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# INFLUENCE OF AGEING OVER NON ACTIVE MEDICAL DEVICES

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## ABSTRACT

This work compares between artificial and real time ageing of non active medical devices after irradiation, analysing the impact of this process over the mechanical properties. The impact of irradiation and ageing influence the materials. The polymers can be damaged by the radiation required to sterilise them. This damage can involve embrittlement, discoloration or additive blooming. Often the chemical damage is not complete when the radiation stops, but continues in a "dark reaction" for some time, often years.

A method of accelerated ageing is required that realistically recreates what a product may experience during storage. Real time ageing is the best way to do this, but no enterprise can afford to delay its products launch waiting for the real time ageing tests.

***Keywords:*** real time ageing, artificial ageing, non active medical devices, irradiation, properties.

## INTRODUCTION

According to the ISO 1113711137-1 - Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization (ANSI, 2006) - and the United States Food and Drug Administration regulations, Medical Devices must be given an expiry date, which indicates how long they may be stored prior to use. Since most of the medical devices have to guarantee 5 years prior to use, we simulated these conditions and compared the results with material that has been stored during 5 years-real time ageing, using the experience acquired in a previous study, were we considered just one year of ageing based on hospital inquiries (Abreu, 2004).

Testing included the evaluation of specific properties essential to the intended function of the product and the minimum dose level of radiation was 25 kGy, according to the European standard EN 552 "Sterilization of medical devices - Validation and routine control of sterilisation by irradiation. Accelerated aging can be defined as a procedure that seeks to determine the response of a device or material under normal-usage conditions over a relatively long time, by subjecting the product for a much shorter time to stresses that are more severe or more frequently applied than normal environmental or operational stresses. This ageing is achieved by storing the product at an elevated temperature. There is a limit to the temperature that can be applied to a medical product or package that is made of plastic. The ageing must be carried out below the glass transition temperature of any components of the product. It is generally accepted that 60 ºC is the maximum temperature that is suitable for the majority of products (ASTM F1980) and the most indicated equipment is a climatic chamber.

The European Norm 556-1 2001: Sterilisation of Medical Devices - Requirements for Medical Devices to be Designated Sterile - Part 1, defines sterility as the state of being free from viable micro-organisms (≤1 × 10-6) and defines sterilisation as the process used to inactivate microbiological contaminants and thereby transform the non-sterile items into sterile ones (Abreu, 2011).

Electron beam radiation consists of electrons with a single negative charge and a low mass, generated from a linear accelerator. In this method, sterilisation is quick, but with limited penetration. Electrons normally cannot penetrate materials deeply, but when produced in man-made machines they can be accelerated to high energies with a subsequent improvement in penetrating ability (Block, 2001). Recent advances in electron beam technology have made it a worthy competitor to traditional gamma sterilisation. Increased power, compact design, improved reliability and a power source that does not deplete with time, in addition to security issues, are contributing to E-beam technology´s gains for medical device sterilisation (Woo and Purohit, 2002).

## RESULTS AND CONCLUSIONS

We have treated and compared the results after irradiation (25 kGy) for real time vs. artificial ageing, to finally indicate the effect of the ageing over the studied materials and properties using the correlation index ($R^2$).

The results were also studied using statistical methods in order to determine the statistically significant results.

The available data suggest that this artificial ageing method has a good correlation with the natural ageing for almost all parameters of the properties studied, although nearly all parameters are statistically significant.

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