

## **Allograft Information**

Allograft was introduced into the UK from overseas donors to meet the demand which the NHS tissue bank was not able to meet. The primary reason for sourcing from America is based on safety and the fact that they use a patented technology which achieves the highest sterilisation level (SAL 10<sup>-6</sup> ) without the use of irradiation. Evidence shows that irradiation affects the bio-mechanical strength of non-bone tendons and alternative aseptic processed grafts are shown not to be as safe (SAL 10<sup>-3</sup>). Other reasons for sourcing include the availability and range of tissue options; and the ability to size match for exact patient requirements.

RTI Surgical is the tissue bank used. They are AATB accredited and FDA approved. To date they have supplied 5 million implants with zero incidence of implant associated infection.

A unique sterilisation process is used to achieve the highest level of sterilisation possible. The process is called BioCleanse; an automated, pharmaceutical grade process. The BioCleanse process sterilises tissue using a complex, proprietary combination of mechanical and chemical processes, working in conjunction with each other. The mechanical component applies oscillating positive and negative pressure in the presence of chemical agents (including detergents and sterilants), which gently perfuse the tissue. This combination removes blood and lipids; and inactivates or removes pathogenic microorganisms. Repeated rinses throughout the process remove debris and final rinses remove residual chemicals, leaving the tissue biocompatible. The BioCleanse process does not sterilise using excessive heat or irradiation.