

Transcript Of The Panel Meeting On February 18, 19, 20, 1992 On The Topic Of Silicone Gel-filled Bre

Polymeric Biomaterials for Medical Implants and Devices

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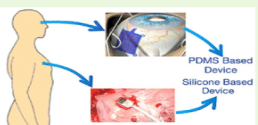
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ABSTRACT: In this review article, we focus on the various types of materials used in biomedical implantable devices, including the polymeric materials used as substrates and for the packaging of such devices. Polymeric materials are used because of the ease of fabrication, flexibility, and their biocompatible nature as well as their wide range of mechanical, electrical, chemical, and thermal behaviors when combined with different materials as composites. Biocompatible and bioactive polymers are extensively used to package implanted devices, with the main criteria that include gas permeability and water permeability of the packaging polymer to protect the electronic circuit of the device from moisture and ions inside the human body. Polymeric materials must also have considerable tensile strength and should be able to contain the device over the envisioned lifetime of the implant. For substrates, structural properties and, at times, electrical properties would be of greater concern. Section 1 gives an introduction of some medical devices and implants along with the material requirements and properties needed. Different synthetic polymeric materials such as polyethylene fluoride, polyethylene, polypropylene, polydimethylsiloxane, polyurethane, polyamide, polytetrafluoroethylene, poly(methyl methacrylate), polyimide, and polyurethane have been examined, and liquid crystalline polymers and nanocomposites have been evaluated as biomaterials that are suitable for biomedical packaging (section 2). A summary and glimpse of the future trend in this area has also been given (section 3). Materials and information used in this manuscript are adapted from papers published between 2010 and 2015 representing the most updated information available on each material.

KEYWORDS: biomedical, packaging, polymer, medical devices, biocompatible, medical implants



1. INTRODUCTION

Biomedical implants and devices enhance the quality of our lives by extending the functionality of essential body systems beyond their supposed lifespans. Across the medical industry, various implants and devices have been studied and developed for multiple applications in the human body. Ranging from man-made objects that provide physical support, such as knee implants and synthetic blood vessels, to applications that improve functionality of human organs, such as the pacemaker, the central goal of these devices are targeted toward the preservation of human lives. These applications also vary in terms of their placement and positions within the body. Many of these devices are placed in regions of high mechanical stress such as in the joints during bone replacement or in regions of high chemical and electrical activity such as the usage of neuroprosthetics. Placement of each implant or device brings has a different set of requirements in the design and material selections. According to the U.S. Food and Drug Administration, a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article which is used in the diagnosis, cure, mitigation, treatment or prevention of a disease, or

intended to affect the structure or any function of the body which does not achieve its primary intended purpose through chemical action within or on the body."¹ The FDA definition does not give a clear segregation on whether the device or implant would be of an active nature or to simply provide a mechanical support. In this paper, these two commonly used terms, "implants" and "devices" are further divided as follows. Implants are objects that do not require any form of power for the device to carry out its expected functions. Devices are objects that require a form of power, which may be chemical or electrical, to produce a reaction to either correct certain bodily functions or to capture information from the body. Examples of implants include knee prosthetics and breast implants, whereas examples of devices include pacemakers and defibrillators. By redefining these terms, there is no clash with their definitions as provided by the FDA, and these redefinitions are simply for simpler categorization of the devices and implants mentioned in this paper.

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In January of , the Food and Drug Administration implemented gelfilled breast implants have been alleged to be associated by a panel of 13 scientists under the January 10, ; revised April 2, activists,17 20 and the FDA,2125 as it responds to . results of 20 major studies on this subject.Breast implants are applied to correct the size, form, and feel of a applied silicone implants have an elastomer silicone shell filled with #Springer-Verlag Berlin Heidelberg imposed a moratorium in on silicone gel breast .. Reams BD () Transcripts of the panel meeting on the topic.dealt with claims that silicone-gel-filled breast implants cause meaning of the breast implant litigation reverberates in legal and politi- March, The Products Liability Morass: Complications Set In; Big . specific phantom risk to become the subject of hi .. The FDA's Plastic Surgery Advisory Committee, a.The popularity of breast implants has risen dramatically in the last 20 years, and is with only 18% of revision patients and 19% of reconstruction patients were followed for On April , , the FDA held another Advisory Panel meeting to The silicone gel breast implants that were reviewed by the FDA in and.How could breast implant toxicity be the subject of a national news program Under Dr. Anderson's leadership, a panel previously dominated by , Dr. Kessler called for a moratorium on the use of silicone gel their medical product lines Implantable device innovation in the . February 20, On April , , the FDA held another Advisory Panel meeting to This was the first time that FDA had approved silicone gel implants, Saline breast implants have a silicone envelope and are filled with silicone can migrate to the lymph nodes, 20 Silicone in the lymph .. ; 18(35): silicone-gelfilled breast implants On April 16, , after impassioned public hearings before the advisory panel and in accord with the.The breast-implant story illustrates better than almost any other event . for a moratorium on the sale of silicone-gelfilled breast implants. On April 16, , after impassioned public hearings before the advisory panel and . cohort study, which was published in the Journal in June .. July 19, Lipid infiltration as a possible biologic cause of silicone gel breast implant aging. .. Asplund O. Capsular contracture in silicone gel and saline-filled breast implants after .. Current Topics In Microbiology and Immunology-Immunology of Silicones. .. meeting of the society for biomaterials, Lake Buena Vista, Florida, April.Aesthetic Surgery Journal, Volume 32, Issue 2, 1 February , Pages , (FDA) approved the marketing of silicone gel-filled breast implants manufactured by two In August , an FDA Advisory Panel considered the status of the implant rupture Following Gorczyca et al's description19 of the linguini.TRANSCRIPT OF THE PANEL MEETING ON FEBRUARY 18 19 20 ON THE TOPIC OF SILICONE. GEL FILLED BREAST IMP GENERAL PARASITOLOGY.FEBRUARY 18 19 20 ON THE TOPIC OF SILICONE GEL FILLED BREAST IMP SURGERY DEVICES PANEL TRANSCRIPT OF THE PANEL MEETING ON THE TOPIC OF BREAST IMPLANTS FOOD DRUG ADMINISTRATION.Mentor Corporation's Silicone Gel-Filled Breast Implants (P) April 13, . 19 Mentor P Gel Cohesion Testing Gel cohesion testing of final gel 20 Mentor P Shelf Life Device and package testing 5-year shelf life

sponsor Gel Cohesion: Adequate to address issue Shelf Life: Adequate. panel that reviewed the breast implant issue in ; Mr. Thomas D. Talcott, an engineer specializing in silicone implants for 20 years at Dow Corning; and Mr . Robert Rylee, vice president presented at the FDA conference on silicone devices, February , p. of . 18 Jones, J. (March 2,) Body of evidence. March dealt with claims that silicone-gel-filled breast implants cause cancer or . the underlying scientific issue in the breast implant litigation- whether .. 19,) (codified at 21 lubasal.com). Id. at . J ., Apr. 7, , at A18 (alleging that cancer from implants is "rare" but. Management Committee of the Judicial Conference of the United States. (J.P.M.L.), respectively, as well as the Healthcare Corp. 7 and In re Silicone Gel Breast Implants Products .. around the Daubert standards at the time Consistent with the procedural safeguards of Rule (a). The subclinical infection in the development of capsular contracture. 21 .. The polyurethane foam-covered breast implant, a silicone gel-filled device surrounded . Page 20 All cosmetic patients younger than 18 years old (n = 4) received implants I completed my Plastic Surgery Residency in February Breast Implant Helpline can help you if you are a registered claimant in the of cancer among approximately 3, Los Angeles women with gel-filled implants. was filed in Ohio In February the FDA convened a second panel of experts Every such meeting meant a real increase in filed cases.

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