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Interstitial laser therapy for fibroadenomas of the breast

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/IPG131

- 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:

- N0865 (full guidance)
- N0868 (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 within the NHS. This guidance covers England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called interstitial laser therapy for fibroadenomas of the breast. 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 interstitial laser therapy is safe enough and works well enough for it to be used routinely for the treatment of fibroadenomas of the breast.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of interstitial laser therapy for fibroadenomas of the breast and how well it works
- 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 interstitial laser therapy for breast fibroadenomas

Fibroadenomas are non-cancerous (benign) solid lumps. Fibroadenomas in the breast are very common, mostly affecting young women. Some fibroadenomas get smaller with time, and some disappear altogether. The guidance NICE has issued covers situations when this doesn't happen.

Usually, once the lump has been diagnosed as a fibroadenoma, the woman and doctor agree to take no further action but to keep a check on it. If the fibroadenoma doesn't go away or gets bigger, or if the woman particularly wants it to be removed, surgery may be carried out. A general anaesthetic is needed, and the breast tissue is opened up so the lump can be removed.

The new procedure NICE has looked at, which is called interstitial laser therapy, uses high-energy light from a laser to destroy the lump. In this procedure, it is not necessary to make an opening in the breast. So scarring should be minimal and there should be less chance of infection.

The woman has a local anaesthetic to numb the area, and then a needle is inserted into the lump. The doctor uses ultrasound images for guidance. A laser fibre is passed through the tip of the needle so that it sticks out a little. The laser is then turned on so that the energy is delivered to the lump for a few minutes. If the woman has a larger lump, several needles and laser fibres are used.

How well the procedure works

What the studies said

In a study that followed what happened in 24 women, the women's lumps got smaller after the laser treatment: the lumps went from an average length of 25 mm before treatment to 14 mm after 3 months, and to 10 mm after 6 months. By 12 months they had gone.

In a second study, the lumps were smaller 8 weeks after the women had had the laser treatment. Statistical tests showed that this was a 'true' improvement that was unlikely to have happened by chance. But in the 27 women in this study, 10 still had a lump bigger than 10 mm across at the 8-week check.

What the experts said

The experts pointed out that because a sample of the lump isn't removed during the laser treatment, it's not possible to confirm that the lump is benign. During the standard operation, a sample can be removed and checked in the laboratory (this is called a biopsy).

Risks and possible problems with the procedure

What the studies said

In one of the studies, 20 out of 24 women said they felt some discomfort during the treatment. Four women had severe pain that meant the treatment had to be stopped. All the women said the area felt tender for 1 to 8 weeks after the treatment, and this was also the case in the study involving 27 women.

In the study involving 27 women, the laser treatment was seen to be affecting the skin in eight women. When they were checked on 8 weeks later, these women had patches of darker skin in the areas that had been treated.

In the other study, four out of 24 women had bruising that disappeared within a week.

What the experts said

The experts said that there were reports of burns at the place where the needle was inserted. It was also possible that the area could become infected or that bleeding might happen if the needle hit a blood vessel.

What has NICE decided?

NICE has decided that, if a doctor wants to carry out interstitial laser therapy for fibroadenomas of the breast, he or she 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. In particular, it should be explained that a fibroadenoma of the breast is not breast cancer, and that one option is to take no further action except to keep an eye on the lump. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

Interstitial laser therapy for fibroadenoma of the breast should be carried out by doctors working within specialist breast services.

NICE may look at the procedure again if more results from studies are published.

Other comments from NICE

Not all doctors do this procedure in the same way, and the differences in technique might make some more likely to be successful than others.

What the decision means for you

Your doctor may have offered you interstitial laser therapy for a fibroadenoma in your breast. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of interstitial laser therapy which you need to understand before you agree to it. Your doctor should discuss the benefits and risks with you, together with your options, which may include just keeping a check on the lump. It should be explained to you that a fibroadenoma is not a cancer. Some of the benefits and risks of laser therapy may be described above.

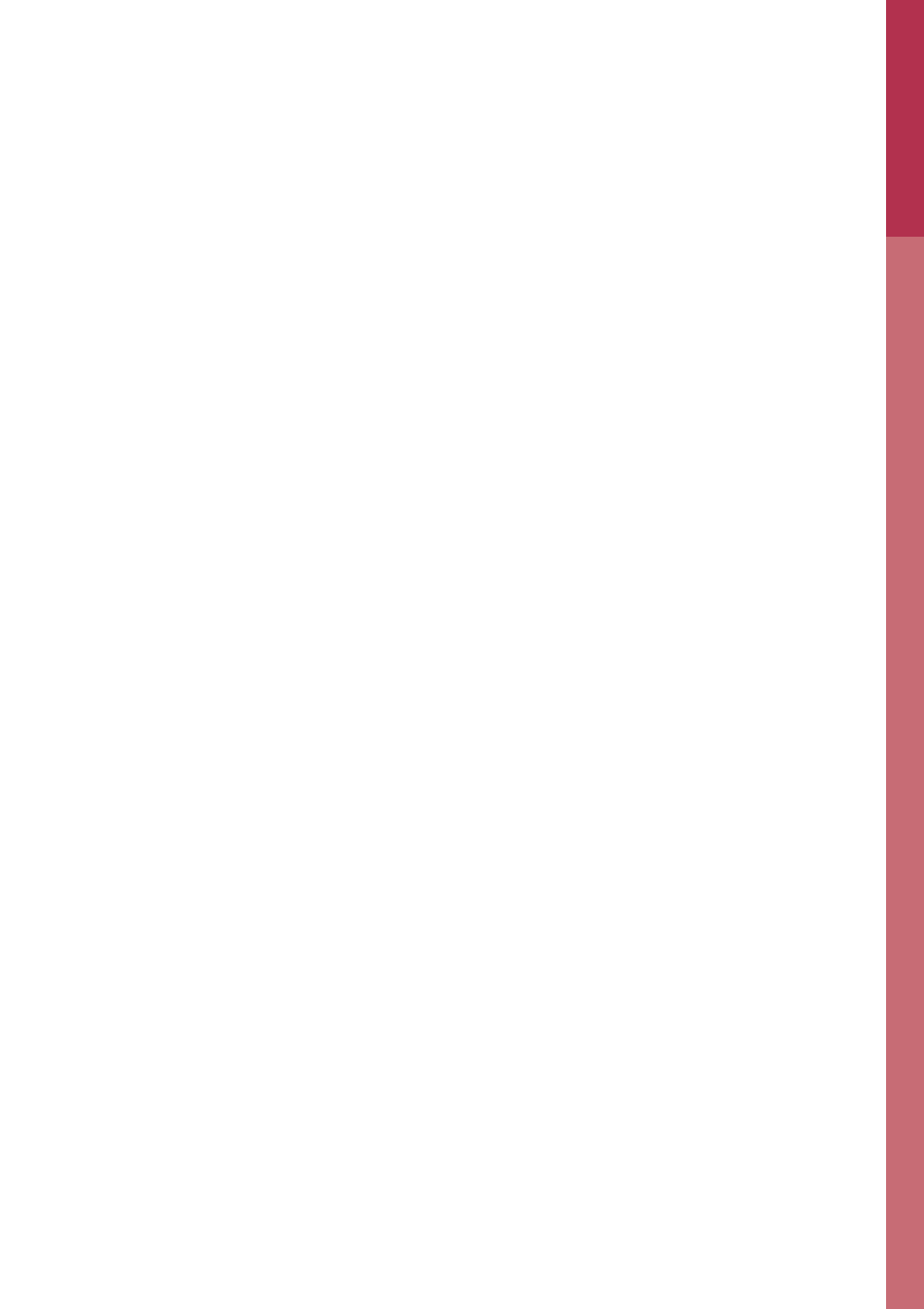
Further information

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) has further information about NICE, the Interventional Procedures Programme and the full guidance on interstitial laser therapy for fibroadenomas of the breast that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on breast lumps on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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