

Biomaterial Case Study

ProTEX Med™

Aran Biomedical leverages its proprietary implantable grade ProTEX Med™ polypropylene (PP) resin, to provide a medical device company with an implantable surgical mesh product solution.

PROBLEM

A market leading medical device company sought to develop a new implantable PP mesh product, requiring sustainable supply of implantable grade PP resin. PP resin has a long history of clinical use in implantable devices and, until recently, has been readily available to biomedical implant manufacturers. The company experienced difficulty in identifying a source of PP resin which was not contra-indicated by the resin manufacturer for human implantation. This posed a serious challenge to the company's product commercialisation plan.



SOLUTION

The company began discussions with Aran Biomedical, culminating in the execution of a supply agreement for ProTEX Med™ implantable grade PP resin, in which long term access to resin was secured. Extensive physical, chemical and biocompatibility data was made available to the company, relating both to the virgin resin and a derivative PP mesh product, VitaMESH™, qualified for long-term human implantation.



Further to availability of the resin, the company was able to leverage Aran's textile development and manufaturing services, as a one-stop supply chain solution to its product commercialisation effort. Such an integrated supply chain solution enabled the customer to streamline product development resources, improve speed to market, while ensuring long term security of supply.

ProTEX MedTM

ProTEX Med™ is Aran Biomedical's proprietary, implantable grade PP resin, which is available to new and existing customers. It is certified to technical specifications and ISO 10993-5 (cytotoxicity), with proven equivalency to currently implanted PP grades. ProTEX Med™ comes with a unique FDA Device Master File (MAF) reference, available to resin users to support associated product qualification. Biocompatibility data is on file and available from Aran both as a resin and in derivative implantable mesh form (Aran VitaMESHTM).

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