

Understanding NICE guidance

Information for people who use NHS services

Female sterilisation using implants (inserted through the vagina) to block the fallopian tubes

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

This leaflet is about when and how female sterilisation using implants inserted through the vagina to block the fallopian tubes can be used in the NHS. 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. 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.

This leaflet is written to help women who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe sterilisation 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 the back page.

What has NICE said?

This procedure can be offered routinely to women provided that doctors are sure that:

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

If a doctor wants to use this procedure, he or she should explain that another method of birth control should be used until tests have shown that the fallopian tubes have been blocked, and that there will still be a small risk of pregnancy even after the fallopian tubes have been blocked. This should happen before the woman agrees (or doesn't agree) to the procedure. The woman should be given this leaflet and other written information as part of the discussion.

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

Female sterilisation using implants (inserted through the vagina) to block the fallopian tubes

The medical name for this procedure is 'hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants'. The procedure is not described in detail here – please talk to your doctor for a full description.

The aim of female sterilisation is to prevent pregnancy by blocking the fallopian tubes. This stops sperm reaching the egg and fertilising it. Female sterilisation is usually permanent.

The usual procedures for blocking the fallopian tubes involve clips or rings being inserted through a small opening in the abdomen or by keyhole surgery. In this procedure implants are inserted through the vagina so there is no need to make a cut in the abdomen.

Before the procedure the woman is usually offered a local anaesthetic or sedation. An instrument called a hysteroscope is passed through the vagina and cervix and two small implants called microinserts are placed into the fallopian tubes. Sometimes a thin layer of cells is removed from the fallopian tubes. The implants cause scar tissue to form in the fallopian tubes, which eventually blocks them. Another method of birth control needs to be used until a test has shown that the implants are in place or that the fallopian tubes are blocked.

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 14 studies on this procedure.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks female sterilisation using implants to block the fallopian tubes is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks, including the risk of pregnancy, before asking you to agree to it. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- 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 procedure?
- What happens if something goes wrong?

How well does the procedure work?

In seven studies involving a total of 2582 women, both implants were inserted successfully in 95% (2441 out of 2582) of the women. Tests done 3 months after the procedure showed that the fallopian tubes were blocked in 96% (2272 out of 2383) of the women. In another 19 women the fallopian tubes were blocked after 6 months.

In a study of 645 women, there were no pregnancies in 99% (639 out of 645 women) of the women whose fallopian tubes were blocked at 3 months and who were followed up for 1 year after that. Another study of 1630 women reported 3 pregnancies, all in the first 3 months after the procedure.

In a study of 1630 women, 94% (1516 out of 1612) said they were 'very satisfied' with the procedure and 6% (96 out of 1612) said they were 'somewhat satisfied'.

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 main success factors are correct placement of the implants, for the implants to remain in position 3 months after the procedure and long-term prevention of pregnancy.

Risks and possible problems

In the study of 645 women, an egg became fertilised and began to grow outside the womb (ectopic pregnancy) in 1 woman. The pregnancy was stopped successfully with drug treatment.

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

In three studies involving a total of 2364 women, there were problems with implant placement, including movement of implants after insertion, in 2% (41 out of 2349) of the women. Three studies involving a total of 846 women reported 12 instances of tearing of the uterus or fallopian tubes.

In the study of 645 women, 68% (436 out of 645) had spotting and 28% (183 out of 645) had bleeding for an average of 3 days after the procedure. In the study of 507 women, 30% had cramps and 13% had pain after the procedure, and 19% had bleeding for up to 7 days afterwards. Pain after the procedure was reported by 79% (60 out of 76) of women in a study of 112 women and 8% (6 out of 76 women) described the pain as severe.

Five studies involved a total of 8 women who had to have the implants removed between 6 days and 3 years after the procedure because of pain.

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 are tearing of the uterus or fallopian tubes, infection, movement of the implants, fainting and pelvic pain.

More information about female sterilisation

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.

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

This leaflet is about 'hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IIPG315

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1994). 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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ISBN 978-1-84936-081-4
N1994 1P Sep 09