Invibio
BIOMATERIAL SOLUTIONS

White Paper

Effects of Gamma Sterilization on Implant Grade Polyetheretherketone

Green, S. Invibio, Ltd., Hillhouse International, Thornton-Cleveleys, Lancashire, UK, FY5 4QD

Introduction:

Polyetheretherketone (PEEK-OPTIMA® grade) is rapidly becoming increasingly significant in the biomedical sector as an implantable polymer. The work described here was undertaken to demonstrate that PEEK-OPTIMA is highly resistant to gamma radiation in terms of its physical properties and biocompatibility.

Methods:

Specimen Preparation – PEEK-OPTIMA grade LT1 from Invibio was injection moulded into tensile, flexural and impact test pieces in accordance with ISO test requirements under standard processing conditions[1]. The batch of moulded parts was arbitrarily divided into two. One half was used as the control, the other half was treated with gamma radiation.

Gamma Sterilization – Treatment consisted of a gamma dose of approximately 75kGy, representing approximately three times the usual dose for a single sterilization cycle. The process was operated by GAMMASTER® in Germany with certification evidence in dosage.

Mechanical and Physical Testing – For both the gamma irradiated and as received samples, an Instron test machine was used to measure tensile strength and elongation and, flexural strength and modulus, in accordance with ISO 527 and ISO 178 test methods. Izod notched impact strength was measured using a Zwick machine fitted with a 1 J hammer. Other measurements included density, thermal transitions and molecular weight. The material was further characterized by FTIR.

Biocompatibility Testing – Both gamma treated and as received materials were tested according to ISO 10993 for biocompatibility. In particular, the samples were evaluated according to ISO 10993-5 cytotoxicity and ISO 10993-18 chemical analysis by headspace GC and GC of extracts. A 1-year implantation study in rabbit paravertebral muscle was also completed using material subjected to approximately 75kGy and artificially aged to simulate 10 years real time ageing.

Results:

Test	Test method	Control	After 75kGy Gamma
Tensile Strength	ISO 527	100 MPa	100 MPa
Tensile Elongation	ISO 527	32%	34%

Flexural Strength	ISO 178	164 MPa	164 MPa
Flexural Modulus	ISO 178	4 GPa	4 GPa
Impact Strength	ISO 180	7kJ/m^2	7kJ/m^2
Density	ASTM D792	1.30g/cc	1.30 g/cc
T_g	DSC	146.8	144.3
T_m	DSC	341.3	339.5
T_c	DSC	289.8	290.3

Mw increased by around 4.8% and polydispersity increased from around 3.0 to around 3.7 in the worst case. FTIR spectra appeared identical for control and irradiated samples.

Biocompatibility testing to ISO 10993-5 showed that no substances were released in cytotoxic concentrations following irradiation treatment and chemical analysis to ISO 10993-18 showed a substantially identical composition in both cases.

Implantation of irradiated PEEK-OPTIMA into rabbit paravertebral muscle showed a normal response, with only mild fibrosis evident around the implanted material.

Discussion:

The mechanical properties of the irradiated and control specimens are almost identical. The small differences in tensile elongation are no considered significant. Biocompatibility testing confirms that PEEK-OPTIMA exceed the requirements for an implant grade. Long-term implantation shows no unusual response for an acceptable implant material.

Conclusions:

The can be concluded that PEEK-OPTIMA LT polymer, irradiated to high levels of gamma radiation (at least 3 times that used for normal sterilization) does not change in terms of physical properties or chemical make-up. There may be small changes in the molecular weight distribution, as recorded by GPC, but these do not apparently affect the mechanical performance of the material. Irradiated material continues to meet the specified parameters for PEEK-OPTIMA LT1 with little if any change in properties compared with the control material.

Invibio
BIOMATERIAL SOLUTIONS

Europe and Asia Pacific
Invibio Ltd.
Technology Centre, Hillhouse International
Thornton Cleveleys, Lancashire FY5 4QD
United Kingdom
Tel: +44 (0) 1253 898000
FAX: +44 (0) 1253 898001

Americas
Invibio Inc.
300 Conshohocken State Road, Suite 120
West Conshohocken, PA 19428
USA
866-INVIBIO (468-4246)
Tel: +484 342 6004
FAX: +484 342 6005

For further information email us at info@invibio.com or please visit our website at:

- www.invibio.com

The information contained herein is believed to be an accurate description of the typical characteristics and/or uses of Invibio product(s). However, it is your ultimate responsibility to determine the performance, efficacy and safety of using Invibio product(s) for a specific application. Suggestions of uses should not be taken as inducements to infringe any particular patent or as a representation that the product is suitable for such uses. INVIBIO MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, A WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF INTELLECTUAL PROPERTY NON-INFRINGEMENT, INCLUDING, BUT NOT LIMITED TO PATENT NON-INFRINGEMENT, WHICH ARE EXPRESSLY DISCLAIMED, WHETHER EXPRESS OF IMPLIED, IN FACT OR BY LAW. FURTHER, INVIBIO MAKES NO WARRANTY TO YOUR CUSTOMERS OR AGENTS, AND HAS NOT AUTHORIZED ANYONE TO MAKE ANY REPRESENTATION OR WARRANTY OTHER THAN AS PROVIDED ABOVE.

INVIBIO SHALL IN NO EVENT BE LIABLE FOR ANY GENERAL, INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL OR SIMILAR DAMAGES, INCLUDING WITHOUT LIMITATION, DAMAGES FOR HARM TO BUSINESS, LOST PROFITS OR LOST SAVINGS, EVEN IF INVIBIO HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, REGARDLESS TO THE FORM OF ACTION.

© 2013 Invibio Biomaterial Solutions.

Invibio® and the Invibio logo are registered trademarks of Invibio Ltd. PEEK-OPTIMA® is a registered trademark of Invibio Ltd.

S-WP-PN-E-0041-A (7/2013)