The meniscus, a crescent-shaped structure located between the sliding surfaces of the femur and tibia, is one of the most highly stressed parts of the locomotive apparatus. When a walk is taken at a normal pace, each knee is subjected to approximately twice the weight of the body, and between five- and ten-fold when a person jogs at a moderate pace. During the course of a single tennis match, these loads add up to as much as 500 tons (Fig. 1). The meniscus cushions these impulses and, at the same time, provides for the lubrication and stabilization of the knee joint.

Particularly in the case of rotary movements, e.g. by quick changes of direction or a fall, the load can be so large that the meniscus tears (Fig. 2). In Europe alone, there are about 300,000 meniscus injuries every year. Although minor lesions and peripheral tears in the vascularized cartilage tissue can be sutured, the meniscus has to be removed partly or completely in about 85% of the cases nowadays. Admittedly, the patients regain their normal knee function quite quickly after surgery. However, studies have shown that the removal of 14 to 34% of the meniscus tissue causes a more than 350% increase in the contact pressure. In the course of time, 35% of the operated patients develop arthrosis of the knee, a degenerative disease with swelling, pain and restriction of movement. In about 20% of these cases, a partial or total knee-joint prosthesis is required long-term.

LIMITATIONS OF THE HITHERTO METHODS
Since 1980, orthopedic surgeons concerned with meniscus injuries have been trying to save the largest part of the cartilage tissue and thus to maintain its function. However, in cases where it is not...
possible to suture, a part of the meniscus has to be removed. In view of this, various possibilities for meniscus replacement have been investigated in order to avoid later damage. Experiments with plastics implants and transplantations, however, did not produce the expected results: synthetic materials frequently cause inflammation, and the risk of infection cannot be completely excluded with the transplantation of human material.

THE COLLAGEN IMPLANT CMI
With the development of the collagen implant, the US company ReGen Biologics Inc., in which Sulzer Orthopedics has a 14% interest, has broken new ground. The Collagen Meniscus Implant (CMI, Fig. 3), which will reach market maturity in the near future, consists of a spongy structure made of high-purity, animal collagen. This material is implanted by means of arthroscopic surgery and sutured in place of the removed meniscus tissue. The CMI subsequently acts as a template for the tissue regeneration. The special structure promotes the formation of new cartilage tissue and is fully invaded by it. A major advantage of the CMI is found in the fact that the exogenous collagen is completely reabsorbed with the time.

POSITIVE CLINICAL RESULTS
The CMI has been tested extensively in the laboratory. In the course of a pilot study in the USA, 10 patients with irreparable meniscus damage were provided with collagen implants (Fig. 4). The purpose of this was to test the safety and implantability of the CMI and to investigate its ability to assist in the natural regeneration of the meniscus. During the follow-up examinations conducted in the ensuing three years, it was found that the CMI could be implanted without any technical difficulties and is safe over this period of time. Histologically, it was proven that the regeneration of tissue was supported in differently sized defects. Furthermore, that new tissue was formed and, parallel to this, the CMI was reabsorbed. Increasing maturation of the newly formed tissue was also established. Negative immunological reactions such as inflammation or rejection reactions were not observed. Although the test was intended as a feasibility study, it also produced results from a qualitative aspect.

2 A torn meniscus. It is not always possible to suture injuries of this kind, because the cartilage tissue is not vascularized throughout. In the past, torn menisci frequently necessitated the surgical removal of the damaged tissue.

3 The collagen implant is implanted in place of the damaged and removed meniscus tissue. Endogenous cartilage tissue grows through this “template”, the implant is reabsorbed.

COLLAGEN
Collagen are long-fibered, high-molecular proteins of the supportive and connective tissue (skin, tendons, cartilage, bones). The bovine tendon material, which is used for the CMI, is purified in a number of chemical treatments and processed in such a way that the following criteria are fulfilled: biocompatibility, mechanical strength, a porous structure to facilitate the invasion of the new cells, permeability for macromolecular nutrient fluids and the necessary stability for the function as “growth template” in a living organism.
The majority of the patients confirmed the reduction of pain by increased activity and mobility.

**MULTICENTRIC STUDY IN EUROPE**

In 1996, Sulzer Orthopedics acquired the exclusive marketing rights for the CMI outside of the USA. To investigate the safety and efficacy of the CMI, a multicentric study was started in twelve leading orthopedic clinics in eight European countries in 1997. The participating patients have had a part of the meniscus removed or experienced a meniscus injury, and were not suffering already from an advanced degenerative arthritis. Should the study produce the expected positive results, efforts will be made to obtain the quickest possible approval of the CMI, so that this new method of treatment can be made accessible to a wide group of patients.

**CONSIDERABLE REDUCTION OF COSTS**

The partial meniscectomy, the partial excision of the meniscus tissue, is a comparatively cost-effective intervention. Nevertheless, the later consequences can be painful and expensive: if an arthritis develops, the knee joint has to be frequently replaced with a prosthesis. Admittedly, such an implant means a great relief for the patient, but the intervention results in high treatment and rehabilitation costs. And what is more, there is the probability that the prosthesis will have to be replaced after 10 to 15 years. It is assumed that the CMI will hinder or appreciably delay the development of arthritis and the subsequent implantation of joint prostheses. This would constitute an enormous cost-reduction potential and mean an enhanced quality of life for patients. These assumptions will be able to be reinforced on the strength of the results of the multicentric clinical study.

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Since the collagen implant is a reproduction of the natural form of the meniscus, the precisely exact pieces can be cut out and implanted.

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**FOR MORE DETAILS**

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