

# National Institute for Health and Clinical Excellence

918 – Percutaneous laser atherectomy for peripheral arterial disease

## Consultation Comments table

IPAC date: 12 January 2012

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Royal College of Radiologists	1	The BSIR has reviewed and approved this consultation document and is satisfied that it adequately reflects the input of the Society. The BSIR is therefore happy to approve the consultation document without further comment. This response is endorsed by the Faculty of Clinical Radiology, The Royal College of Radiologists (RCR), and is submitted by the RCR on behalf of both organisations.	Thank you for your comment.

<b>Com . no.</b>	<b>Consultee name and organisation</b>	<b>Sec. no.</b>	<b>Comments</b>	<b>Response</b> Please respond to all comments
2	Consultee 2  Manufacturer Spectranectics Corporation	1.1	1.1 – Although current evidence of efficacy of percutaneous laser atherectomy, in relationship to underdescribed technical indications in published literature, as a debulking tool, laser atherectomy is widely accepted as precursor treatment to balloon PTA and stenting. The technology has demonstrated its ability to remove atheroma and improve vessel wall compliance assisting dilatation and/or stent apposition. The need for specific device training, informing Trusts, team review of treatment plans and patient informed consent processes are reasonable but should also allow for trained Interventional Cardiologists, Angiologists and other Endovascular specialists to perform procedures and participate in team review/audit of care plans.	Thank you for your comment. A revised consultation document was issued following further work on the guidance which included: That the procedure should be detailed as adjunctive to balloon angioplasty (with or without stenting). The guidance recommends that the intervention is carried out by a multidisciplinary team with the necessary skills and training.
3	Consultee 3 Secretary Vascular Society	1	The Vascular Society is in agreement with these recommendations. The results of laser atherectomy have been dissapointing to date but we are aware that the technology continues to develop.	Thank you for your comment.

<b>Com . no.</b>	<b>Consultee name and organisation</b>	<b>Sec. no.</b>	<b>Comments</b>	<b>Response</b> Please respond to all comments
4	Consultee 4 Specialist Adviser	<b>1</b>	The potential indications should be added: 1- Failed wire crossing (step-by-step technique, see publication on this by Steinkamp) 2- Failed balloon crossing (after successful wire crossing) 3- Failed balloon inflation/recoil (laser used for plaque modification/debulking) 4- Debulking for in-stent restenosis and occlusion	Thank you for your comment. The indication for this intervention is peripheral arterial disease and the procedure is used as an adjunct to balloon angioplasty (with or without stenting). The detail suggested by the consultee is beyond the scope of this guidance.
5	Consultee 3 Secretary Vascular Society	<b>2.1</b>	Agreed	Thank you for your comment.
6	Consultee 4 Specialist Adviser	<b>2.1.2</b>	2.1.2 Endovascular procedures are preferred because of the lower morbidity and mortality rates. In a contemporary series 30-day mortality of bypass procedure is 2.7% and morbidity 17.6% (Conte MS, Bandyk DF, Clowes AW, Moneta GL, Seely L, Lorenz TJ, et al. Results of PREVENT III: a multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery. J Vasc Surg 2006;43:742-51 discussion 751.)	Thank you for your comment. Section 2.1.2 is a brief description of the current treatments for peripheral arterial disease. The list of current treatments and alternatives is not intended to be definitive or make judgements on the efficacy of those alternative management options. This paper was not included in the overview.
7	Consultee 3 Secretary Vascular Society	<b>2.2</b>	Agreed	Thank you for your comment.

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
8	Consultee 4 Specialist Adviser	2.2	<p>The non-randomised controlled study of 67 patients with critical limb ischaemia (CLI) in diabetic patients reported patency rates (freedom from target lesion revascularisation) of 96.6% at 12 months and 82.7% at 24 months. Limb-salvage rate at 12 and 24 months were 100% and 94%, respectively. Abstract: Excimer Laser Ablation in the Treatment of Total Chronic Obstructions in Critical Limb Ischaemia in Diabetic Patients. Sustained Efficacy of Plaque Recanalisation in Mid-term Results* 2009 European Society for Vascular Surgery. F. Serino a,* , Y. Caoa, C. Renzi c, L. Mascellari a, F. Toscanella d, D. Raskovic d, P. Tempesta b, G. Bandiera a, A. Santini b Department of Vascular Surgery, Istituto Dermopatico dell’Immacolata, IRCCS, Rome, Italy</p> <p>2. Paper: Mid-term results with laser atherectomy in the treatment of infrainguinal occlusive disease. J Vasc Surg 200746:289-95 Michael C. Stoner, MD, Dorian J. deFreitas, MD, Sachin V. Phade, MD, Frank M. Parker, DO, William M. Bogey, MD, and Steve Powell, MD, Greenville, NC</p>	<p>Thank you for your comment. A revised consultation document was issued following further work on the guidance which included:</p> <p>Reference 1: The Committee added this paper to Appendix A.</p> <p>Reference 2: The Committee added this paper to Table 2.</p>

<b>Com . no.</b>	<b>Consultee name and organisation</b>	<b>Sec. no.</b>	<b>Comments</b>	<b>Response</b> Please respond to all comments
9	Consultee 2 Manufacturer Spectranectics Corporation	<b>2.3</b>	These study findings and statements support the efficacy of percutaneous laser atherectomy as a precursor treatment to balloon PTA and stenting. The technology demonstrates its ability to effectively remove atheroma and improve vessel wall compliance assisting dilatation and/or stent apposition. It is acknowledged that adjunctive balloon dilatation and/or stenting typically follow debulking procedures.	Thank you for your comment. A revised consultation document was issued following further work on the guidance which included: That the procedure should be detailed as adjunctive to balloon angioplasty (with or without stenting). The committee considered the evidence on efficacy and safety sufficient to receive normal arrangements.
10	Consultee 3 Secretary Vascular Society	<b>2.3</b>	Agreed	Thank you for your comment.
11	Consultee 2  Manufacturer Spectranectics Corporation	<b>2.4</b>	These study findings and statements support the safety of percutaneous laser atherectomy as a precursor treatment to balloon PTA and stenting. The technology demonstrates its ability to safely remove atheroma and improve vessel wall compliance assisting dilatation and/or stent apposition.	Thank you for your comment. Please see response comment from consultee 2 at 2.3 above.
12	Consultee 3 Secretary Vascular Society	<b>2.4</b>	Agreed	Thank you for your comment.
13	Consultee 3 Secretary Vascular Society	<b>2.5</b>	Agreed. See comments on section 1.	Thank you for your comment.

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
14	Consultee 4 Specialist Adviser	<b>General</b>	I have training and experience using the Excimer laser atherectomy device for peripheral vascular disease.	Thank you for your comment.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*