

# PROTECTIVE COATING FOR METAL IMPLANTS



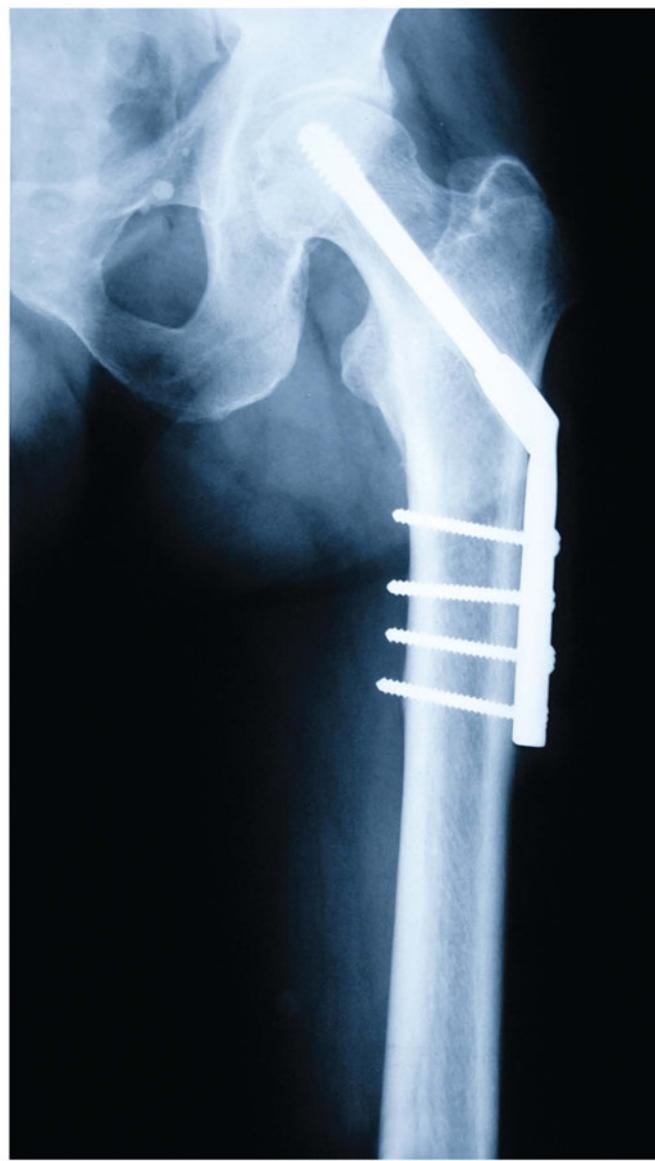
(TECHNOLOGY OFFER P-133)

*The subject of the offer is a polymer multi-layer coating that protects surfaces of metal implants, in particular made of steel. The coating effectively prevents the harmful release of heavy metal ions from the implant surface into the human body.*

Diseases of the musculoskeletal system have become one of the most serious threats to human health. Their effects can be minimised with the progress of medical science, which results in the observed **rapid increase in demand for implants**. In particular, the growing demand for metal implants is noticeable. They effectively take over the tasks of the bone and allow patients to participate in normal daily life activities. This applies not only to the elderly, e.g. affected by osteoporosis, but also quite often to young people who have suffered sports-related injuries. Statistics show that in this group an increasing number of fractures requires the use of metal implants in treatment.

The best metal materials available for implanting are currently titanium alloys and platinum; however, due to the high price the scope of their application is limited. **Implants made of non-noble metal alloys, particularly of stainless steel, are a more available alternative.** However, their use is associated with serious problems resulting from insufficient biocompatibility.

Surgical procedures involving introduction of a metal implant into the body are complex and associated with the risk of implant rejection by the organism. On the border of implant-tissue a series of complex processes occur; in particular, there is a **problem of migration of metal ions from the implant into the body**, including iron, chromium, nickel, titanium, vanadium, aluminium, cobalt, molybdenum. The mechanism of this phenomenon is directly related to corrosion processes, which occur in the environment of physiological fluids. Kinetics of release of metal ions from the implant surface is relatively slow, but given the long life of the implant in the body (up to ten years or more) the quantity of metal passing into the body is significant for the patient's health. Metal ions in concentrations





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greater than the limit (e.g. for iron: about 4.5 g/70 kg body weight, chromium: ca. 6 mg/70 kg b.w., nickel: ca. 1 mg/70 kg b.w.) may cause inflammation, allergic reactions or even tumours. The release of metal ions is therefore a serious obstacle to long-term use of steel implants.

In order to solve this problem, the implant surface is modified, both by optimising the surface treatment (e.g. polishing) and by use of protective coating that prevent corrosive action of body fluids. However, anti-corrosion coating technologies are complex and costly. For this reason, low-cost solutions based on polymer layers are in request. Despite intensive research, an efficient solution that would completely or substantially inhibit the process of metal ions release into the body is still lacking.

The subject of the technology offer is a polymer multi-layer coating for protecting the surface of metal implant materials against corrosion processes and the release of heavy metal ions from the implant into the patient's body. The coating consists of a passive layer and multiple polymer layers: silane (internal) and parylene (external) plus an additional layer of elastomer. The passive layer is between the implant surface and the silane layer, whereas the elastomeric layer is on parylene layer. Passive and silane layers provide good adhesion of parylene layer to the surface while parylene layer is the actual protective layer used to inhibit migration of metal ions from the implant surface into the body. Elastomeric layer, due to its plastic properties, prevents the crystalline and rigid parylene layer from cracking. Using the offered steel coating results in a high quality implantation material. Noteworthy, the useful properties of the metal itself are retained after coating, while the level of medical safety significantly increases, particularly referring to the affordable steel implants.

The main advantages are:

- highly effective protection against corrosion of the implant surface in the environment of body fluids resulting in a significant reduction of the release of metal ions into the body;
- high durability of the coating;
- simple manufacturing method;
- relatively low price.

Those features have been confirmed experimentally. Metal ion release laboratory tests performed in the incubator, in the environment simulating the physiological conditions inside the human body, have shown that the application of the protective coating described above can reduce the amount of heavy metal ions released from the steel surface by 50÷95% compared to the uncoated surface.

The polymer multi-layer is a subject of patent application, which covers both its composition, manufacturing method and the industrial applications. Further development of the invention is under progress at the Faculty of Chemistry of the Jagiellonian University in co-operation with Swerea KIMAB, a leading materials research institute in Sweden. Currently the Centre for Innovation, Technology Transfer and University Development is looking for entities interested both in technology development and its licensing and application.

