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Effects of sterilization methods on key properties of specialty optical fibers used in medical devices

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ABSTRACT

Optical fibers with different types of polymer coatings were exposed to three sterilization conditions: multiple autoclaving, treatment with ethylene oxide and treatment with gamma rays. Effects of different sterilization techniques on key optical and mechanical properties of the fibers are reported. The primary attention is given to behavior of the coatings in harsh sterilization environments. The following four coating/buffer types were investigated: (i) dual acrylate, (ii) polyimide, (iii) silicone/PEEK and (iv) fluoroacrylate hard cladding/ETFE.

Keywords: Optical fiber, sterilization, autoclave, ethylene oxide, gamma radiation, polyimide coating, silicone coating, PEEK, polymer cladding

1. INTRODUCTION

Optical fibers are successfully used in various areas of medicine, including urology, general surgery, ophthalmology, cardiology, endoscopy, dentistry and medical sensing.[1-4] Prior to use inside a human body the fiber must be sterilized to ensure it is free of microorganisms such as fungi, bacteria, and virus or spore forms. Sterilization can generally be defined as any process that effectively kills or eliminates all microorganisms from a surface, contained in a fluid, equipment, food, medication or biological culture medium.[5] Many types of physical or chemical treatments are known as effective sterilization techniques. Roughly, the methodologies can be subdivided into three groups: (i) use of elevated temperatures, (ii) chemical treatment, and (iii) exposure to radiation. The first group includes flaming, exposures to dry heat and hot steam (autoclaving) and boiling in water. Chemicals such as ethylene oxide (EtO), formaldehyde, cresol, hydrogen peroxide, phthalaldehyde and peracetic acid in the gas phase and/or solutions are used for chemical sterilization. Finally, microorganisms can be effectively killed by UV light, X-rays, gamma- and e-beam radiation.

Generally speaking, sterilization is a "harsh" process that may represent a challenge to the performance of treated objects. Thus, exposure of optical fibers to harsh conditions may significantly affect their properties.[6,7] Ideally, sterilization of optical fibers should be such that it eliminates all the microorganisms but does not affect their optical attenuation and mechanical strength. It should be noted however, that no systematic study of possible effects of sterilization on optical fiber properties has been reported thus far.

In this work we investigate effects of different sterilization methods on performance of several optical fibers designed for medical applications. Three common sterilization methods were selected: (i) steam sterilization (autoclaving), (ii) treatment with ethylene oxide and (iii) gamma radiation.

Each of the selected sterilization methods has certain advantages and disadvantages. Steam sterilization is widely used because of its short processing time, nonreactivity and safety. On the other hand, items sensitive to heat and moisture cannot be sterilized by this method. EtO sterilization is preferable for

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- (i) dual acrylate
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