

# National Institute for Health and Clinical Excellence

## 1022 – Irreversible electroporation for treating primary lung cancer and metastases in the lung

### Consultation Comments table

IPAC date: 13 December 2012

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Galil Medical manufacturer	1	Agree. The data for this treatment has not matured enough to evaluate this treatment for normal arrangements.	Thank you for your comment.
2	Consultee 1 Galil Medical manufacturer	2.1.2	The long term outcome data for IRE does not exist and therefore we disagree that because IRE is non-thermal, IRE has been shown to have minimal damage to surrounding structures when compared to other thermal ablation techniques.	Thank you for your comment.  Section 2.1.2 of the Guidance has been changed.

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3	Consultee 1  Galil Medical  manufacturer	<b>2.3</b>	We agree with NICE that both quality and quantity of data is lacking at this point. We also agree with the Specialist Advisors who have acknowledged that there is very little data available for IRE and particularly specific data for the treatment of lung tumours. The current studies are small in size with only short term outcomes.	Thank you for your comment.
4	Consultee 1  Galil Medical  manufacturer	<b>2.4</b>	The most serious of complications or side effects with IRE are the cardiac arrhythmias and grand mal seizure. We believe the safety concerns related to this procedure should be explored further and taken very seriously. More experience with this new technology is needed with results being reported in a peer reviewed journal or registry. Early indications are that the safety of this procedure is questionable.	Thank you for your comment.  The current lack of evidence on efficacy and safety for this procedure is acknowledged in the guidance.

5	<p>Consultee 1</p> <p>Galil Medical manufacturer</p>	<b>2.5</b>	<p>Since different tumor tissue types react differently to ablative techniques, NICE should consider only IRE data specific to lung for this guidance document. We disagree that the IRE procedure may cause less damage to surrounding structures than other types of ablative treatment for lung cancer and there is not the available data to justify this claim.</p>	<p>Thank you for your comment.</p> <p>The Guidance only included studies where safety and efficacy findings for at least 1 patient treated with IRE for lung tumours were reported.</p> <p>Section 2.5.2 of the Guidance reports the Committees view that more evidence is needed to support the claim that IRE might cause less damage to surrounding structures than other ablative techniques.</p>
6	<p>Consultee 2</p> <p>Royal College of Physicians</p>	<b>general</b>	<p>The NCRI/RCP/RCR/ACP/JCCO agree with the conclusion that this procedure should not be used outside the research setting.</p>	<p>Thank you for your comment.</p>