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## **Insertion of biological slings for stress urinary incontinence in women**

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

## **Ordering information**

You can download the following documents from [www.nice.org.uk/IPG154](http://www.nice.org.uk/IPG154)

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0967 (full guidance)
- N0968 (information for the public).

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## About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on the insertion of biological slings for stress urinary incontinence in women. It is not a complete description of what is involved in the procedure – the woman's healthcare team should describe it in detail.

NICE has looked at whether inserting a biological sling for stress urinary incontinence in women is safe enough and works well enough for it to be used routinely.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of procedures to insert biological slings and how well they work
- asked experts for their opinions
- 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 the procedure

Stress urinary incontinence is when urine leaks out during exercise, coughing, sneezing or laughing. It usually happens because the muscles and tissue that make up the pelvic floor have become weakened or damaged. The pelvic floor acts as a support to the bladder, helping to keep it closed until the person wants to pass urine. Sometimes stress urinary incontinence happens because the ring of muscle (the sphincter) that keeps the exit from the bladder closed has become weak.

Women who have stress urinary incontinence are usually offered non-surgical treatments at first, such as advice on losing weight and pelvic floor exercises. If these treatments don't help, a woman may be offered surgery.

There are different types of surgery for stress urinary incontinence. The type of surgery NICE has looked at involves what are known as biological slings. These are sections of tissue that are placed in the abdomen to give additional support to the bladder.

The sling may be made from the woman's own tissue, in which case it is called an autograft. It may be made from tissue from a human donor, in which case it's called an allograft. Or it can be made from animal tissue, in which case it's called a xenograft. Autografts are used most often.

To put the sling in place, small openings are made in the lower abdomen and the front of the vaginal wall. These openings are connected, and the sling is put through and positioned around the opening of the bladder to form a supportive hammock. There are different ways of putting the sling in position. The sling can be fixed by stitches to the front of the abdominal wall or it can be secured to the pubic bones using special surgical bone screws. Once the sling is in place, the surgeon may use a special viewing tube called a cystoscope to check that the bladder hasn't been damaged.

## How well the procedure works

### What the studies said

In two studies, one group of women had an allograft sling while the other group had an autograft sling. The incontinence improved in about three quarters of women in both groups and in both studies (the total number of women in these studies was 268). One of the studies reported that 89% (93/104) of women in the allograft group and 90% (237/30) of women in the autograft group were satisfied with the procedure and would have it again (89% means 89 out of 100 women).

Another study of long-term results found that 24 out of 26 women (92%) with allograft slings were continent 42 months after the procedure, and 19 out of 21 women (91%) with autograph slings were continent 35 months after the procedure.

In a study that followed what happened in 198 women who had autograft slings, the procedure was said to have been successful in about three quarters of the women when they were checked around 6 years later (142 out of 197 women, or 72%). Another study found that 75 out of 88 women (85%) were free from incontinence when they were checked more than 5 years after the surgery.

Another study compared what happened in women who had a xenograft sling and women who had a slightly different procedure that uses special tape inside the vagina to support the bladder. About the same number of women in each group had improved continence, and the groups were equally satisfied with the results of their procedure.

In another study of 139 women, 6 out of 48 women (13%) who had a xenograft sling needed another operation within the first 12 months because the procedure hadn't worked. There were no reports that the procedure had failed for women who had been given vaginal tape or autograft slings.

## What the experts said

The experts said that there are concerns about how long the benefits of the sling last.

## Risks and possible problems with the procedure

### What the studies said

The two most common problems that affected the women in the studies were urge incontinence and urinary retention. Urge incontinence is when you have a sudden and urgent need to pass urine (known as urgency), and urine leaks out before you can get to the toilet. Urinary retention is when you can't empty your bladder completely.

The number of women who had urge incontinence ranged from 5 out of 152 women in one study (3%) to 5 out of 10 women in another (50%). In one study, nearly all the women (232 out of 247, or 94%) had urinary retention for a short time. The number of women who had urinary retention for a longer time ranged from 1 out of 63 women (2%) in one study to 3 out of 30 women (10%) in another.

In one study, 1 woman out of 74 (1%) said she'd had severe pain after the procedure. In another study, 5 women out of 134 (4%) said they'd had persistent pain.

Other problems that affected the women in the studies included infection, the formation of a blood-filled swelling called a haematoma in the area, bleeding (haemorrhage), and narrowing of the urethra, which is the tube that carries urine out from the bladder.

## What the experts said

The experts said that the potential problems included blockage of the urethra and retention of urine, damage to the bladder, haemorrhage, infection and urgency. Also, using tissue from a human donor carries a possible extra risk of infection.

## What has NICE decided?

NICE has considered the evidence on the insertion of biological slings for stress urinary incontinence. It has recommended that when doctors use this procedure for women with stress urinary incontinence, they should be sure that:

- the woman understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has encouraged doctors to monitor women who have a biological sling inserted for a longer period after the operation than they might do otherwise. This is because, so far, there is only information on how well autologous slings work in the long term. Information is needed about all the types of sling.

Finally, NICE has said that doctors should make sure that women understand that the sling might be made of tissue from a human donor (that is, a dead person) or an animal. A woman should agree to this before the procedure is carried out.

## Other comments from NICE

The results of the procedure may depend on the type of sling used and the method used to put it in place.

The biological sling procedure is different from the procedure to insert vaginal tape, which is also used to treat stress urinary incontinence (see 'Further information').

## What the decision means for you

Your doctor may have offered you a biological sling procedure. NICE has considered this type of procedure because it is relatively new. NICE has decided that the procedure to insert a biological sling is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks before you agree to the procedure. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

You should also understand that sometimes the slings are made from tissue from a human donor or from animal tissue. If this type of sling is being used for you, your doctor should let you know and check that this is acceptable to you.

## 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.

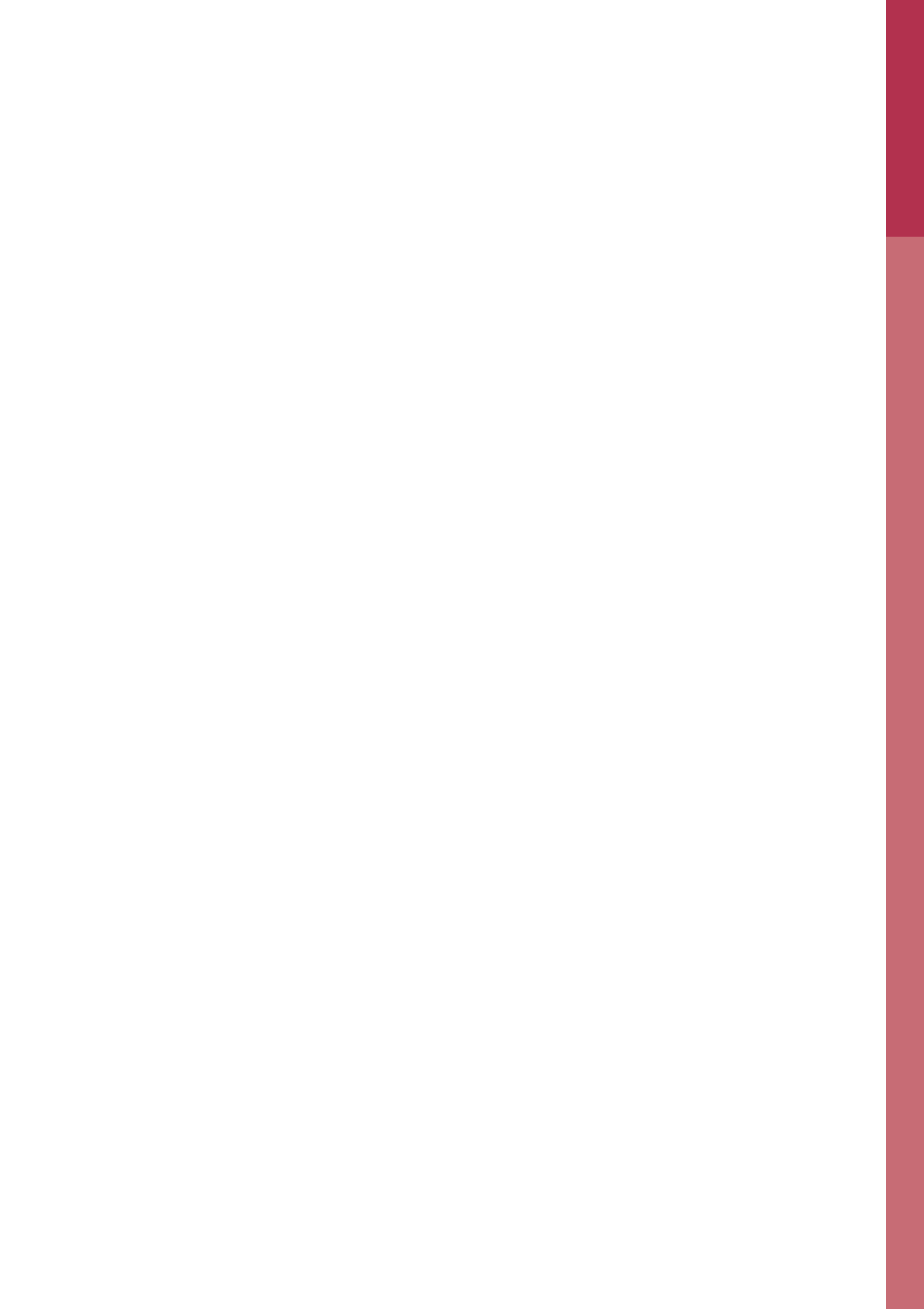
The NICE website ([www.nice.org.uk](http://www.nice.org.uk)) has further information about NICE, the Interventional Procedures Programme and the full guidance on the insertion of biological slings for stress urinary incontinence that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has also issued guidance on other procedures to help with urinary incontinence:

- tension-free vaginal tape insertion (this is being updated as part of a NICE clinical guideline – see [www.nice.org.uk/TA056](http://www.nice.org.uk/TA056) for more information)
- insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence ([www.nice.org.uk/IPG133publicinfo](http://www.nice.org.uk/IPG133publicinfo))
- intramural urethral bulking agents for stress urinary incontinence in women ([www.nice.org.uk/IPG138publicinfo](http://www.nice.org.uk/IPG138publicinfo)).

If you have access to the internet, you can find more information on incontinence on the NHS Direct website ([www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)).

You can also phone NHS Direct on 0845 46 47.





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