



Nickel and Surgical Implants

Nickel Stewardship



One of the most commonly utilised materials today for surgical uses is stainless steel. It is biocompatible, easy to clean and sterilise, strong, and resistant to corrosion. These characteristics make stainless steel ideal for surgical instruments such as hypodermic needles and catheters. Specialty stainless steels are also used for surgical implants such as bone fixation screws and prosthetic joints.

While there are over 60 grades of stainless steel, stainless steels are essentially iron alloys bearing at least 10.5% chromium and less than 1.2% carbon by weight. The specialty grades of stainless steel that are most commonly used in surgical implants also contain molybdenum (about 3%) and nickel (about 14%).

In recent years, a specialist alloy called Nitinol has emerged as another nickel-containing material for biomedical applications. Comprised of nickel and titanium, Nitinol is commonly used in stents – small hollow tubes used to keep arteries open, and in kink-resistant guidewires for placing implants.

Amongst the millions of surgical implant operations carried out each year in short and long-term applications, an isolated number of occasions have been reported where the presence of nickel in the implant alloy is suspected of causing an allergic reaction. This advisory note aims to provide reassurance and advice about the safe use of nickel as part of an alloy in surgical applications.

Assessing the risk

Materials used in surgical implant procedures, such as artificial joint replacements, are usually well tolerated. Complaints after such operations are mostly related to infection or mechanical problems but may also be caused by allergic reactions. Allergic reactions may



If you know you are allergic to nickel or have any concerns about possible side effects from the use of nickel-containing alloy implants, consult your doctor and/or surgeon in the period leading up to the operation.

include skin changes (i.e. eczema), delayed wound/bone healing, pain, or implant loosening. In contrast to the high incidence of allergy caused by skin contact to various metals (including nickel), allergies associated with implants are a rare condition. Typical elicitors are nickel, chromium, cobalt, and constituents of bone cement.

A number of clinical and laboratory studies have been conducted to determine the potential for stainless steel to elicit an allergic reaction. In patch tests on patients already sensitised to nickel, the low and medium sulphur-containing stainless steels did not produce a statistically significant number of allergic reactions. However, the high sulphur grades (e.g. AISI grade 303) did elicit allergic reactions in some 14% of sensitised individuals. In summary, it is generally agreed that stainless steels do

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not cause nickel contact dermatitis. However, stainless steels and, in particular, the high sulphur-containing grades may elicit an allergic reaction in a few hyper-sensitised individuals.

No implant material is totally inert or totally free from wear used for a long-term application such as a joint. Current standards for implant materials ensure that metal release into body fluids and tissue surrounding implants is kept to a minimum. However, the amount of metal release can be further controlled by reducing the amount of wear on a metal implant. For example, the first prosthetic hip joints in the 1960s were metal-on-metal. This early design caused high frictional wear that produced particulate deposition of the alloy components in the tissues around the joint. Today, prosthetic hips are more likely to be metal-on-plastic and have been designed to minimise frictional wear. As a result of this design change, there is a high success rate of stainless steel metal-on-plastic hip prostheses in patients, even those with pre-existing allergies to nickel or other metals.

Compared to the beneficial properties of nickel-containing implants, the side effects of using such implants are modest and can be further minimised by checking for nickel sensitivity before a nickel-containing implant is used.

Recommendations

For manufacturers of medical devices

- Refer to the current ISO standards:
 - ISO standards 5832-1 and 5832-9 specify wrought (austenitic) stainless steel and high-nitrogen (austenitic) stainless steel, respectively, for surgical implants
 - ISO 7153-1 specifies stainless steel for surgical and dental instruments, and also provides an indication of medical device applications for each grade.
- In Europe, comply with the EU Medical Device Directive [93/42/EEC, as amended].
- Note that high sulphur stainless steel (AISI grade 303, or reference steel grade 'N' according to the ISO standards) can release sufficient nickel to induce dermatitis in some nickel-sensitive patients. This grade of stainless steel should be avoided for pro-

longed skin-contact applications and it is unsuitable for implant applications.

For doctors and surgeons

- Prior to an implant operation, consult with a patient about their current and prior sensitivity to nickel and assess the risk of a potential adverse allergic reaction from the procedure being undertaken.
- Carry out the necessary allergy checks to ascertain an individual's sensitivity to nickel, other metals, and constituents of bone cement, where applicable.

For patients:

- If you know you are allergic to nickel, have suffered from any itching, rashes or other adverse reactions associated with jewellery, belt buckles, wrist watches or body piercings, or have any concerns about possible side effects from the use of nickel-containing alloy implants, consult your doctor and/or surgeon in the period leading up to the operation.

Nickel Institute policy and practice

Surgical professions are already proactive in minimising the risk of allergy. As an industry body, we readily provide necessary support and guidance as required.

As part of our overall Nickel Stewardship programme, much research and peer review work has been undertaken over many years in collaboration with the industry about the general topic of nickel allergic contact dermatitis. The best scientific knowledge about the induction of nickel sensitivity, the elicitation of allergic responses and the public health aspects of nickel sensitization are available through research sponsored by the Nickel Institute.

Useful reference information

For a comprehensive review of materials used in implants and prosthetic devices, see "Handbook of materials for medical devices", J.R. Davis, ASM International, 2003, ISBN 0-8717-0790-X.

If you have any questions or inquiries regarding the use of nickel alloys in surgical instruments or implants, please direct them to Peter Cutler at: pcutler@nickelinstitute.org.