NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

MTG Review Decision

Review of MTG11: Mega Soft Patient Return Electrode for use during monopolar electrosurgery

This guidance was issued in August 2012.

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

1. Recommendation

Transfer the guidance to the static list

A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper.

2. Original objective of guidance

To evaluate the case for adoption of the Mega Soft Patient Return Electrode for use during monopolar electrosurgery.

3. Current guidance

1.1 The use of the Mega Soft Patient Return Electrode during monopolar electrosurgery may offer advantages for selected patients: for example, those who would need shaving before the application of adhesive electrode pads and those with fragile or damaged skin.

1.2 It is plausible that the Mega Soft Patient Return Electrode reduces the risk of burns related to the diathermy patient return electrode where surgery is carried out in the context of good operating theatre practice. The published clinical evidence comparing the Mega Soft Patient Return Electrode against disposable single-use patient return electrodes for use during monopolar electrosurgery is limited, but there have been no reports of burns as a result of its use in the UK.

1.3 There may be system benefits for operating theatre staff using the Mega Soft Patient Return Electrode in terms of increased convenience and reduced setting up time. These benefits are more likely to be realised for inpatient operating lists than for day case surgery, and do not appear to lead to a significant reduction in resource utilisation. The economic evidence and cost modelling demonstrate near equivalent resource use to current practice.

1.4 Clinicians and managers considering the adoption of the Mega Soft Patient Return Electrode should therefore, in judging the likely benefits, take into account current practice in their operating theatres with regard to prevention of alternative site burns and the proportion of inpatient operations for which it would be used.

4. Rationale

No new information which would change the recommendations was identified from studies published since the guidance was issued, expert advice, updated cost modelling or care pathway changes. There have been only minor changes to the technology.

5. Implications for other guidance producing programmes

No comments were received from other guidance producing programmes or implications for other guidance producing programmes identified, during this review.

6. New evidence

The search strategy from the original assessment report was re-run, references from 2011 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below.

6.1 Technology availability and changes

The company has stated that a new version of the technology, Mega Soft Universal, is available and that the original Mega Soft is still sold in the UK. The Mega Soft Universal has the same technical specification as Mega Soft but differs with respect to its size, weight, and pressure reduction capacity: Mega Soft Universal is smaller and lighter, has a lower minimum patient weight at 350g compared to 11kg, but has a lower pressure reduction

capacity. Mega Soft Universal costs £2500, Mega Soft (Adult) £2000, and Mega Soft (Paediatric) £2950. The company name has been amended for factual accuracy.

6.2 Clinical practice

Two expert advisers have indicated that there has been no significant changes to the care pathway since the guidance was produced. The technology would still be used instead of a disposable patient return electrode during monopolar surgery.

6.3 NICE facilitated research

No research has been commissioned by NICE on this technology.

6.4 New studies

The evidence searches identified 1 new study by Liodaki et al (2013). This is an observational study reporting on the authors' overall experience of using the device in 67 patients admitted to a burns unit in Germany over a year. They note that no additional burns were identified on the patients' body as a result of the use of the device, and that its use quickens electrosurgery procedures which is particularly beneficial to patients with burns because they are more susceptible to hypothermia due to skin loss and damage. In addition the authors considered that the placement of the device beneath the patient is advantageous because it avoids the difficulty of placing electrodes on the skin of a patient with burns. They conclude that their positive experiences supports it use in other burns units.

6.5 Updates to cost modelling

An External Assessment Centre updated the cost model to reflect present day values for staff, consumable, and technology costs with little overall difference in the base case results. These are shown in Table 1 below:

Table 1, reproduced from Table 3.1 in the updated costings produced by the EAC

Cost Element	2012				2017			
	Adult		Infant		Adult		Infant	
	No lead wire	With lead wire	No lead wire	With lead wire	No lead wire	With lead wire	No lead wire	With lead wire
Mega Soft Patient Return Electrode								
Cost	£1.93		£1.93		£2.03		£2.54	
Diathermy pathway								
Pads	£0.76	£1.92	£0.68	£5.91	£2.02	£1.76	NA	£4.84

Reusable cable	£0.22		£0.22		£0.32		£0.32	
Band 3 to affix cable	£0.11		£0.11		£0.12		£0.12	
Mattress	£0.33	£0.33	£0.33	£0.33	£0.33	£0.33	£0.33	£0.33
Shave	£0.63	£0.63	£0.00	£0.00	£0.63	£0.63	£0.00	£0.00
Total cost	£2.05	£2.88	£1.34	£6.24	£3.42	£2.72	NA	£5.17
Savings with Mega Soft*	£0.12	£0.95	-£0.59	£4.31	£1.39	£0.69	NA	£2.63
NA = Not available. *A positive value indicates a saving with Mega Soft; a negative value indicates a higher cost with Mega Soft. Numbers may not add precisely due to rounding.								

7. Summary of new evidence and implications for review

The new evidence supports the recommendation that the technology is useful in burns. No evidence was identified that has a material impact on the recommendations.

8. Implementation

The UK distributor has stated that the technology is currently used in 21 hospitals in the English NHS, and in some of those it is used in every theatre. Of the 2 experts from whom advice was sought, 1 uses the device and 1 would like to but it is not available in their trust.

9. Equality issues

The guidance equality impact assessment noted that the technology was considered to have particular advantages for people where cultural sensitivities exist surrounding the shaving of body hair, and for those with fragile or damaged skin which includes patients with burns, patients with skin conditions, paediatric patients and older patients.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	*No*
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	*No*
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	*No*
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	*No*

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

References

Liodaki E, Stang F, Lohmeyer J, et al. (2013) Noncontact electrosurgical grounding – A useful and safe tool in the initial surgical management of thermal injuries, Burns, Volume 39, Issue 1, 2013, Pages 142-145, ISSN 0305-4179, https://doi.org/10.1016/j.burns.2012.05.017

Consultation Comments table

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	1. National Institute for Health and Care Excellence	General	The adoption team at NICE has not undertaken any work on this topic and is unaware of any issues in its use.	Thank you for your comment
2	2. Department of Health & Social Care	General	I wish to confirm that the Department of Health and Social Care has no substantive comments to make, regarding this consultation.	Thank you for your comment
3	3. Johnson & Johnson Medical Limited	General	Johnson & Johnson Medical is fully supportive of the decision by NICE not to review at this time, and to keep the guidance 'live' to support further NHS adoption.	Thank you for your comment
4	3. Johnson & Johnson Medical Limited	General	Please could the Guidance be updated to reflect the company change since 2012. Manufacturer details should be 'Megadyne, Johnson & Johnson Medical Ltd'. Many thanks.	Thank you for your comment. The guidance will be updated to reflect the change in company name.

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