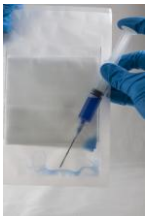
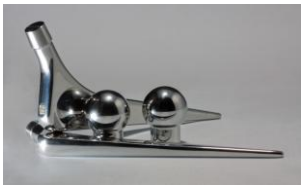
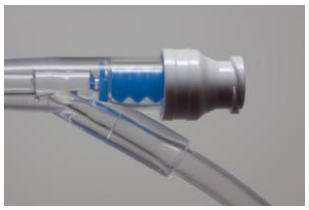
MEDICAL ENGINEERING TECHNOLOGIES

EXCELLENCE IN DEVICE TESTING

MET News – June 2015
Excellence in Medical Device Testing



Degradation Testing to ISO 10993 Parts 13, 15 and 17.

As part of the design validation for long term implants it is necessary to provide evidence that toxic degradation products are not released by the device. The process for doing this is described by biological and chemical means in ISO 10993. The chemical analyses involve the use of hydrolytic and oxidative solutions. The test devices are stored in these solutions for a set period of time. Following this the solutions, the device (by extraction) and any solid material released are subjected to sophisticated molecular and elemental identification and quantification. MET carries out this work on a variety of instruments following a risk analysis of the component materials in a device.

MET Has Clean Room Production Capacity

MET's class 7 clean room has available capacity for assembly and packaging of medical devices under ISO 13485. Equipped with pouch making equipment and supported by our ISO 17025 laboratory this is an ideal resource for early stage production.

MET is Offering Very Competitive Pricing on Biocompatibility Testing

Evidence of biological safety is required for every medical device. This can sometimes be provided by chemical analysis of component materials and the final product. The biocompatibility standard ISO 10993-18:2005 *Biological evaluation of medical devices -- Part 18: Chemical characterization of materials,* can be combined with risk analysis as described in part 1 of the same standard, to confirm a device's safety. MET provides these chemical studies and consultancy services, but in many cases formal biocompatibility testing can not be avoided. You can find more information here.

When biological testing is required MET is currently offering very competitive pricing to all sections of the standard. This includes CE and GLP studies. You can find more information here.

Does The Tyvek Transition Require Packaging System Revalidation?

DuPont's replacement production facilities for Tyvek are due to come on line before the end of the year. Does you packaging need re-validation? DuPont have carried out a considerable amount of lab work to evaluate the new material, the results from this are made available online. Can these results be applied to your production? Well, maybe yes? As confirmation, MET are offering 'cut down' validation programme to allow clients to ensure that their machine qualifications, shelf life verifications and transit validations are still valid.

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