

# Exposed customised titanium implants for orofacial reconstruction

**Understanding NICE guidance –  
information for people considering  
the procedure, and for the public**

December 2003



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**Exposed customised titanium implants for orofacial reconstruction:  
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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0386. A version in Welsh and English is also available, reference number N0387. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0387. The NICE interventional procedures guidance on which this information is based is available from the NICE website ([www.nice.org.uk](http://www.nice.org.uk)). Copies can also be obtained from the NHS Response Line, reference number N0385.

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## About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called exposed customised titanium implants for orofacial reconstruction. It is not a complete description of what is involved in the procedure – the patient’s healthcare team should describe it in detail.

NICE has looked at whether exposed customised titanium implants are safe enough and work well enough for them to be used routinely to help rebuild the face or mouth after severe damage to the bones (doctors call this orofacial reconstruction).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of exposed customised titanium implants and how well they work
- asked experts for their opinion
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE’s work on ‘interventional procedures’ (see ‘Further information’ on page 10).

## About exposed customised titanium implants for orofacial reconstruction

Exposed customised titanium implants are one way of rebuilding the face after severe damage to the bones. This may be needed after surgery for cancer, or because of serious injuries to the face. The implants can also be used to treat deformities of the face that have been present from birth.

The first step in making a customised titanium implant is to make a very accurate resin model of the bones of the person's face. This is a computerised process and uses information from CT (computer tomography) or MRI (magnetic resonance imaging) scans. The implant itself is made to fit this model precisely using another computerised process. It is then fixed into position on the person's face using titanium screws. Unlike other types of implant used on the face, the titanium implant is not covered with a flap of skin.

## **How well it works**

### **What the studies said**

There have been only a few studies of this procedure, and they produced differing results. There was not enough information to be sure how well the procedure worked.

### **What the experts said**

The experts said that the procedure was very new, and still being developed, and that it was not yet clear how well it worked.

## Risks and possible problems

### What the studies said

Some people who had an exposed customised titanium implant had problems after it was fitted. In one study involving 14 people, two of them developed ulcers next to the implant and three developed a small hole in the face near the implant leading to the inside of the mouth or nose (called a fistula). One person in the study had to have the implant taken out because of an infection.

### What the experts said

The experts said that there was a risk of infection with this procedure. They also thought it would be possible for the body to reject the implant, in a similar way to rejecting a transplanted kidney or other organ.

## What has NICE decided?

NICE has decided that exposed customised titanium implants should only be used for orofacial reconstruction for patients taking part in studies of this procedure. The doctor who carries out the procedure should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works.

## What the decision means for you

Your doctor may have asked you to think about taking part in a study of exposed customised titanium implants for orofacial reconstruction. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of exposed customised titanium implants for orofacial reconstruction. Your doctor should discuss the benefits and risks with you, and you need to understand them before you decide whether to take part in the study. Some of these benefits and risks may be described in this booklet.

## Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

You can visit the NICE website ([www.nice.org.uk](http://www.nice.org.uk)) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on exposed customised titanium implants for orofacial reconstruction is on the NICE website ([www.nice.org.uk/IPG028guidance](http://www.nice.org.uk/IPG028guidance)), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0385. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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