

# Laser sheath removal of pacing leads

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg63](http://www.nice.org.uk/guidance/ipg63)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# 1 Guidance

- 1.1 Current evidence on the safety and efficacy of laser sheath removal of pacing leads appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Laser sheath removal of pacing leads should be used only in patients for whom standard methods of removal are ineffective.

## 2 The procedure

### 2.1 Indications

- 2.1.1 This procedure is used to remove pacemaker leads that have been in place for a few months. Pacemaker leads may need to be removed or changed if they malfunction, cause heart rhythm problems or become infected. If the leads have been in place for more than a few months they can become tightly attached by scar tissue to the heart and to the veins through which they pass, making removal difficult and risky. This procedure may also be used to remove defibrillator leads.
- 2.1.2 The conventional technique for removing pacing leads involves inserting locking stylets and telescoping sheaths around the pacing leads to separate them from the surrounding scar tissue. If this fails, open chest surgery may be required. Alternatively, in some cases, the leads may be detached from the pacemaker unit and simply left inside the patient.

## 2.2 Outline of the procedure

- 2.2.1 Laser sheaths are similar to standard extraction sheaths, but vaporise rather than tear the scar tissue surrounding the pacing leads. The use of laser sheaths involves passing a double-layered sheath over the pacing leads. The inner layer of the sheath is made from fibre-optic material that transmits a laser beam; the outer layer is more rigid. The double-layered sheath is passed slowly over the lead and laser energy vaporises the scar tissue around the lead as the sheath is advanced over it. When scar tissue has been vaporised up to a point near the heart, the more rigid outer sheath is advanced to provide countertraction for removal of the pacing lead.

## 2.3 Efficacy

- 2.3.1 In the studies reviewed, complete lead removal ranged from 89% (596 out of 671 leads) to 98% (44 out of 45 leads). In a randomised controlled trial, complete lead removal was 94% (230 out of 244 leads) for patients in the laser group and 64% (142 out of 221 leads) for patients in the non-laser group. In the same study, mean operation time per lead was 11 minutes in the laser group compared with 15 minutes in the non-laser group ( $p < 0.04$ ). For more details, see the [overview](#).
- 2.3.2 The Specialist Advisors had no concerns about the efficacy of this procedure. They considered it to be at least as efficacious as, and probably more efficacious than, standard techniques.

## 2.4 Safety

- 2.4.1 In a randomised controlled trial, 3 of 153 patients randomised to laser sheath removal required subsequent surgery (two patients required a thoracotomy and one patient required a chest tube). One patient later died after a cardiac tamponade, but this was not directly related to the use of laser energy. In the largest case series, major complications (defined as cardiac tamponade, haemothorax, pulmonary embolism, lead migration and death) were observed in 2% (31 out of 1,684) of patients, and 1% (13 out of 1,684) of patients died in

hospital. For more details, see the [overview](#).

- 2.4.2 The Specialist Advisors considered the complications of laser sheath removal of pacing leads to be similar to those of standard extraction techniques. They commented on the small risk of cardiac tamponade caused by rupture of major veins or the myocardium, and noted that this could result in the need for emergency surgery and, in some cases, cause death.

## 2.5 Other comments

- 2.5.1 Removal of pacing leads can cause serious complications, requiring cardiac surgery, regardless of the extraction technique used.

# 3 Further information

## Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

## Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).