NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

SCOPE

Mega Soft Patient Return Electrode for use during monopolar electrosurgery

1 Technology

1.1 Description of the technology

The Mega Soft Patient Return Electrode (Megadyne Medical Products Inc.) is intended for use during monopolar electrosurgery, specifically to reduce the risk of burns and to provide pressure relief.

The Mega Soft Patient Return Electrode conducts high frequency electrical current from the target tissue to an electrosurgical unit, or generator. The electrical circuit includes the electrosurgical unit, the active electrode, and the patient's tissues. Once the electrical current is applied to the target tissue, it is distributed widely throughout the body and then returns to the electrosurgical unit via a dispersive patient return (grounding) electrode.

In current NHS clinical practice, a patient return electrode is attached directly to the patient’s body using a sticky pad whereas the Mega Soft Patient Return Electrode is incorporated into a padded layer on which the patient lies during surgery. It is also claimed that the pad acts as a pressure-relieving device.

The Mega Soft Patient Return Electrode is made of a layer of conductive material between two sheets of urethane and sealed between two asymmetrical layers of a viscoelastic polymer called Akton. The conductive layer is connected to a standard monopolar electrosurgical unit via a proprietary cable (‘DetachaCable’) which is insulated and attaches deep inside the device in order to prevent burns to the patient or user.

The adult size device extends to at least half the length and the full width of a typical patient torso with a pad size of approximately 117cm x 51cm x 1.25cm. The paediatric size device is approximately 66cm x 30.5cm x 1.3cm and is intended for patients weighing between 0.4kg and 22.7kg.

Complete electrical contact is achieved with the patient lying on the device.

1.2 Regulatory status

The Mega Soft Patient Return Electrode received a CE mark in April 2003 with indications to reduce the risk of burns and to provide pressure relief during monopolar electrosurgery.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- A reduction in burns in patients undergoing monopolar electrosurgical procedures.
- The avoidance of skin shaving for the device to be effective.
- A reduction in skin irritation since Mega Soft does not need to be attached directly to the patient's skin.
- Particular applicability to patients with burns or other skin conditions as well as to paediatric and older patients with fragile skin.
- A reduction in the risk of pressure related injury due to immobility during surgery.

The benefits to the health care system claimed by the manufacturer are:

- A reduction in staff time given that the patient is placed on the Mega Soft pad and there is no need to attach a single use sticky pad to the patient which means the clinician does not actively have to avoid bony prominences, scar tissue and tattoos.
- A reduction in the need for treatment and litigation costs associated with burns.

- Cost saving and improved sustainability as compared with current practice due to the fact that the Mega Soft Patient Return Electrode is re-usable and because a separate pressure-relieving device may not be required.

1.4 Relevant diseases and conditions

In the UK during 2009/10 approximately 9.7 million inpatient surgical procedures were undertaken. It has been estimated that 2.81 million (29% of the total) involved general anaesthesia and lasted for more than 30 minutes. Based on conservative estimates that monopolar electrosurgery is used in a minimum of half of all surgical procedures, the Mega Soft Patient Return Electrode could be used in at least 1.4 million procedures each year in the UK.

Burns occur as a complication of electrosurgery caused by the improper application of the return electrode. Such burns result from a failure of energy dispersion through the return electrode and account for two-thirds of all electrosurgical accidents.

In current NHS clinical practice, a patient return electrode is attached directly to the patient's skin using a 'sticky' pad. This may require the shaving of skin and can cause skin irritation that may persist during post-operative recovery. Other possible skin complications problems include hypersensitivity and the denuding of dermis at the time of pad removal.

1.5 Current management

Current practice during monopolar electrosurgery involves the application to the skin of a single use return electrode. Standard electrodes comprise a conductive foil that is covered by a polymer and a sticky surface that allows for skin adherence. The electrode pad must be large enough to keep the temperature low as the electrical energy exits from the patient. A rise in skin temperature and a risk of burning occurs if there is impedance to electrical conduction at the skin to pad interface. Excessive impedance may be caused by body hair, adipose tissue, bony prominences, fluid invasion, adhesive failure, scar tissue and a reduced patient return electrode contact area. To

prevent this occurring, pads need to be strategically placed to avoid bony prominences and should be placed on hair free areas of the body. This may require preliminary skin shaving.

2 Reasons for developing guidance on Mega Soft Patient Return Electrode for use during monopolar electrosurgery

The Committee considered that the Mega Soft Patient Return Electrode may offer patient and system benefits compared to current practice.

- The Committee considered that the risk of patient burns may be reduced during monopolar electrosurgery by using the Mega Soft Patient Return Electrode.
- The Committee recognised that the reusability of the Mega Soft Patient Return Electrode gives the potential for cost savings and improved sustainability as compared to single use disposable return electrodes.
- The Committee considered that the Mega Soft Patient Return Electrode may be of particular value in patients with extensive skin burns, skin conditions and those with fragile skin.
- The Committee recognised that the Mega Soft Patient Return Electrode may offer system benefits through the saving of staff time. Skin preparation is not required and the pad can remain on the operating table between patients (with the usual hygiene precautions) and does not require strategic placement.
- The Committee noted that some surgical patients are susceptible to post-operative pressure ulcers and that the Mega Soft Patient Return Electrode may serve an additional function as a pressure-relieving device.

The Committee suggested that the following technical issues should be considered and be used to support the development of associated NICE Implementation tools:

- The manufacturer states that the Mega Soft Patient Return Electrode is a self-contained current limiting device making it safe to use if the patient is in contact with only a small portion of the pad. Clarification is required regarding the minimal contact area between the patient and the pad before safety is compromised.
- Concern was raised about whether the spillage of alcohol based products onto the pad would collect in pools and lead to a higher risk of burns.
- Clarification is required as to whether the product can be used with all other equipment in the operating theatre environment.
- Clarification is required about safety implications if the outer skin of the Mega Soft pad is punctured.
- Clarification is required about the thickness of intervening material between the Mega Soft and the patient before conduction is compromised.
- The sticky pad patient return electrodes, which are to be used as comparators, are resistive coupling electrodes while the Mega Soft Patient Return Electrode is a capacitive coupling electrode. Clarification is required about whether Mega Soft can be used with all electrosurgical units since these are likely to have been tested for use with resistive coupling electrodes rather than capacitive coupling electrodes.

3 Statement of the decision problem

	Scope issued by NICE
Population	Monopolar electrosurgery patients.
Intervention	Mega Soft Patient Return Electrode
Comparator(s)	•Return electrode monitoring single use sticky pads (non-split pad) •Return electrode contact quality monitoring single use sticky pads (split pad).
Outcomes	The outcome measures to consider include: •Incidence of dispersive electrode burns •Incidence of stray electrosurgical burns •Incidence of post-operative pressure ulcers •Other device-related adverse events •Sustainability and cost impact due to the re-usable nature of the pad •Resource utilisation and staff time; to include cleaning time
Cost analysis	Intervention: Mega Soft Patient Return Electrode Comparator(s): •Return electrode monitoring single use sticky pads (non-split pad) •Return electrode contact quality monitoring single use sticky pads (split pad). Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared including the treatment of adverse events. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, including an analysis of whether or not there will be a requirement to buy new diathermy equipment that is compatible with the Mega Soft Patient Return Electrode.
Subgroups to be considered	•Patients with burns •Patients with skin conditions •Babies and children •Patients with fragile skin. (E.g. older patients) •Patients with high or low BMI
Special considerations, including issues related to equality	Cultural sensitivities exist surrounding the shaving of body hair; this may be an issue when using ‘sticky pad’ electrodes but is potentially avoidable through the use of the Mega Soft pad. Although the device may have particular advantages for people who do not wish to shave body hair, it is suitable for all skin colours and types.

4 Related NICE guidance

Published

- Suction diathermy adenoidectomy. NICE interventional procedure guidance 328 (2009). Available from www.nice.org.uk/guidance/IPG328
- Electrosurgery (diathermy and coblation) for tonsillectomy. NICE interventional procedure guidance 150 (2005). Available from www.nice.org.uk/guidance/IPG150

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association of Laparoscopic Surgeons of Great Britain and Ireland
- Association of Surgeons of Great Britain and Ireland
- British Association of Day Surgery
- Institute of Physics and Engineering in Medicine
- Royal College of Nursing
- Royal College of Surgeons

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of Laparoscopic Surgeons of Great Britain and Ireland
- Association of Perioperative Practice
- Association of Surgeons of Great Britain and Ireland
- British Association of Day Surgery
- Institute of Physics and Engineering in Medicine

- Royal College of Nursing
- Royal College of Anaesthetists
- Royal College of Surgeons

5.2 Patient organisations

At the selection stage, NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- CritPaL - Patient Liaison Committee of the Intensive Care Society
- ICU Steps
- Royal College of Anaesthetists Patient Liaison Group
- Royal College of Surgeons Patient Liaison Group
- The Patients Association