

BoneAlbumin human allograft

Questions and Answers

BoneAlbumin is a human allograft. What does that mean?

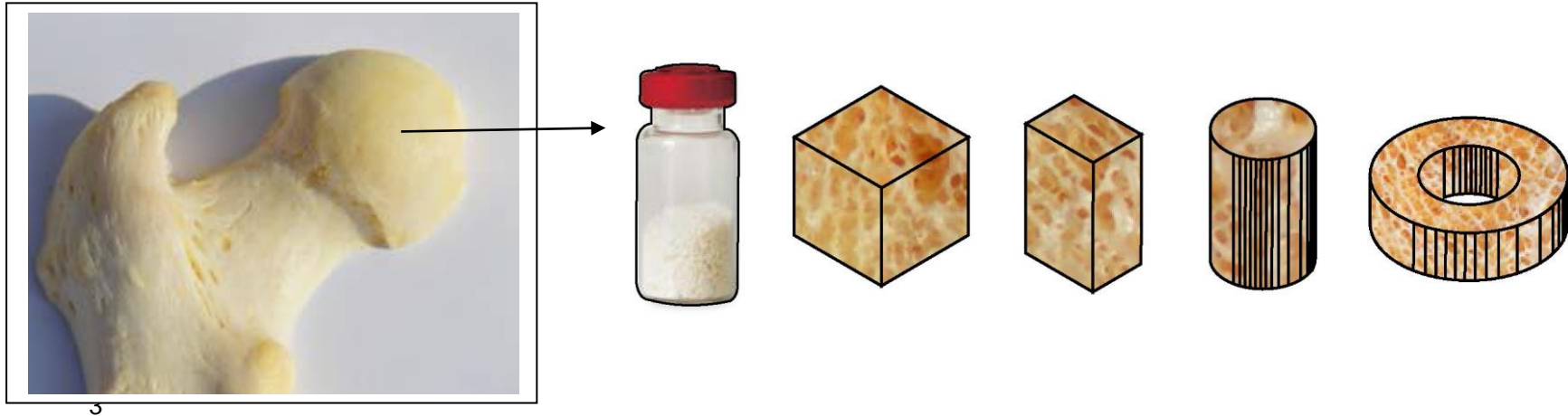
Bone replacement material can be:

- synthetic, mineral-based,
- a xenograft taken from animal tissue,
- an allograft taken from human tissue,
- an autograft taken from the patient's own body.

Although the latter would clearly be the ideal solution, risks arise from double surgery that are avoidable and unnecessary when a good allograft is available.

BoneAlbumin is an allograft derived from human tissue.

What does “human bone graft” mean?



BoneAlbumin is a bone graft obtained from a living donor.

Living donation means that during hip replacement surgery the head of the femur, a sphere of bone about 2 inches in diameter, is removed. From this bone sphere, granules (chips) are collected, blocks (standard

geometrical shapes of different sizes: square, prism, cylinder, ring, etc.) are fashioned, and, with the help of a CT scan, individually designed 3D shapes are created.

Why is it better to use human bone?

Human tissue is the best way to help a human.

When a blood transfusion or organ transplant is needed, we do not even consider using material from another species. Although tissue transplants between different species are possible in certain situations, the ideal solution is tissue donation from the same species. A steak is a delicious meal, but most people would not want one inserted into their body.

The human graft and the receiver's bone tissue have the same trabecular structure. Our bones are made up of compact outer bone (cortex) and spongy inner bone, similar to the supporting structure of modern stadiums that resemble the shape of a bird's nest, which ensures sufficient stability with reduced static weight. If our bones consisted of compact

cortex only they would be so heavy that they would constantly fracture. These smart, weight-bearing "bird's nest" little columns are called trabeculae. In the case of human bones, their cross-sections are circular, but cow bone trabeculae, for example, are flatter.

This difference may also contribute to the fact that the body recognizes human bone replacement as more compatible, and accepts it more easily than variations from other species.



How risky is it?

Bone tissue transplant is one of the safest medical procedures.

The risk of transmission of viral or bacterial pathogens is quite low with bone allografts. The last known fatal bone graft transmitted infection happened in 2001, and it was caused by a serious violation of strict manufacturing regulations. The transmission of a virus (hepatitis, HIV), even during the window-period, occurs in less than 1 in 1,600,000 cases, and in recent years there hasn't been a single report of this type of transmission.

These security features are highly favourable compared to other biological materials. Patients

waiting for hip replacement can only become bone donors after the same strict testing methods used for blood or organ donors. Filtering and sterilization of the materials are carried out in an aseptic environment using cutting-edge technology. One of the principal steps of the technology is lyophilisation (freeze-drying), which freezes and then uses vacuum technology to remove all the soft tissues from the “bird’s nest”-like trabeculae, and then the product – minus the connective tissue proteins - becomes a skeleton void of alien cells and proteins.

Then it is safe. Why hasn't it been used yet?

In clinical practice, there is a constant need for human bone replacement, with numerous attempts worldwide to create it, but the risk of early resorption of the untreated bone was always high. The best solution to this tricky problem is the albumin coating technique.

Albumin is an essential blood protein, one of the most prominent life-saving medications for patients with extensive burns, an extremely serious condition. Albumin is essential because it triggers the functioning of bone marrow stem cells and osteoblasts, while its antibacterial effect reduces inflammation, decreases the risk of infections and eases pain.



With its help the resorption of the implanted graft (transplanted block of tissue) and the construction of new bone proceed hand in hand. This parallel development is important, because if the graft resorbs before the bone construction starts this area will not ossify. Instead, fibrotic tissue will replace the bone. If it resorbs too late, during the ossification graft islets could remain in the bone, which can cause stability problems in the future.

Where is BoneAlbumin made?

BoneAlbumin is a product made by the West Hungarian Tissue Bank of Petz Aladar Country Teaching Hospital in Győr, Hungary.

The essence of the BoneAlbumin product comes from the resulting synergism of the bone tissue and the albumin extracted from blood serum. Both components have been well known separately in Hungarian and international clinical practice for decades and extensively used cures that were

merged into an outstanding combination in the development of BoneAlbumin.

The bone used is provided by the tissue bank, and the albumin is an infusion of very high purity available in pharmacies.





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