

COMPANY | PRESENTATION





CONTENTS



For improved quality of life 4

Unmet clinical needs 6

With dedication and skill 7

Encouraging solutions 8



Other emerging areas 12

Securing clinical outcome 13

Quality for patient safety 14



An exciting future 15

All of us 16

Some of you 17

Impaired musculoskeletal conditions are the most frequent causes of disability worldwide. The disorders include injuries and diseases in the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs. The prevalence of these conditions is expected to increase rapidly in the light of the aging population worldwide with a longer average life expectancy.

There are products and methods that can help many of these people. However, most of them involve replacing or removing tissue, with insertion of metal implants or changes in the body's anatomy.

Artimplant is resolute in its endeavor to replace old implant technology and methods with innovative, tissue-preserving solutions.

*How can we help you
make a difference?*



FOR IMPROVED QUALITY OF LIFE

Some 20 years ago, my mother, who is a dentist, was suffering from pain and instability in her thumb base joint. The problem was caused by osteoarthritis. The clinical treatment she was offered provided pain relief but did not give her back the functionality of the thumb and, as a result she had to give up her career.

A few years ago, another dentist was looking for a cure for osteoarthritis in both his thumbs. He opted for the Artimplant Resurfacing concept and had an Artelon® CMC Spacer implanted in his left thumb. About a year later, he also underwent successful surgery on his right thumb. He is still working as a dentist. This is one of the many success stories that come to our attention at Artimplant.

When Artimplant was in the process of being founded, there were thoughts regarding a number of possible uses where Artelon® could create conditions for the body to heal itself. Thumb base osteoarthritis was one such area and the product is now the Artelon® CMC Spacer.

"The idea behind our spacer concept is as simple as it is ingenious: stabilizing the arthritic joint and creating conditions for producing a new joint surface."

In doing so, the patient becomes free from pain and regains a functioning joint.

The excellent biocompatibility and the controlled, long-term degradation and mechanical properties make Artelon® unique among biomaterials.

"It was developed specifically for medical applications and has clinical documentation with long follow-up periods."

Artelon® aids the healing process through the creation of functional tissue, which is the ultimate aim of an Artelon® implant - to improve quality of life. ■

Hans Rosén, CEO

“Many applications have been developed from Artelon[®], improving the quality of life for many patients around the world.”





UNMET CLINICAL NEEDS - *medical pathfinders*

The original idea behind the development of Artelon® was to create a material that could be used to repair torn anterior cruciate ligament (ACL) in the knee. Synthetic materials used previously for ACL reconstruction had a number of obvious deficiencies. The non-degradable materials used were often too rigid and the degradable materials degraded too quickly. Lars Peterson, Per Flodin and Bengt Edberg, three of the founders of Artimplant, began working on this problem back in the 1980s.

Lars Peterson, professor of orthopedics, defined the requirements for the material:

"It had to have suitable mechanical properties and it needed to be degradable and biocompatible."

Per Flodin, professor of polymer technology, introduced his work on polyurethane ureas. This group of materials has previously exhibited good biocompatibility. By changing the chemical structure, the mechanical properties and the rate of degradation, they can be varied considerably. Predictable, long-term degradation is crucial if the body tissue that is formed between the Artelon® fibers is to take over.

The work also involved the development of production processes, including the spinning of the polymer into fibers. Bengt Edberg, professor of textile technology, developed products with different constructions in order to utilize the properties of

the fibers. In doing so, the products were adapted to the intended application and the demands of orthopedic surgeons.

Artimplant's original applications centered around the knee and the ACL, which is a very challenging indication.

Today, many applications have been developed and are in clinical use, improving the quality of life for many patients around the world.

We have solutions in different areas, such as the treatment of osteoarthritic joints and the repair of soft tissue injuries.

In collaboration with centers of excellence, Artimplant is exploring the potential of Artelon® with medical pathfinders to develop the medical solutions of tomorrow. ■

WITH DEDICATION AND SKILL - *research and development*

Artimplant has focused on research and development throughout its existence. We have acquired unique, in-depth knowledge and experience in many fields and we are resolute in our endeavor to replace old implant technology with innovative, tissue-preserving solutions.

Regenerate body functions

The aim of Artimplant's research and development is to develop degradable implants that regenerate body functions and improve quality of life. To maximize the benefits for patients and doctors, our work is as broad as possible.

We strive to develop methods that offer optimal efficiency from indication through to surgical procedure and rehabilitation instructions. This means that our customers receive a system solution that should be taken into account in order to optimize the clinical outcome. Our claims are carefully documented in package inserts, technical files and scientific communications.

Variety of medical applications

Artelon® is our proprietary degradable material, which has been developed specifically for medical use. The biocompatibility of the material in different tissues is well documented. We have in-depth knowledge of polymer processing of the material, which can be formed into various shapes, such as fibers, porous sponge-like materials and films. Using textile techniques, the fibers can also be adapted into complex structures.

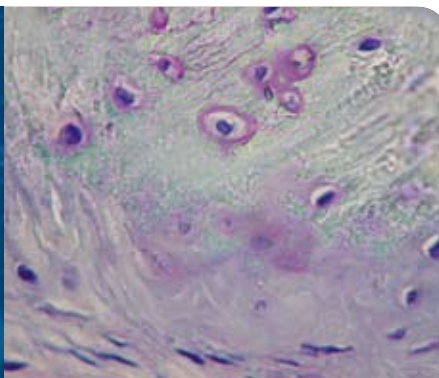
Our extensive knowledge of the Artelon® material allows us to develop medical devices that are designed specifically to meet the demands encountered in a wide variety of medical applications. The continued expansion of the product portfolio is based on the knowledge of Artelon® from a biological, material and process engineering perspective. ■

"We are resolute in our endeavor to replace old implant technology with innovative, tissue-preserving solutions."

*Katrin Gisselfält,
Vice President R&D*

Artelon®

helps the body to heal



Human biopsy that shows excellent biocompatibility and ingrowth of host tissue in close contact with Artelon®

ENCOURAGING SOLUTIONS - Artelon®

Artelon® is a unique, degradable biomaterial that serves as a scaffold for tissue ingrowth and provides temporary support for healing tissue.

Different Artelon® concepts have been developed, based on a logical approach to facilitate or promote the normality of tissue repair. The sequence of events that takes tissue from injured to 'normal' state is bleeding, inflammation, proliferation and remodeling. Inflammation is a normal and necessary prerequisite for healing. Following the tissue bleeding, a number of substances will remain in the tissue, making a contribution in the later phases. Artelon® absorbs blood cells and stabilizes the clot. Fibrin, which is important for the adhesion of various cells, begins to form and at this stage the new tissue is very fragile and needs the support of the Artelon® material. In time, Artelon® degrades and the tissue remodels and matures. The remodeling phase mainly involves collagen and its associated extracellular matrix. Final remodeling may continue for months, and possibly over a year, depending on the kind of tissue.

A key benefit of Artelon® is that it has a slow rate of degradation.

It degrades in the body in the presence of water. The rate of degradation is predictable and is tailored to provide initial stability and, then, as the implant loses its strength, to progressively transfer the load to tissue to stimulate remodeling. If the rate of implant

degradation produces more degradation products than the tissue is able to tolerate, there is a danger of adverse tissue reaction. This risk is greatest when implant strength and mass are lost rapidly.

Extensive histological surveys of implanted material and surrounding tissue have revealed that Artelon® shows excellent biocompatibility in soft tissue and bone throughout its implantation period. Since the material is synthetic, no risk of disease transfer is involved in its use.

Artelon® can be produced in a number of shapes to meet specific needs in a wide variety of applications.

Its structural design can be tailored to produce the required combination of mechanical properties and handling of the implant.

Artelon® can be spun to elastic fibers and adapted into complex structures using textile techniques, thereby creating implants suitable for load uptake. Artelon® can also be formed into highly porous sponge-like structures suitable for applications that require volume to be created and maintained. This material is soft and pliable and is suitable for minimally invasive surgery. ■

ENCOURAGING SOLUTIONS - Reinforcement

Artelon® reinforcement products are based on elastic Artelon® fibers and are intended to strengthen weak or repaired soft tissue.

Ruptures or tears in ligaments and tendons may occur as a result of repetitive motion and traumatic or sports-related accidents. Unfortunately, the ligaments and tendons have relatively poor vascular supply and have no ability to heal a complete tear. They also heal slowly.

Artelon® reinforcement products are based on elastic Artelon® fibers and are intended to strengthen weak or repaired soft tissue. The fiber structure permits host tissue ingrowth and blood vessels between the fibers. The remaining autologous tissue and bleeding are important to ensure early ingrowth of cells in the reinforcement structure.

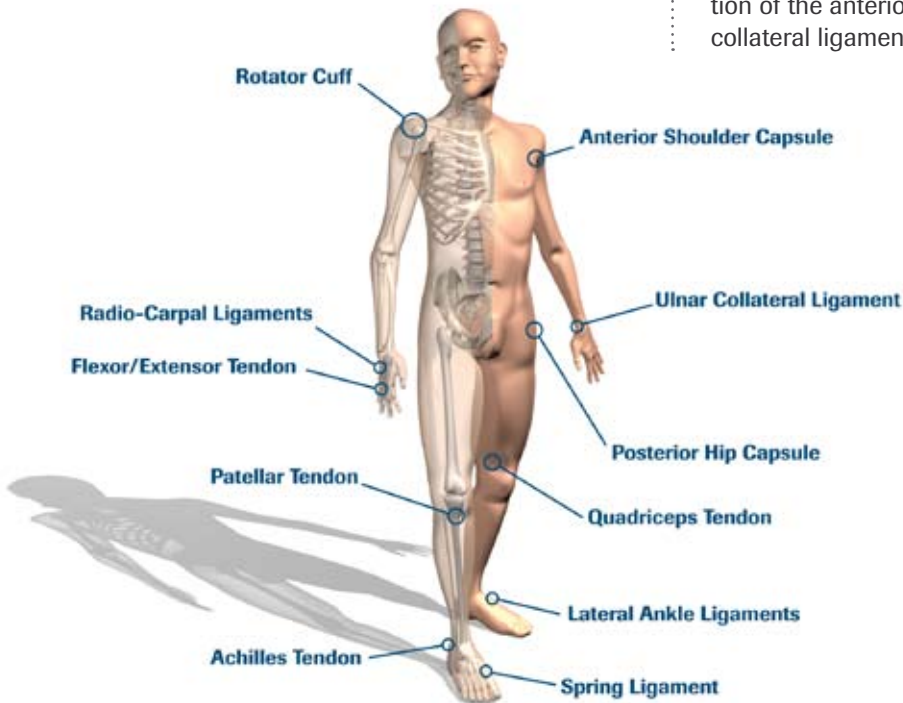
An important function of the reinforcement is to relieve the load during the sensitive initial healing period and thus achieve long-term stability.

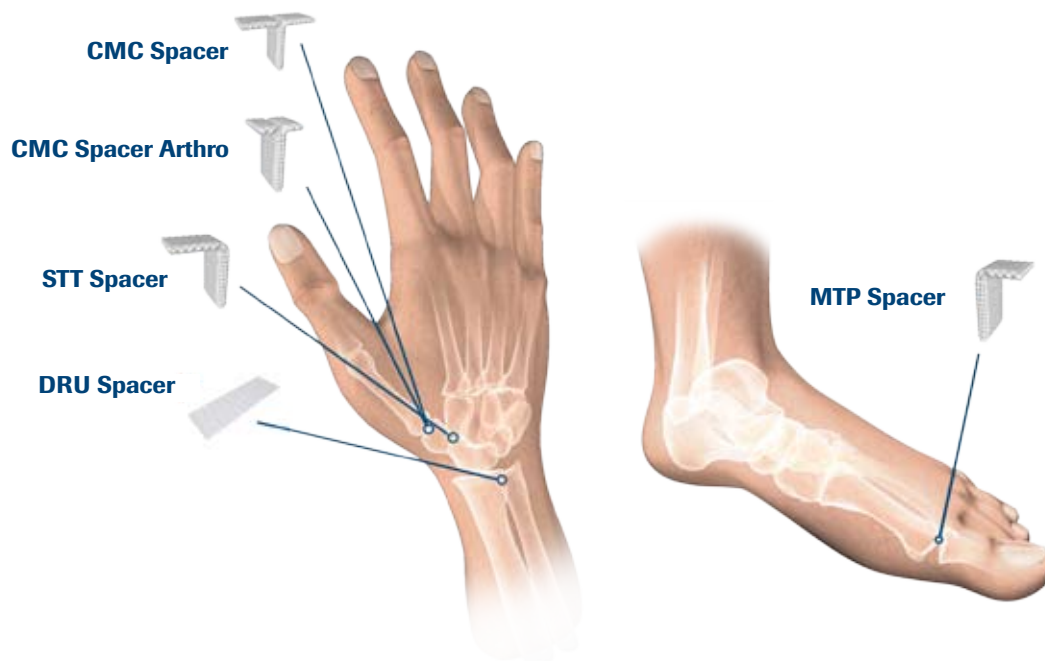
With time, the strength of the implant is reduced, enabling newly formed tissue to take over the function.

A controlled degradation rate is crucial if the body tissue that is formed between the Artelon® fibers is to take over. If the rate of degradation is too slow, the tissue will not be exposed to mechanical loads and will thus not mature. If the rate of degradation is too high, the tissue is exposed too early and there is a tangible risk of re-rupture.

The effect of having an elastic material working together with the weak tissue has been observed in preclinical and clinical studies. Histological studies have confirmed that collagen type I and blood vessels are formed between the fibers. The tissue is in close contact with the material and the newly formed connective tissue has an organized, ligament-like structure oriented in parallel to the Artelon® fibers, which is a sign that the tissue is taking the load.

Today, Artelon® has been used for the reinforcement of the suture repair of the rotator cuff tendons, Achilles tendons and spring ligaments to avoid re-ruptures. Other applications studied are the reinforcement of tendons used for the reconstruction of the anterior cruciate ligament and the ulnar collateral ligament. ■





ENCOURAGING SOLUTIONS - *Resurfacing*

Even when Artimplant was in the process of being founded, there were thoughts regarding a number of conceivable uses where Artelon® could create conditions for the body to heal itself.

Cartilage has very little capacity to repair itself and defects will eventually result in osteoarthritis, the most common form of arthritis.

The Artelon® resurfacing concept is a tissue-preserving method for the treatment of osteoarthritis.

The original joint surface and a few millimeters of the bone are removed to induce bleeding from the cancellous bone and thereby secure the recruitment of cells into the scaffold. This method saves tissue and leaves the joint almost intact. The Artelon® implant separates the bones and resurfaces the bone, while acting as a scaffold on which cells can climb and create a new, functional articular surface.

Clinical results have shown that the body starts to build a new articular surface and that Artelon®

supports the formation of fibrous cartilage. In situations where stabilization is important, the implant can be designed with supporting structures to stabilize the joint.

The concept of creating a new articular surface with the aid of Artelon® is general and can be used for many of the joints in the human body.

The resurfacing concept is used clinically for joints in the hand and wrist, such as the carpometacarpal (CMC), the scaphoid trapezium/trapezoid (STT) and the distal radioulnar (DRU) joints, as well as the metatarsophalangeal (MTP) joint in the foot. There is considerable future potential in extending the Spacer family to include new joints in the hands and feet but also by applying the Artelon® resurfacing concept to joints like the facet joint, which is a logical step and in line with the trend towards motion preservation in the spine. ■

ENCOURAGING SOLUTIONS - *Replenish*

If the load on a bone decreases, the bone will adapt and become weaker, which eventually leads to the gradual loss of bone. After the loss of teeth, there is therefore a continuous reduction in the residual ridge.

To be able to install dental implants, it may be necessary to increase the bone volume. Even if the bone volume is sufficient for the fixation of dental implants esthetic problems such as cavities around the threads and/or black triangles in connection with the implants may occur in the short or long term. In these cases, soft tissue volume is needed. Increased soft tissue volume is also needed in order to improve the prerequisites when using dentures or prosthodontic treatment (bridges).

In 2005, an Artelon® scaffold was developed. It can be likened most closely to a sponge or a porous matrix structure and it comprises only around 10% Artelon®, while the remaining volume is air. An exciting area of use for this porous matrix is tissue augmentation within odontology.

In the Artelon® replenish concept, Artelon® assists the building of new tissue by supporting the volume and providing a scaffold for tissue ingrowth.

In the short term the Artelon® scaffold creates space for new tissue formation and immediate

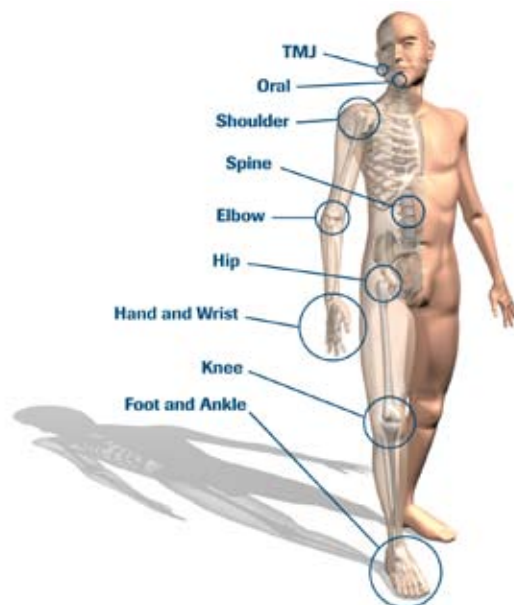
esthetic treatment. In the long term, new tissue is formed in the scaffold. The tissue formed depends, for example, on the environment and local stresses on the newly formed tissue.

Artelon® has been used in cosmetic applications in the treatment of periodontal and periimplant defects to regain soft tissue volume.

Using current methods, the patient is currently treated using tissue taken from the gums and transplanted to the jawbone. Artelon® has also been used in sinus lift procedures performed using the osteotome technique. An Artelon® cylinder is used as a tent pole to lift the maxillary sinus membrane and new bone is then formed under the membrane.

There are a number of conceivable applications for Artelon® that have yet to be exploited outside the stated odontological applications. They include craniomaxillofacial surgery, as well as plastic and reconstructive surgery. ■





OTHER EMERGING AREAS - *Artelon® opportunities*

Since the invention of knee replacement in the 1970s, orthopedic development has mainly been driven by mechanics. However, the concept of helping the body to heal itself has come to the fore in recent years.

In the trend towards a more biological approach the concept of using Artelon® as a scaffold for cartilage repair can be shown to have benefits for patients with early-stage osteoarthritis in different body parts, including the knee.

There is a need for cartilage regeneration in order to treat patients in the early stage of the disease, instead of using metals as replacements in the late stage. When tendon or ligament injuries occur, the options for treatment are limited. The alternative is often to use an autograft, which leads to longer operation times and donor site morbidity. Another need is to repair or regenerate 'shock absorbers' such as the menisci or discs.

In the spine area, the trend has also shifted from mechanics to a more biological approach.

This includes the movement from fusion to motion preservation and non-fusion technologies, which has become the standard surgical care for numerous pathologic conditions of the spine. Applying the Artelon® resurfacing concept to the facet joint or using Artelon® in dynamic stabilization are logical steps in line with the trend towards motion preservation.

Moreover, researchers and clinicians use a variety of stem cells and matrices to try to turn cells into bone, muscles and cartilage. They are attempting to find matrices that will be compatible with different tissue. Apart from just being a scaffold, Artelon® also has the prerequisite to act as a carrier for blood, bone marrow or cells that can boost healing.

To date, Artimplant has focused on the reinforcement and resurfacing concepts in orthopedics, i.e. knee, shoulder, hand and foot surgery. Recently, the focus has also included the replenishment concept in oral surgery.

There are many similarities between the different areas of therapy in which Artelon® is used.

The principle of resurfacing or supporting the healing of soft tissue does not differ to any great extent from one part of the body to another. Using data derived from clinical experience of Artelon® and by adjusting the design of the implant, the product range will be extended to include new therapy areas in which there are currently unmet needs. ■

SECURING CLINICAL OUTCOME

Introducing a new medical concept and a new way of thinking is a stimulating challenge.

The product is not only the implant itself but also the surgical procedure and the rehabilitation instructions. All the parts are equally important when it comes to achieving a successful result for any treatment concept.

- Indication – working with a correctly defined patient group which has the prerequisites for responding to the treatment
- Surgical procedure – the implant is applied correctly
- Rehabilitation instruction – that immobilization of the joint/tissue during the initial healing phase is sufficient for new tissue to grow into the implant

If any of these important parts of the 'treatment chain' were to go wrong, the treatment could fail.

Before a product is released for sale, verification and validation are completed and approved for each product claim. Once on the market, education and continuous contact with our customers is vitally important for successful treatment. In addition, Artimplant strives continuously to obtain feedback on surgical techniques, experience with rehabilitation and the potential extension of the indications for Artelon® products. ■





QUALITY FOR PATIENT SAFETY

Artimplant maintains control over the entire process of producing the biomaterial Artelon® from development, through production to finished implants. By doing so we ensure that we maintain control of product quality.

Production takes place at Artimplant's own facilities in Gothenburg, Sweden. The production premises and machinery have been adapted and built up for the sole purpose of producing Artelon® and they are operated by qualified personnel. Production has been refined gradually over the years to improve capacity and productivity in preparation for the increased demand for Artelon® products.

Quality Management

Artimplant has implemented a quality system in accordance with the standard 13485:2003, Quality management systems - Requirements for regulatory purposes. The quality system meets the applicable requirements stated in the Medical Devices Directive 93/42/EEC (Medical Devices) in order to obtain market entrance into the European Union.

The quality management system has been audited by Artimplant's Notified Body, Lloyd's Regis-

ter Quality Assurance, and Artimplant has been granted certificates to prove compliance with the standard and regulations mentioned above. Furthermore, the system is designed to comply with the US requirements stated in 21 CFR, Part 820.

Clearance to market - regulatory aspects

In order for Artimplant to be able to market and sell its degradable implants, the regulatory requirements must be met in all the markets where the products are to be sold. The aim is to ensure that products that come on to the market always comply with the high quality and safety stipulations laid down by the company and the regulatory authorities.

Most importantly, it is a question of guaranteeing the patient's safety. ■

AN EXCITING FUTURE

With a clear focus and extensive knowledge of degradable implants, we are positioning ourselves for the future with a biological approach to solving unmet clinical needs.

By making use of more than nine years of clinical experience for Artelon® we can provide patients and surgeons with safe, tissue-preserving implants that help the body to heal. Our knowledge and control of the complete process of producing the material Artelon® from development, through production to finished implants, gives us the opportunity to tailor future solutions.

Simply conducting research to produce new products is not sufficient. Together with a network of medical professionals and scientific investigators, we are working to identify the medical needs that are most compatible with our technology and to develop products to meet those needs.

*Sometimes the body is a master at healing.
On other occasions, it needs encouragement.*

For more than a decade Artimplant has been at the cutting edge when it comes to establishing tissue-preserving concepts based on scaffolds made from a new degradable material. Our aim is to continue to explore the potential for supporting tissue ingrowth and remodeling to restore and recreate functional tissues.

"In close collaboration with the medical community we continue to work towards realizing our vision of improving the quality of life for millions of people by helping their bodies to heal".





ALL OF US

We do not only monitor the development of alternative implant methods and regeneration of body functions – we also take the lead.

Expertise within and outside

Artimplant is a knowledge-intensive company that uses expertise within and outside the company. As a producer of medical devices, we naturally rely on healthcare practitioners to conduct clinical trials on our products. At the same time, as an R&D company, our own employees must have cutting-edge expertise in our areas of specialization: orthopedic surgery, odontology, biomaterials and polymer and textile technology.

R&D based on market knowledge is vital to Artimplant's past and future.

Several leading researchers in orthopedic surgery have been involved with the company since its inception.

Their work has attracted other prominent researchers from inside and outside the organization. While

project leaders direct the available resources towards the commercialization of a specific product concept, new ideas are constantly emerging. We learn about the unmet needs of patients and doctors through all phases of development.

Our product managers have long experience from their field of expertise. Together with our customer service, distributors and their sales representatives, they are focused on providing you with the best possible training and service.

Transparency

Artimplant is listed on the Nordic Exchange. Being a listed company ensures long-term thinking and transparency in every facet of the company's operations. ■

SOME OF YOU

More than 700 clinics all over the world have experience of Artelon® implants. We work closely with clinicians in orthopedics and odontology. Their opinion today and your opinion tomorrow make a difference to us.

"For over nine years I have been using Artelon® as an augmentation in the surgical treatment of ligament, tendon and joint capsule injuries and will continue to do so."

Professor Lars Peterson, Gothenburg Medical Center, Sweden
MD, PhD, Orthopedic surgeon

"I have been using Artelon® Tissue Reinforcement in two types of surgical procedures. At rotator cuff repair the triangular defects in old, complete ruptures were reinforced and closed with the mesh. When doing the Waever-Dunn procedure, due to chronic dislocation of the lateral clavicle, the ligament between the coracoid and the clavicle can be reinforced and reconstructed. Artelon® Tissue Reinforcement gives an augmentation during the entire healing period 3 - 6 months and the patient can be permitted to start exercises earlier."

Dr Carl Zetterberg, Department of Orthopedics,
Uddevalla hospital, Sweden
MD, PhD, Orthopedic surgeon

"At the Brånemark Clinic we have great expectations of what Artelon® can achieve to rebuild soft tissue around dental implants."

Dr Bertil Friberg, Brånemark Clinic, Gothenburg, Sweden
DDS, MDS, PhD, Specialist in oral and maxillofacial surgery

"When performing a sinus lift using the osteotome technique the synthetic material Artelon® is ideal due to its biocompatibility and ease of use."

Dr Robert Fermergård, Västervik Hospital, Sweden
DDS, Specialist in oral and maxillofacial surgery

"For thumb base osteoarthritis there is no optimal treatment available. For this purpose Artelon® is a perfect biomaterial thanks to its slow rate of degradation and that it provides a scaffold for tissue ingrowth. The tissue-preserving Artelon® Spacer concept, where resected bone and cartilage is replaced, offers a new opportunity for the treatment of thumb base osteoarthritis."

Dr Sten Björnum, Gothenburg Medical Center, Sweden
MD, Orthopedic surgeon





www.artimplant.com

HEAD OFFICE

Artimplant AB
Hulda Mellgrens gata 5
SE-421 32 Västra Frölunda
Sweden

phone +46 31 746 56 00
fax +46 31 746 56 60
e-mail info@artimplant.com



Disclaimer

This information is based on our present knowledge and is intended to provide general information about products and services. Artimplant assumes no responsibility for errors or omissions in this document. In no event shall Artimplant be liable for any special, direct, indirect, consequential, incidental loss or any loss whatsoever resulting from the loss of use, data or profits, whether in an action of contract, negligence or other tortuous action, arising out of or in connection with the use of the information or this document. Artimplant reserves the right to make additions, deletions or modification to the information in this document at any time and without any prior notice.

INFORMATION IN THIS DOCUMENT IS PROVIDED "AS IS" WITHOUT A WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

Products described in this document may not be available or cleared for marketing in all countries or may be available under different names.

Copyright on any information or any part of this document remains the property of Artimplant.

© Copyright Artimplant AB, 2007

Production: Artimplant in cooperation with mkmedia produktion ab
Photography: Carl Swensson, Max Fredriksson, Johan Olsson, iStockphoto, Jupiterimages and Stockbyte



1014294A

Artimplant AB, Hulda Mellgrens Gata 5, SE-421 32 Västra Frölunda, Sweden
Phone +46 31 746 56 00, Fax +46 31 746 56 60, www.artimplant.com



Artimplant
Degradable Materials for Optimal Tissue Repair