The new Puros Allograft Bone is treated with the Tutoplast® process developed by Tutogen Medical GmbH. In spinal surgery, surgeons insert human bone tissue (allograft) between adjacent vertebrae and then fixate the spine with devices. Sulzer Medica plans to expand the product range including more specialized bone shapes and delivery instruments. Human tissue products (allografts) are used for a variety of surgical procedures. In the case of a spinal fusion, the bone tissue, which is inserted between adjacent vertebrae, assists in stabilizing the vertebrae and provides a structural support for the growth of new bone that will fuse the vertebrae together. It is commonly accepted by surgeons that the use of allograft bone products is a safe and biocompatible substitute for bone harvested from the patient’s hip (autograft). This allows minimizing the use of autograft bone and eliminates the need to open a second operative site, a painful, complicated and costly procedure.

The Tutoplast® process has been developed by Tutogen Medical GmbH (Neunkirchen am Brand, DE), the international division of Tutogen Medical, which is a global provider of Tutoplast-processed allograft tissue. Since the process was introduced more than 25 years ago, more than one million allograft procedures have been performed in Europe and elsewhere using Tutoplast tissues. However, these tissues have not previously been readily available in the U.S.
The Tutoplast process uses a combination of baths to remove cellular material, viruses, and prions, resulting in a sterile and antigenically inactive bone tissue that is mechanically sound.

STERILE AND MECHANICALLY SOUND TISSUE

The Tutoplast process begins with very carefully screening of donors to ensure that only tissue deemed suitable for transplantation is recovered. The bone tissue then undergoes a series of baths (Fig. 2):

- An acetone wash removes fat from the tissue, allowing subsequent baths to be more effective. Acetone is also effective in inactivating viruses and prions.
- An osmotic contrast bath disrupts the membranes of non-bone cells. This step exposes any viruses and prions present within those cells, so that they can be washed away or inactivated in following steps.
- A hydrogen peroxide bath destroys any remaining viruses and removes remaining donor-specific protein materials that could cause rejection or immune reactions.
- The preservation by solvent dehydration (using acetone) removes water from the remaining tissue without weakening the bone structure. This preservation method was adopted as an alternative to fresh freezing and freeze drying – commonly used methods for preservation that can result in weakened bone structure due to expansion of ice crystals in the tissue. The solvent evaporates, leaving no residue or water behind.

The terminal sterilization with limited levels of gamma irradiation insures the sterility of the material, but does not affect the biomechanical properties and the healing.

INFECTIOUS AGENTS REMOVED

Compared with other processing methods used for allograft bone tissue, Puros has many advantages: The risks of infections and of immune reactions are reduced. In addition, the biomechanical strength of the grafted bone is conserved since the allograft material is not stressed at the cellular level in the same way as with freezing and thawing. Puros has also the advantage that it can be stored at room temperature.

The introduction of Puros Allograft Bone is the first step of the implementation of the global marketing agreement that Sulzer Medica and Tutogen Medical have signed in March 2000.

FOR MORE DETAILS

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