Technical Focus

THE ZYMO-TECK® PROCESS

A cutting-edge biotechnological process to obtain tissue substitutes having unique properties.

Bioteck Academy Editorial Office

Regenerative medicine is a rapidly evolving clinical sector. Its aim is tissue regeneration in cases of injury or atrophy. The ultimate goal is *redutio ad integrum* of tissue, with complete structural, aesthetic, and – above all – functional recovery. Its success relies on in-depth knowledge of biological tissue repair mechanisms and of the interaction between the body and the biomaterials. The functional paradigm is the presence of the three components of the tissue triad in the injured site: cells, growth factors and scaffold. Their ever more effective uptake is the current aim of research efforts, both in academia and at the cmost advanced companies in the sector.

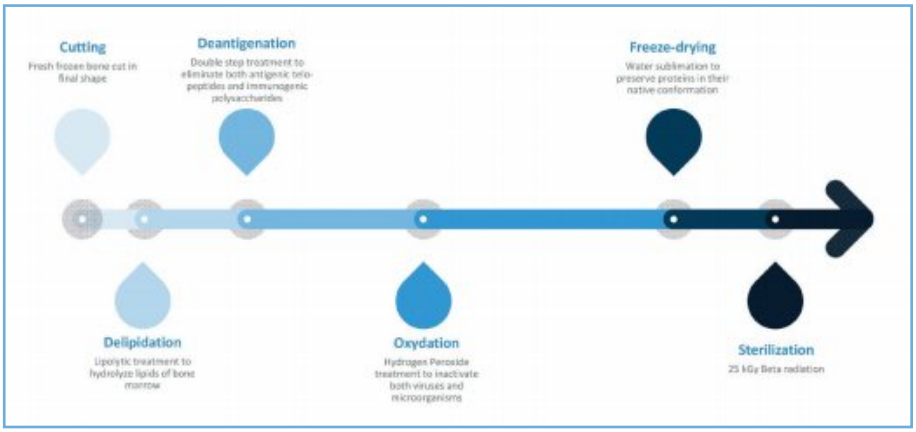
Biological origin scaffolds are believed to be the most promising as they support the best interaction with cells and growth factors, at least in theory. Tissue from mammal species other than Man may be used to obtain them, due to the many features shared by different species. However, safe and effective use of tissue from a different species requires removing the antigens from it, without affecting the other biological properties that assure interaction with the other elements of the triad.

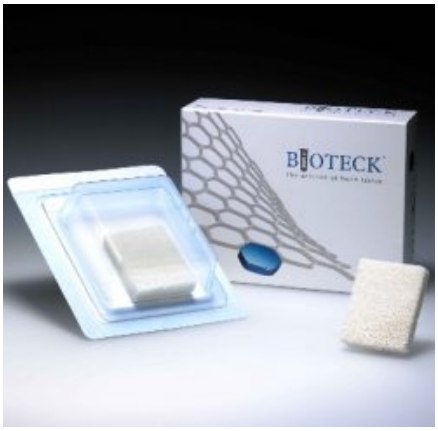
It is a well-known fact that simple physical processes – such as high temperature treatment – do not meet this requirement, as they deeply alter the features of the tissue of origin, including mechanical ones. Bioteck offers an innovative method for treating mammal tissue, based on the application of cutting-edge bio-technological processes – the Zymo-Teck process.

Zymo-Teck

The Zymo-Teck process is designed to selectively eliminate three specific molecular targets: lipids – which are not antigenic, yet mask the actual antigens – collagen telopeptides and immunogenic epitopes, consisting of cellular polysaccharides. The core of the process is the use of hydrolytic enzymes: protein molecules that assure the degradation of specific targets, thanks to their selectivity. The lipids are removed by using lipases, the telopeptides through telo-peptidases, the immunogenic epitopes by carbohydrases.

The advantage of using enzymes consists both in their specificity, and in being active at temperatures that do not alter the properties one seeks to preserve in the tissue of origin. Firstly, the bone tissue is dissected into the desired shapes and sizes then it undergoes delipidation to allow the antigens to be unmasked. Finally, telo-peptidases and carbohydrases are used to assure antigen elimination from the tissue. At the end of processing, the product is freeze-dried and sterilized by beta radiation at 25 kGy.





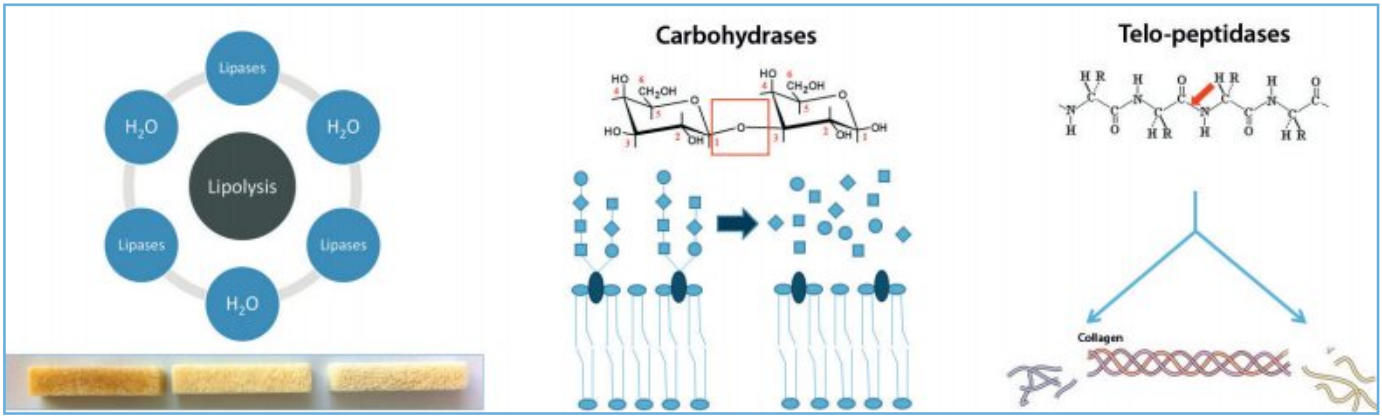


Fig. 1 *– Top: a simplified flow chart showing the stages of the Zymo-Teck process leading to production of Bioteck devices. Bottom: the core of the Zymo-Teck process consists of the sequential action of three types of enzymes; lipases for lipid degradation; carbohydrases for degradation of immunogenic polysaccharides; telo-peptidases for removing the antigenic telopeptides of collagen.*

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The advantages

The Zymo-Teck process offers manifold advantages. The use of hydrolytic enzymes makes it possible to avoid using organic solvents, guaranteeing greater safety for the patient. By selectively eliminating antigens at temperatures never exceeding 60°C, the process is able to preserve the integrity of the physical-morphological properties of the original tissue, as well as the components of the extracellular matrix including bone collagen in its native structure.

The oxidative stage of the process assures the elimination of viruses and bacteria, as well as possible cellular residues from osteocyte lacunae.

The freeze-drying process provides the graft with the stability required to be stored at room temperature, with the product's features being retained for the shelf life indicated in the label.

Finally, beta-ray sterilization assures the utmost microbiological safety, and due to the fact that beta rays are less destructive than the better-known gamma rays, the graft's physical-chemical properties are unaltered.

Every single aspect in the application of the Zymo-Teck process undergoes accurate checks. Every reagent batch is tested to ascertain its purity and activity, every batch of tissue is checked for contaminants and for conformity to statutory health requirements, but what sets Bioteck apart from its competitors is the strict "in-line" Quality Control.

As a matter of fact, the in-house Laboratory deals with validating product conformity to the Quality requirements, batch by batch. Lipid concentration, residual DNA and collagen integrity are just some of the tests performed to guarantee antigen elimination and decellularization and to ensure the finished product's biocompatibility standards are maintained. The quality checks are performed by highly specialized personnel, using state- of-the-art analytical instruments.In conclusion, tissue substitutes with excellent biological and mechanical features are produced thanks to the Zymo-Teck process, as evidenced by the number of successful clinical applications in Orthopedics, Neurosurgery and Oral Surgery.

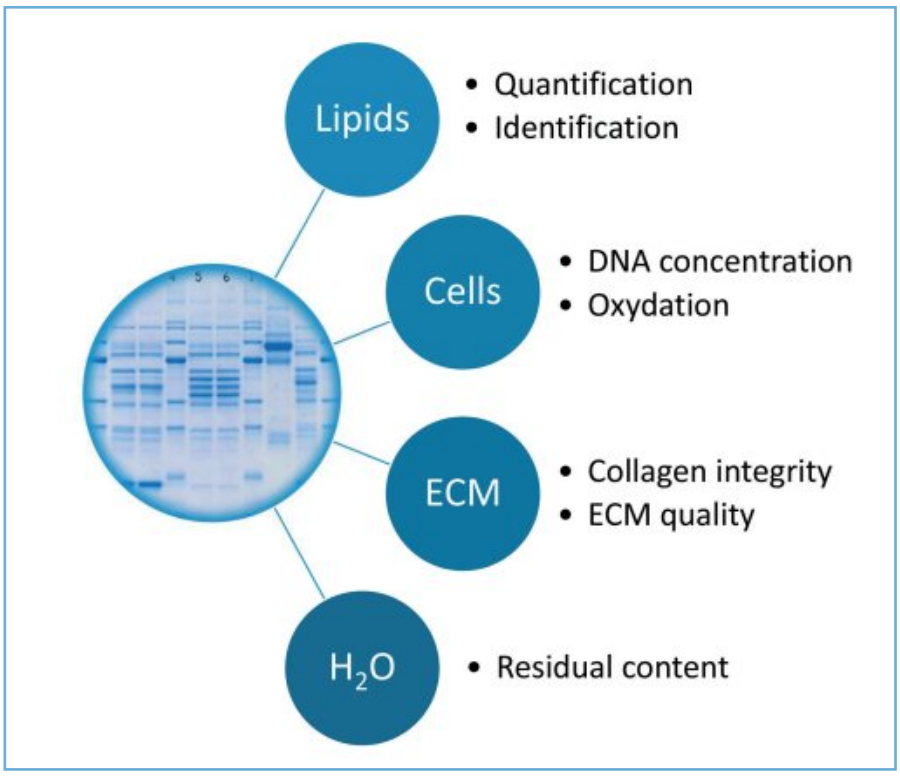

Fig. 2 *– Despite the heterogeneity of the raw material, the high number of checks carried during application of the Zymo-Teck process ensure tissue substitutes with highly reproducible biological performance are obtained, curbing the risk factors arising from the complexity of surgery and specific patient cases.*

Fig. 3 *– A step in the application of the Zymo-Teck process: programming the bioreactors where enzyme reactions take place.*

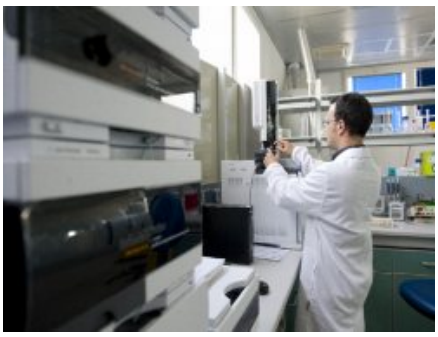

Fig. 4 *– The checks are carried out at Bioteck's biochemical lab, equipped with state-of-the art analytical instruments.*

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