

Laser sheath removal of pacing leads

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

June 2004



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197

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Contents

About this information	4
About laser sheath removal of pacing leads	5
What has NICE decided?	8
What the decision means for you	9
Further information	10

About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called laser sheath removal of pacing leads. 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 laser sheath removal of pacing leads 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 laser sheath removal of pacing leads 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 laser sheath removal of pacing leads

A pacemaker is a device that's implanted under the skin to help the heart beat normally. It's connected to the heart with leads, which are placed in the blood vessels that take blood away from the heart (the veins). After a few months, scar tissue can build up around the leads and make them adhere to the sides of the veins and the heart.

If the pacemaker isn't working properly, it's causing problems with the heart, or if there's an infection, the leads need to be removed. This is more difficult and risky if there is scar tissue attaching them to the veins and heart.

Laser sheath removal involves placing a special tube (sheath) over the leads in the veins and then moving it along them towards the heart. The tube has two layers. The inside layer uses a laser beam to destroy the scar tissue around the leads, while the outside layer is more rigid. As the tube gets near to the heart, the outer layer is moved up and is used to pull the pacemaker lead away from the heart. Laser sheath removal may also be used to remove the leads from a defibrillator, which is a piece of equipment that stops the heart beating too fast.

The standard way of removing pacemaker leads is to separate them from the scar tissue manually. A tube is put around the leads, and narrow probes are used to lock the arrangement into place. The tube is designed like a telescope and as it's pushed out and made longer, it tears the scar tissue and releases the leads. If this doesn't work, the patient may have to have major surgery through an opening in the chest. Sometimes, the leads are just disconnected from the pacemaker unit and left in place.

How well it works

What the studies said

In the studies that looked at how well laser sheath removal worked, the leads were removed completely in most people (the best result was that the procedure was nearly 100% successful, while the worst result was that the leads were completely removed in nearly nine out of ten cases). The results of a study that compared people who had laser removal with people who had the standard method were:

- 230 out of 244 leads were removed using the laser method (as a percentage, this is 94%)
- 142 out of 221 leads were removed completely using the standard method (as a percentage, this is 64%).

This study also showed that the laser method was faster than the standard method. On average, it took 11 minutes to remove a lead using the laser method, while it took 15 minutes without a laser.

What the experts said

The experts thought that the laser procedure worked as well as the standard procedure, probably better.

Risks and possible problems

What the studies said

In one of the studies, 3 out of 153 patients who had laser removal needed another operation afterwards. In another study that followed what happened in 1684 patients, 31 patients had a serious problem after the procedure and 13 patients died in hospital. The serious problems were cardiac tamponade (which is where fluid builds up around the heart and stops it from beating normally), haemothorax (bleeding into the space around a lung), a blood clot on the lungs (pulmonary embolism), and movement of the leads.

What the experts said

The experts thought that the problems that could happen with the laser method of removing leads would be similar to those that happen with the standard method of taking the leads out. They said that cardiac tamponade was a particular risk if one of the main veins or the heart was damaged during the procedure. This would be very serious and the patient would need an operation at once to save their life.

What has NICE decided?

NICE has considered the evidence on laser sheath removal of pacing leads. It has recommended that the laser sheath method of removing pacing leads should be used only if the standard methods of removing the leads don't work. When doctors use it, they should be sure that:

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

Other comments from NICE

There's a risk of serious problems when pacing leads are removed, regardless of which method is used. Having one of these problems may mean that a patient would need a life-saving operation.

What the decision means for you

Your doctor may have offered you laser sheath removal of pacing leads. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of laser sheath removal of pacing leads before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these benefits and risks 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.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on laser sheath removal of pacing leads is on the NICE website (www.nice.org.uk/IPG063guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0588. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on heart problems and pacemakers, a good starting point would be NHS Direct (telephone 0845 4647) or NHS Direct Online (www.nhsdirect.nhs.uk).

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