Healthcare industry BW

The use of regenerative biomaterials is likely to grow

Tuttlingen-based Aesculap AG is committed to using different materials including ceramics, titanium and high-performance polymers for the development and production of implants. The medical technology company has come up with a solution to prevent people from developing allergies against substances used in prostheses. Dr. Harald Stallforth, CEO Research & Development and Vice Chairman of the Aesculap AG management board talks with a BioLAGO representative on the use of special surface coating materials and the company's decision to use regenerative biomaterials, amongst other materials.

Dr. Harald Stallforth, CEO Research & Development and Vice Chairman of the Aesculap AG management board

Dr. Stallforth, your development department has come up with CeSpace® PEEK, an implant for cervical interbody fusion used to treat degenerative diseases of the cervical disc. Polyetheretherketone (PEEK) is one of the compounds used in the implant. What are the properties of this material?

PEEK is what we call high-performance polymer. It has been used since 1999 and over the last few years has become a popular material for the production of orthopaedic products. In addition to being able to tolerate huge mechanical strain and being transparent to X-rays, PEEK is also biocompatible. It also exhibits excellent resistance to a wide range of organic and inorganic substances. Its extreme hardness and high rigidity enable the optimal transmission of force between the implant material and the natural bone, which leads to the stimulation of bone healing processes. Comprehensive biocompatibility tests have shown that PEEK is excellently suited as a long-term implant.

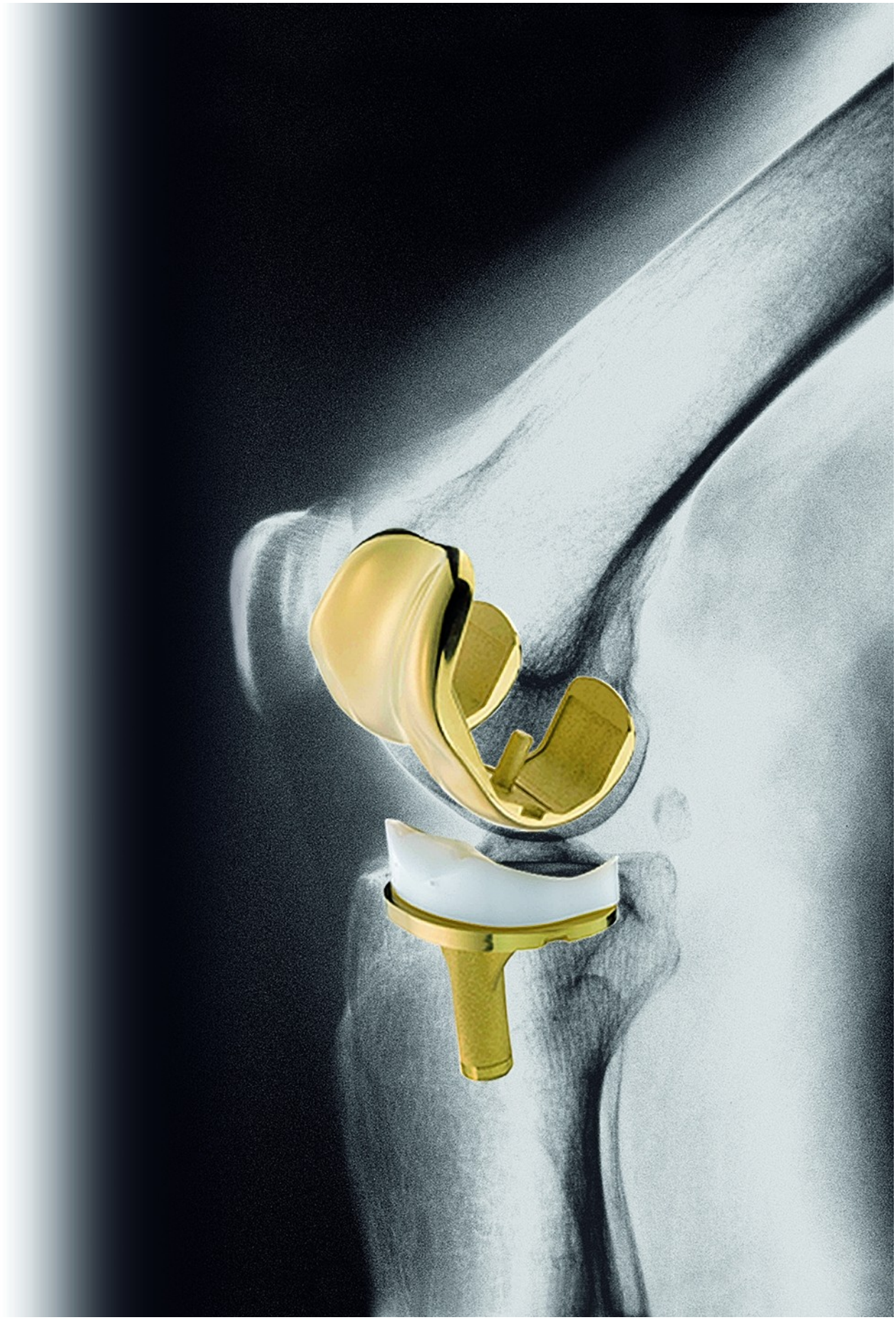
The CeSpace® Titanium implant is made of a solid titanium core mantled with a pure titanium (Plasmapore®) coating. What advantages does using titanium have?

In order to increase the implant surface, in other words, to achieve a contact area between implant and endplate that is as large as possible and to expedite a solid osseointegration, the titanium implant is mantled with a pure titanium coating that has a sponge-like structure approximately 0.3 mm thick. The coating is produced by spraying the raw material with pure titanium powder. When liquid titanium comes in contact with the implant core, the surface of the implant cools down, thereby leading to perfect form fit between the implant core and the coating. In addition, blood vessels can grow in this coating, which means that the body treats the implant as a crossover to normal bone rather than as an interface. We also use pure titanium to coat knee joint and hip prostheses.

Which factors decide whether CeSpace® Titanium or CeSpace® PEEK implants are used?

As far as the quality of the materials is concerned, neither of the two implants has a specific advantage or disadvantage. It is the operating surgeon who decides on a case-by-case basis. Health insurance companies and hospital administrations tend to go for the most economically attractive solution. However, only the

surgeon can and should decide whether and why he chooses PEEK or titanium. Insurance companies and hospital administrations usually follow the advice of the surgeon.



Aesculap coats knee endoprostheses with special coatings to prevent allergic reactions.

Which materials are currently in great demand and will continue to be in the future? For example, materials that are sought-after for their high

level of biocompatibility.

I am convinced that regenerative biomaterials will become more important over the next few years, for example for use as knee cartilage replacements. Cartilage does not heal after injury, and this eventually leads to arthrosis. For a long time there was no effective treatment for people with injured cartilage. Nowadays, cartilage injury can be treated with ACT, autologous chondrocyte transplantation, which involves the removal of cartilage cells from the knee at a site that is not under strain. The cells are then expanded in the laboratory and reimplanted into the defective area. The cartilage cells produce collagen fibres that form a tissue matrix. In general, the cartilage is made up of only 2% cells, the other 98 per cent being matrix tissue. ACT is expected to be suitable for the treatment of diseases for which no surgical therapy is yet available. It is assumed that demographic change will eventually require all people to be supplied with joint prostheses. The degeneration of tissue cannot be halted; it is an inevitable part of the natural ageing process. With the growing number of old people, the demand for such substitutes is also increasing.

What is Aesculap AG's focus in the field of 'regenerative biomaterials'. What advances are you currently involved in?

We are very well positioned in the market, in particular because of the Reutlingen-based company TETEC AG which we spun off in 2000. TETEC is our competence centre for regenerative materials; the company has around 35 staff and is relatively autonomous. It works in close cooperation with the NMI Natural and Medical Sciences Institute in Reutlingen. I would like to point out that the development of this biotechnology sector is in general massively and systematically obstructed by ever increasing safety demands at the point when companies seek marketing authorisation for such materials. I find this difficult to understand because the material we are using stems from the patients themselves. The process related to placing a biomaterial-based product on the international market involves huge sums of money, around 20 million euros. Such barriers have led to the closing down of many companies that were active in this area. Only two companies of the 10 to 15 that previously existed in Germany are still up and running. Nevertheless, I am sure that in the future regenerative materials will be accepted.

Does your company work on the modification of surfaces? By this I mean modifications to increase an implant's resistance to wear and corrosion, and hence increase its compatibility with the human body.

Ceramic materials are very brittle, which is why they are not used for the production of knee endoprostheses. Instead, we focus on new coatings in order to improve wear and biocompatibility. We attach a great deal of importance to materials that reduce or prevent allergic reactions. Allergic reactions might occur because all materials release substances, i.e. typically ions. We have developed a coating that to a large extent prevents the exchange of ions.

Are allergies in general a huge obstacle for the medical technology sector?

Many research investigations have shown that implant failure is often due to allergic reactions. The major difficulty is that it is impossible to look inside an implant once it has been implanted, at least not yet. Allergies to materials are becoming more frequent, in the same way as hay fever allergies. Implants have also been shown to cause infections as bacteria might accumulate and form a mucous layer that cannot be targeted by antibiotics. Infections tend to develop two to ten years after implantation. However, it is difficult to predict when an infection will occur. It has been found that infections are more frequent in people supplied with plastic implants than in people supplied with metal implants. We are able to prevent the development of such inflammations with the coatings we use for the implants we produce.

Further information:

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