

Customised implant for osteoarthritis of the knee

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

This leaflet is about when and how a customised implant can be used in the NHS to treat people with osteoarthritis of the knee. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. 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 osteoarthritis of the knee or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. 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 page 5.



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What has NICE said?

Currently there is not enough evidence to be certain about how well this procedure works or how safe it is.

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). The research should look at the technical results of the procedure and record patients' experiences and views. The research should also look at the length of time before knee joint replacement is needed.

Customised implant for osteoarthritis of the knee

This procedure may not be the only possible treatment for osteoarthritis of the knee.

Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options

The medical name for this procedure is 'insertion of individually magnetic resonance imaging-designed unicompartmental interpositional implant in osteoarthritis of the knee'.

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

Osteoarthritis develops when the cartilage that covers the end of the bones in a joint becomes worn. In early arthritis, uneven wear of the inner and outer sides of the joint lead to bowing of the knee, which overloads the damaged side so that the joint becomes painful and inflamed.

Depending on how severe the osteoarthritis is, it may be treated with medication to relieve pain and swelling, physiotherapy or exercise, or injections of corticosteroids (medicines that reduce swelling and pain). People who have severe osteoarthritis may need to have surgery to realign the knee or to replace part of or all of the knee.

In this procedure the damaged and worn surfaces of the knee are separated by a customised implant that acts as a spacer and straightens the bowed knee. The aim of the procedure is to reduce pain

and delay the progression of osteoarthritis and the need for knee replacement surgery.

A magnetic resonance imaging (MRI) scan of the knee is taken and used to individually design the implant. The operation to put in the implant is usually carried out with the patient under a general anaesthetic and may be done as day surgery. Arthroscopy (a keyhole procedure using a small telescope) is used to remove any osteophytes (small bone spurs). The implant is then inserted through a small cut next to the knee cap.

What does this mean for me?

Your doctor can only offer you this procedure as part of a research study (also called a clinical trial).

NICE has recommended that some details should be collected about every patient who has this procedure in the UK. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- 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?

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

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 2 studies on this procedure.

How well does the procedure work?

In a study of 27 patients with early- to mid-stage osteoarthritis, who also had removal of osteophytes, 23 patients had a successful outcome (defined as realignment of the knee so that it is in line with the hip and the ankle).

As well as looking at this study, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that success factors include reduced pain and whether the person is able to return to work, perform activities of daily living and resume sports. They thought that the uncertainties about how well this procedure works are similar to the uncertainties linked with traditional, non-customised implants, namely pain, dislocation or misalignment of the implant, and a higher risk of needing further procedures. One expert adviser was concerned that loosening of the implant might result in more damage to the joint, which may make knee replacement surgery more difficult to do.

Risks and possible problems

In a study of 60 patients, the implant became dislocated in 4 patients. In the study of 27 patients the implant did not become dislocated in any of the patients.

In a study that has not been published, out of 84 patients who had a customised implant inserted, 5% needed further procedures.

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 dislocation of the implant, infection, continuing pain and formation of blood clots.

More information about osteoarthritis

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on osteoarthritis and its treatments, visit our website at www.nice.org.uk

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. This 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

This leaflet is about 'insertion of individually magnetic resonance imaging-designed unicompartmental interpositional implant in osteoarthritis of the knee'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG203

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1998). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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