Megadyne's Mega Soft(R) Pad Supported for Use in the U.K.'s National Health Service by the National Institute for Health and Clinical Excellence (NICE)

The Associated Press

Megadyne Medical Products, Inc., a recognized authority in the electrosurgery industry, today announced that its Mega Soft® Patient Return Electrode has been endorsed by The National Institute for Health and Clinical Excellence (NICE) for use in the United Kingdom's National Health Service (NHS). NICE, the body that advises the NHS on the prevention and treatment of ill health including use of new medical devices, published positive final guidance on the new medical technology device, advising that the use of Mega Soft Patient Return Electrode could help reduce the risk of localized burns during electrosurgery for selected patient groups.

Interglobal Surgical, Megadyne's UK distributor, played a significant role in submitting the product for review. The previous distributor, Advance Surgical, notified the product to NICE and was responsible for the sponsor submission of evidence.

"We are excited about this positive endorsement from NICE and are eager to expand the use of our Mega Soft product into medical centers throughout the U.K.," said Michael Hintze, vice president of marketing for Megadyne. "Providing patient safety, clinical efficacy and comfort to patients is of utmost importance. When you can offer a product that achieves this and also helps preserve our environment, you have a win-win situation for everyone involved."

Designed for safety, patient care and comfort, Mega Soft replaces previous technology where the electric current leaves the patient via a disposable single-use patient return electrode which is attached directly to the patient's skin via a 'sticky surface.'

With Mega Soft the patient return electrode is incorporated into a padded layer on which the patient lies during surgery. The patient is simply placed on the pad prior to surgery, there are no adhesives used on the skin. It is also environmentally friendly, as it is completely reusable.

The NICE guidance advises that the Mega Soft Patient Return Electrode may offer particular advantages for selected patients, such as those who would require shaving for application of disposable electrode pads and those with fragile or damaged skin. In addition, the device may benefit operating theatre staff in terms of increased convenience and reduced setting up time. The economic

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Published on Medical Design Technology (http://www.mdtmag.com)

considerations show that cost/resource requirements are similar to current practice. However, expert advice suggested that the resource consequences of the Mega Soft Patient Return Electrode are greatly influenced by the circumstances in which it is used. A full report can be found at

http://guidance.nice.org.uk/MTG11/Guidance/pdf/English.

"Placing and removing adhesive backed return electrodes pads is particularly challenging with neonates and elderly patients due to their very fragile skin," added Hintze. "Mega Soft more evenly distributes pressure, further protecting the patient from the risk of skin breakdown and pressure ulcers."

NICE first began to evaluate the technology in September 2011. Positive guidance from the London-based agency helps speed the adoption of new treatments across the 168 NHS hospital trusts in England. The Mega Soft electrode reusable mats cost 1,900 pounds (\$3,000) each and can be used for as long as 24 months. The Medical Technologies Advisory Committee has considered the evidence submitted and the views of expert advisers.

"With more than 45 million Mega Soft-assisted procedures with zero pad-site burns(1), patient safety remains a top delivery priority," said Melissa Fischer, RN, MSN, CNOR, Clinical Specialist and Marketing Product Manager at Megadyne. "The reusable Mega Soft can easily replace thousands of disposable sticky-pad electrodes enabling hospitals and surgical centers to offer excellent patient care while(2) preventing excessive waste."

Benefits(3) of the Mega Soft compared to small adhesive pads are: Easy to set-up. No shaving or searching for an adequate patient pad site. Safer than the sticky-style monitoring pads. Kinder to the patient. NO adhesive-related skin irritations and all the benefits of a pressure reduction pad. Save Money. The reusable pad reduces cost per procedure -- up to a 70% savings Sized to fit an O.R. table, bassinet or isolette. Compatible with most isolated electrosurgical generators. Environmentally friendly -- eliminates the waste of the disposable "sticky" pad. Radiolucent and latex-free. Hold harmless guarantee against pad site burns. About MEGADYNEMEGADYNE, www.megadyne.com, is the recognized authority on non-stick electrosurgical electrodes and cost-effective surgical devices.

- (1) Benefits, cost savings and procedure estimates are based on Megadyne's company sales and surveillance data, and marketing information, and are not from the NICE guidance.
- (2) As for footnote 1 above
- (3) As for footnote 1 above

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