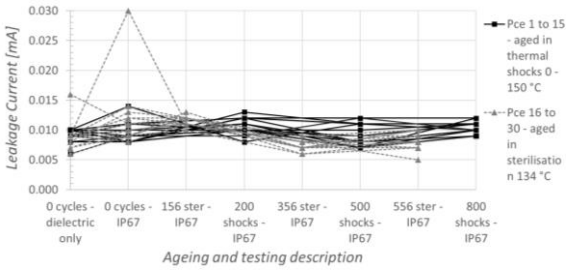

Fig. 1: Leakage current after an IP67 immersion in water and different ageing stages.

DISCUSSION & CONCLUSIONS: The results show a very low and stable leakage current, proving the sealing-performance between the PTFE and overmolding material interface in harsh environments. Additional tests also have been conducted in real environments (over a thousand machine cleanings plus steam sterilization cycles) without any failure of the electronic, which confirms the laboratory results. Similar work is currently in progress to study the performance of pre-treated gold pins in overmoldings.