UroTec

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Founded (year)	2005
Areas of activities	tissue engineering for urinary organs
Shareholders	Technologiegründerfonds Sachsen, High-Tech Gründerfonds

Products

UroTec develops functional tissue constructs for the urinary organs from patient-owned cells, which can be individually adapted to the anatomical location by tissue engineering in size, shape, and function.

MukoCell®

UroTec GmbH is the first company to provide an autologous oral mucosa transplant with the name MukoCell® for reconstruction of the urethra.

There are 15 patients suffering from diseases of the urethra, mostly stenoses (strictures), for every ambulant working urologist in Germany. In addition, deformations of the urethra occur at a rate of 1:200 in male neonates.

At present, the treatment of a urethra stricture or deformation by transplanting patient-owned oral mucosa(o.m.) is the most advanced method, because this tissue is well suited for the substituting urethra cells. However, removing the 5 cm -10 cm o.m. required for this is extremely painful for the patient and associated with a lot of complications, e.g. cicatrizations, injuries of the salivary gland opening, sensori¬motor disorders and hence problems with speaking, eating, drinking, limited oral cavity and other complications.

At the same time the removing of o.m. for the reconstruction of the urethra is a second surgical procedure, aggravating the original operation of reconstructing the urethra, prolonging the duration to more than 90 minutes. MukoCell® makes extensive removal of o.m. from the patient obsolete, simplifying the reconstruction of the urethra and preventing secondary complication. Therefore, the autologous o.m. transplant is an essential innovation with great medical benefit for the treatment of urethral stenoses or deformations. There is a German production license for the product MukoCell®. The product was legally introduced by December 30, 2008, so it can be commercially used for a transitional period until December 31, 2012. Thereafter, authorization by the EMEA is necessary. Animal trials have already been successfully completed. Using a pig as an animal model, the autologous o.m. transplant was sewed onto the urethra after opening the organ. After

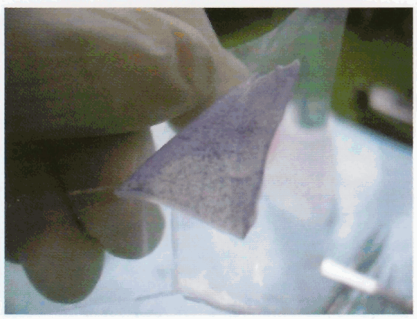
4 weeks, there was nothing unusual at the operation site. Thus, the regeneration of the urethra was complete in the sense of a restitutio ad integrum.

Urinary Bladder Tissue Transplant
As a further product, an autologous cell transplant for the reconstruction of the urinary bladder is under development. This product consists of autologous mucosa, vessel, and muscle cells. The animal trials shall start in 2010. Attainment of the production license (GMP production establishment) is planned for 2011.

Markets

MucoCell®
Urology departments of all hospitals and operating ambulant urological practices are considered possible consumers. About 50.000 urethral operations a year are carried out in Germany. In Europe, there are six times as many. However, the actual need is substantially greater, but there is presently a lack of optimal types of therapy, so for many patients urethra reconstructions are not performed. The selling price of 5.000 – 8.000 EUR for the o.m. transplant results in an economic "market" of > 250 Million EUR, only for the number of the presently performed operations in Germany, and of > 1.5 Billion EUR in the EU. A gross margin of at least about 50% from the turnover after reaching the break even can be obtained here due to the position of a "First Mover". The selling price is in accordance to the current market price of tissue engineering products, such as skin and cartilage transplantation.

This year the product will be used for the first time in urological patients. In 2009, 3 to 8 clinics in Germany and 2 to 3 clinics in Europe will use the product for the reconstruction of the urethra. In 2010 it shall be used in up to 10 clinics in Germany with a total volume of ca. 500 to 600 units. Simultaneously, a drug license is supposed to be obtained by EMEA until December 31, 2012. During the EMEA permission procedure, an FDA permission will be prepared. After the drug license is obtained reimbursement of health insurance schemes all over Europe may be expected within one further year. From 2014 a market share of 5% in Europe is expected.



MucoCell®