

## Understanding NICE guidance

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Information for people who use NHS services

# Treating snoring by inserting implants into the roof of the mouth

*NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures can be used in clinical practice.*

This leaflet is about when and how inserting implants into the roof of the mouth can be used in the NHS to treat people who snore. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. The word 'procedure' means any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or body cavity. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe the procedure in detail – a member of your healthcare team should also give you full information and advice about this. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

## What has NICE said?

There is evidence to say that this procedure is safe. However, there is currently not enough evidence to say whether it works or not. This is because the studies that were available only looked at small numbers of people, and did not directly compare the procedure with other treatments or procedures. For this reason, NICE has said that this procedure should only be carried out as part of a research study (also called a clinical trial) to gather more evidence.

NICE has said that the research studies should include details about the patients who have the procedure. These studies should also record what happens after the procedure, from both a medical and a quality-of-life point of view.

## Other comments from NICE

NICE has said that it has not seen any evidence about using this procedure in children.

*This procedure may not be the only possible treatment for snoring. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.*

## Treating snoring by inserting implants into the roof of the mouth

The procedure is not described in detail here – please talk to your doctor for a full description.

Snoring can disturb sleep and can affect relationships with others. The sound of snoring is the sound of the soft palate and other parts of a person's mouth, nose and throat vibrating (the soft palate is the back part of the roof of the mouth).

The standard treatment for snoring is lifestyle change (for example, losing weight, stopping smoking, changing sleeping position, and avoiding alcohol and sleeping tablets).

NICE has looked at a procedure called soft-palate implants for simple snoring. In this procedure, thin implants are inserted into the soft palate under a local anaesthetic. The aim of the procedure is to make the soft palate stiffer and less likely to vibrate.

## Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at six studies on this procedure.

## How well does the procedure work?

Several studies used the intensity of snoring to decide whether the procedure worked well enough. This involved the patient's bed partner assessing the patient's snoring on a scale of 0–10, where 0 was no snoring and 10 was snoring that made the partner leave the room. One study looked at 10 patients with standard implants and 10 patients with more rigid implants. When checked 90 days after the procedure there was no significant difference in snoring between the implants used. The procedure only improved snoring by a maximum of 3 points on the scale. The results

## What does this mean for me?

NICE has said that there is not enough evidence about how well this procedure works to recommend it for general use in the NHS.

Your doctor can only offer you this procedure as part of a research study. NICE has recommended that some details should be collected about every patient who has this procedure in the UK. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to have the procedure, you will be asked to agree to your details being entered into an electronic database for this purpose. A doctor looking after you will fully explain the purpose of collecting the data and what details will be held (all information will be held according to the Data Protection Act). You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you can still have the procedure.

### You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get and are they likely to be permanent?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

*You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.*

of five further studies all showed similar results. In two studies, the average scores before the procedure were 7.6 and 8.5. Ninety days after the procedure, the average scores were 3.7 and 5.0, and after a year, the average scores were 4.0 and 4.4.

A further three studies were looked at. In the first two studies (one study of 40 patients and another of 34 patients), the average score before the procedure was 7.1. Ninety days after the procedure, the average scores in the two studies were 4.2 and 3.4, but after a year, the average score had worsened to 4.8 in both studies. The third study only looked at 12 patients and used a scale of 0 to 100. It showed that before the procedure the average score was 79. Ninety days after the procedure the average score was 48.

Several studies also looked at daytime tiredness to decide whether the procedure worked well enough. These studies used a scale ranging from 0 (best) to 24 (worst). In two studies involving 120 patients in total, the average score was 8 before the procedure, 7.3 after 90 days in one study and 5.2 after 1 year in the other. Three studies involving 83 patients had an overall average score of 8.1 before the procedure, 5.7 after 90 days and 5.2 after 1 year.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the goals of treatment are reducing snoring intensity, reducing daytime tiredness and improving satisfaction and quality of life for both the patient and their bed partner.

## Risks and possible problems

There were no postoperative infections or serious complications reported.

In some patients the implants became dislodged. In five studies this happened in between 4% and 25% of patients. A study of 20 patients showed that this only happened in patients who had more rigid implants. It happened in 4 out of 10 patients who had rigid implants and in none of the 10 patients who had standard implants.

Studies also looked at pain, and used a scale, where 0 was no pain and 10 was extreme pain. They showed that pain was worse just after the procedure (the reported score was 4.9), but 90 days after the procedure, the reported score was only 0.2.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible problems include infection, the implants moving or becoming dislodged, the sensation of a foreign body, bleeding, minor scarring and possible airway problems.

## More information about snoring

NHS Direct online ([www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

### About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

*To find out more about NICE, its work and how it reaches decisions, see [www.nice.org.uk/aboutguidance](http://www.nice.org.uk/aboutguidance)*

*NICE's guidance on soft-palate implants for obstructive sleep apnoea is available from [www.nice.org.uk/IPG241](http://www.nice.org.uk/IPG241). NICE has also issued guidance on radiofrequency ablation of the soft palate for snoring, which is available from [www.nice.org.uk/IPG124](http://www.nice.org.uk/IPG124)*

*This leaflet is about 'Soft-palate implants for simple snoring'. This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/IPG240](http://www.nice.org.uk/IPG240)*

*You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1415).*

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ISBN 1-84629-553-X  
N1415 1P Nov 07