PRESS RELEASE

June 11, 2001

ARTIMPLANT'S CRUCIATE LIGAMENT IMPLANT APPROVED IN EUROPE

The biotechnology company Artimplant in Gothenburg, Sweden, has obtained approval to sell its first product in Europe: an anterior cruciate ligament implant. The CE mark is associated with the LRQA notified body number 0088.

Approval was the result of comprehensive research and development efforts conducted by the Company on polymers, efforts that began in 1986 by a group of researchers at Chalmers University of Technology and the University of Gothenburg. In recent years, the implant has been tested in several clinical trials.

The augmentation device is made of a patented polyurethane urea (PUUR) that is spun and then woven into a band that is inserted into the knee as an augmentation in patients with anterior cruciate ligament (ACL) injury. The material replaces the damaged ligament but, while the body is forming its own new tissue, it decomposes. Clinical trials have shown that the material in the implant is replaced by naturally formed connective tissue, the same tissue that forms the body's own ligaments.

"CE marking is an important milestone for Artimplant and signals that the Company is now a market-oriented, research-intensive growth company in the medical-technology field," says Artimplant CEO Anders Cedronius, commenting on the approval. "Now we can start to proactively influence orthopedic surgeons throughout Europe, so they can help hundreds of thousands of patients to avoid, even more than before, knee instability resulting from damage to anterior cruciate ligaments."

The implant, an ACL augmentation device, will be released in the Nordic countries during the third quarter of 2001. The product is slated for release elsewhere in Europe during the first six months of 2002. A launch in the United States is possible no earlier than the latter half of 2003 and depends on the amount of time it takes to obtain approval from the U.S. regulatory authority, the Food and Drug Administration (FDA), and on the strategy that Artimplant chooses in its application for registration.

Cruciate Ligament Injuries

Every year approximately one million people in the world are impacted by anterior cruciate ligament injuries. In Sweden, torn anterior cruciate ligaments are responsible for 85% of all debilitating knee injuries that affect athletes participating in team sports and downhill skiing. Half of the injured cruciate ligaments are not treated with surgery but are treated with physiotherapy to compensate for the joint's lost stability. The long-term results have often been poor because of increasing wear-and-tear injuries to the cartilage and other structures in the joint.

ARTIMPLANT

Artimplant focuses on solving problems in the field of reconstructive surgery. Artimplant is active in research and development, manufacturing and marketing of degradable implants with the goal of recreating active lives for patients. The material the Company has developed is based on a new technology that opens up new markets in the field of orthopedic surgery and a variety of other specialized fields where there are significant medical needs. After many years of development work, Artimplant is now entering a marketing phase.

Among other things, Artimplant has developed and patented several different decomposable ligament implants now undergoing clinical trials. The Company is focusing on three high-priority areas for this degradable material: an augmentation device for anterior cruciate ligament reconstruction, hand surgery, and augmentation sutures.

Artimplant is listed on the OM Stockholm Stock Exchange's O list and Attract 40 list.

For further information, please contact:

Ulf Åkerblom
Director Corporate Communications
Phone: +46 (0)31 746-5600
Mobile: +46 (0)709 675-999
E-mail: ulf.akerblom@artimplant.se

Anders Cedronius
Chief Executive Officer
Phone: +46 (0)31 746-5689
Mobile: +46 (0)706 422-745
E-mail: anders.cedronius@artimplant.se

Website: www.artimplant.se

Artimplant Corporate profile

Background: The Company

Artimplant focuses on solving problems in the field of reconstructive surgery. The company's innovative and degradable material supports the body's unique ability to repair and regenerate itself. The specifically designed products give patients new chances to return to a healthy and active life.

A high-priority product close to its market launch is an augmentation device for reconstruction of the anterior cruciate ligament: an ACL augmentation device. This is the product that has just received CE approval. In the next few years, Artimplant anticipates being able to certify several additional products for orthopedics and hand surgery. In the field of hand surgery, studies with Artimplant's material are being conducted for arthrosis and ligament injury in the thumb. The Company is planning to start clinical trials with augmentation sutures for thoracic surgery during the autumn.

Anterior Cruciate Ligament Injuries

The significance of the knee and its function

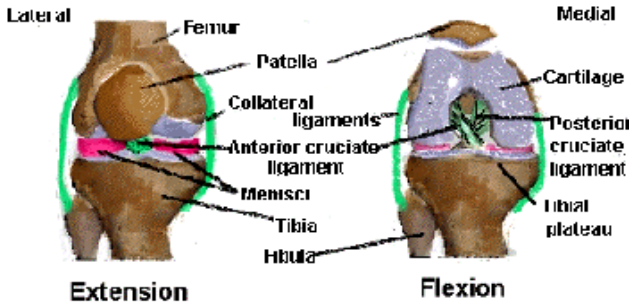
The functioning of the knee is of the utmost significance in everyone's daily life. The knee is a joint that combines strength and motion in a way that none of the body's other joints do. Whether it is a matter of taking a walk, jogging, running, or jumping, the knee is the strong, stable basis for motion. The anterior cruciate ligament is the most important stabilizing structure in the knee joint.

A ruptured anterior cruciate ligament in the knee is the most commonly occurring ligament injury. The condition affects leading athletes, in particular athletes who play soccer, handball, and basketball as well as downhill skiers. An injured anterior cruciate ligament limits opportunities for a physically active life. In the long run, a torn anterior cruciate ligament often leads to disabling wear and tear injuries to other structures in

the knee. Anterior cruciate ligament injuries in the knee also entail significant costs for society.

LIGAMENT STRUCTURE

The anterior cruciate ligament is made of collagen (a fibrous, connective tissue), which is positioned intra-articularly, i.e. inside the knee joint. The anterior cruciate ligament is approximately 10 mm wide and 40 mm long.



THE FUNCTION OF THE CRUCIATE LIGAMENT

The anterior cruciate ligament is the ligament that stabilizes all the specific motion that occurs in the knee. The ligament prevents the tibia (shinbone) from sliding forward in relation to the femur (thighbone). For the most part, the anterior cruciate ligament stabilizes the motion so that humans cannot rotate, twist, or hyperextend their knee joints. The anterior cruciate ligament also protects the knee joint's ability to bend inwards and outwards when the other ligaments are missing.

THE CONSEQUENCES OF AN INJURY

When the anterior cruciate ligament is injured and cannot perform its protective functions, movements in the knee become unstable and uncontrolled. This leads to an inability to do all the daily activities that require movement in the knee joint. It is also well known that an anterior cruciate ligament injury speeds up the process of wear and tear to the joint cartilage, which then leads to decreased movement and pronounced

pain for those who are affected. Surgical reconstruction offers the best prognosis for those who are affected by an anterior cruciate ligament injury.

Competing Methods

CONSERVATIVE TREATMENT

Conservative treatment entails doing without surgical measures and trying to compensate for lost joint stability with ongoing physiotherapy and adapted muscular exercises. The long-term results of this treatment method are often unsatisfactory because of increasing wear-and-tear injuries to the other structures in the knee.

Reconstruction with Transplantation

PATELLAR TENDON

At the present time, the most common operative technique in anterior cruciate ligament reconstruction is to replace the injured ligament with a portion of the patient's own patellar tendon. One of the disadvantages of this method is that the elasticity and strength of the tendon tissue decreases after a few weeks, which increases the risk of rupture or stretching, thus creating unsatisfactory joint stability during rehabilitation and afterward. Measurements suggest that the inserted tendon tissue never achieves the strength of a healthy anterior cruciate ligament. Not infrequently, there are also complications at the donor site itself.

HAMSTRING

Approximately 25% of the anterior cruciate ligament operations performed today use tendon from the inside of the rear portion of the thigh, the hamstring, instead of a portion of the patellar tendon. The advantage to this method is that it causes fewer problems at the donor site. The disadvantage is that these tendons are harder to connect to bone than the patellar tendon.

Clinical Results

The long-term follow-ups performed after cruciate ligament reconstruction with autograft tissue have shown a significant complication frequency. A study that was performed at Sahlgrenska University Hospital in Gothenburg and that was presented at the Swedish Society of Medicine Convention in 1999 evaluated functional and objective observations four to seven years after surgery and compared them with clinical results after a two-year follow-up. The conclusions included the fact that the results four to seven years after reconstruction were worse than those obtained after two years. One in four patients had had another operation before the follow-up performed four to seven years after the first operation.

Other larger compilations of long-term results have shown that, on average, in almost 40% of the cases complications in the form of pain, limited mobility, or wear and tear in the autograft material arise four and a half years after the operation.

Non-Degradable Implant

The non-degradable implants that were used previously as prosthetics in anterior cruciate ligament reconstruction have not been able to satisfy the demands made on them and therefore largely have been withdrawn from the market. None of these prosthetics were manufactured from material that was developed for the principal purpose of being used in cruciate ligament reconstruction.

Artimplant's Augmentation Device for Anterior Cruciate Ligament Injuries

If a ligament or a tendon tears, a biological defect arises. The "ligament cells" are not capable of making up for defects. On the other hand, a biodegradable scaffold with the same mechanical characteristics as a healthy ligament, together with autograft tissue, can create the requisite conditions for the formation of a new ligament. The scaffold, or implant, replaces the injured ligament so that the joint's function and stability are maintained before the scaffold is successively broken down through the effects of bodily fluids and replaced with endogenous ligament tissue.

While the implant maintains the functionality of the cruciate ligament, the body's own cells have the opportunity to grow into the implant and form a functional biological unit. This is possible because the implant is biocompatible and possesses mechanical characteristics that correspond to a natural cruciate ligament.

Over the long term, the implant loses its strength, being broken down through the effect of water in the body (hydrolysis) into small molecules that can pass through the body's membranes. It is important that the implant break down at a rate that is as slow as the rate at which the body's cells are able to form new support tissue. As the implant is exposed to mechanical stresses, the cells are stimulated to form a new ligament.
A natural ligament consists in large part of connective tissue (collagen) that can be compared with the fibers of a rope. The collagen is responsible for mechanical characteristics like strength and a certain amount of ductility. The fibrous material in Artimplant's ligament implant is spun and woven using a tested technology, so the resultant strength and elasticity characteristics are equivalent to those found in a natural cruciate ligament. The body's cells infiltrate the ligament implant to build up a natural ligament as the implant is being broken down.

Laboratory studies of Artimplant's cruciate ligament implant have shown that the degradation occurs at a rate that is slow enough to enable the endogenous connective tissue to fill in. Animal testing has shown that the ligament implant is biocompatible and that it recreates satisfactory joint stability. The testing has also confirmed that the implant can handle the mechanical stresses that normally arise in a knee and that the rate of degradation does not fall below the minimum limit (>12 months).

Artimplant’s augmentation device for the anterior cruciate ligament

Market Potential

Approximately one million anterior cruciate ligament injuries occur each year in the world. Approximately half of all injuries are treated conservatively. The market potential for implants for ruptured anterior cruciate ligaments is estimated at SEK 10-15 billion globally.

Gothenburg Medical Center

In 1998, Artimplant acquired Gothenburg Medical Center (GMC). GMC is a forum for clinical research, application, and training in the field of orthopedic surgery. GMC was started by Professor Lars Peterson and is one of the leading sports clinics in Europe. Artimplant Clinical Academy, a part of GMC, is a research and marketing strategy initiative that enables Artimplant to develop new applications and maintain closer contact with its primary target groups in the field of orthopedic surgery. The clinic collaborates with selected orthopedic clinics around the world to develop and disperse expertise about new treatment methods.

Artimplant
Degradable Materials for Optimal Tissue Repair

ARTIMPLANT IN BRIEF

Founded

1990

Management

Anders Cedronius, CEO

Lars-Erik Nygren, CFO

Hans Bertilsson, Research Director

Ulf Åkerblom, Director Corporate Communications

Mikael Nordh, Director Sales and Marketing

Ingrid Ekenman, Medical Director

Kristina Lindberg, Director HR

Anders Östin, Director Production and Logistics

Board

Akbar Seddigh, Chairman

Anders Cedronius

Per Flodin

Helge Ramseng

Svante Rasmuson

Lennart Ribohn

Number of Employees

77, 33 of whom work for the subsidiary Gothenburg Medical Center

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