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Collagen for the knee

Cartilage damage is the most common form of joint disease. Recently, the German biotechnology company Amedrix has developed collagen implants for damaged cartilage that allow cells from surrounding tissues to migrate into the implants. The processes for collagen purification as well as GMP-compliant manufacturing of the collagen implants were developed in cooperation with the Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB.

Five million people suffer cartilage damage to the knee every year in Germany. Cartilage injuries are not only painful; they can lead to osteoarthritis decades later. In the course of the disease, the protective shock absorbing cartilage that covers the bone within the joint slowly is removed until the bone is finally exposed, typically requiring an artificial joint replacement.

An early alternative to the artificial knee joint are biological therapies, such as autologous chondrocyte implantation (ACI), where chondrocytes are isolated from a small piece of cartilage of the patient, expanded in the laboratory and after three weeks implanted into the defect, often in combination with a shaping matrix. Over time, the implanted cells will reconstruct the matrix until the injured cartilage is completely regenerated. However, the cost of treatment is high and not always fully reimbursed by health insurance. In addition, two surgical interventions are always required: one to remove the cartilage cells and a second to implant the proliferated cells.

The German biotechnology company Amedrix GmbH developed a one-step minimally-invasive surgical procedure for the treatment of cartilage defects using their cell-free collagen implants – with comparable good autoregeneration of the cartilage defects. Their first gel-like implant was approved for the European market in 2012. In December 2013 a further development of this product, a liquid application form, received European CE certification, which ensures that the implant is safe and medically-technically efficient. "Our new product is arthroscopically injected as a liquid collagen implant. Once injected, the liquid collagen forms a stable cartilage replacement in minutes", describes Dr. Thomas Graeve, CEO of Amedrix. After injection, cartilage and stem cells from the surrounding tissue migrate into the implant and stimulate the self-healing of the cartilage. Within a short time, the result is a new and resilient cartilage. "Patient MRI studies show that the cartilage defect is nearly completely filled after six months", says Graeve.

In order to optimize the purification and manufacturing process according to current legal regulations, Amedrix cooperates with the Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB in Stuttgart. The institute supports a 215-square-

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meter Good Manufacturing Practice (GMP) unit certified for developing production processes for medical devices or cell-based tissue-engineered products. "Our specially trained staff work together with Amedrix employees to isolate collagen protein from animal tendons and then process the collagen in the IGB clean rooms," explains Markus Schandar, head of the GMP Group.

The Fraunhofer IGB has also applied for the manufacturing authorization of medicinal products on behalf of industrial partners. "Previously, we have developed GMP processes for autologous endothelial cells for the colonization of a vascular prostheses, autologous cartilage grafts and autologous bone marrow stem cells for regenerative medicine under GMP conditions and according to the guidelines of the Medicines Act", according to Schandar.

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Collagen for company Amedrix is processed in the GMP-unit at the Fraunhofer IGB (left).

The liquid collagen implant is arthroscopically injected with a special syringe (right).

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