GCM GLOBAL COMPONENTS MEDICAL LTD

Safety Information Concerning Eye Patches relating to TIVA Sets

Field Safety Notice

To: - The Procurement Manager
The Head of the Department of Anaesthetics

31 March 2014

Dear valued customer,

Global Components Medical Limited has become aware through a customer complaint of a safety issue associated with the use of the eye patches supplied with the TIVEA sets detailed in Section 2 below. Please inform all end-users in your facility of this issue. Please acknowledge receipt of this FSN by return by signing the FIELD SAFETY NOTICE REPLY FORM at the end of this document by email to egulatory@global-medical.co.uk .

Internal Reference: -	FSN 1312001
Date: -	26th February 2014
Product Code: -	GCM-223 sets
Applicable Products: -	See section 2 of this document.

1. Description of Incident

1.1. Damage was reported to a patient's eyelid when the eye patches provided' in the company's GCM-223 TIVA set, were removed post surgery. The patient did not have a previous history of tissue problems but it also had not been established whether the patient's treatment regime would have had any compromising effects on tissue integrity.

1.2. The reported incident relates to a single problem with a patient using the eye patches provide with the above-mentioned product.

1.3. No specific training relating to the eye patches had been given to the end-user as tapes [of a similar material] are commonly used to close the eye during surgery.

1.4. The eye patch was in contact with the patient skin for approximately 2 hours.

1.5. Tissue viability had not been accessed prior to use of the eye patches.

1.6. The Instructions for Use (IFU) did not contain a reference, recommending precaution regarding tissue viability.

GLOBAL COMPONENTS MEDICAL LTD
Watchmoor House, Watchmoor Road, Camberley Surrey, GU15 3AQ, UK.
Tel: +44 (0) 1276 679394
Fax: +44 (0) 1276 679055
E-Mail: info@global-medical.co.uk

2. List of Product Affected

PRODUCT CODE	DESCRIPTION
GCM-1003	10 METRE TIVA MRI SET
GCM-223	3 WAY TIVA SET 2.2 METRE
GCM-223B	3 WAY MULTIPLE INFUSION TIVA SET 2.2 METRE BASIC
GCM-253	3 WAY TIVA SET 2.5 METRE
GCM-253B	3 WAY MULTIPLE INFUSION TIVA SET 2.5 METRE BASIC
GCM-303B	3 WAY MULTIPLE INFUSION TIVA SET 3.0 METRE BASIC
GCM-304	4 WAY TIVA SET 4.0 METRE
GCM-SPCA	SEDATION PCA SET 2.2 METRE

3. Corrective Action

3.1. During future in-market training secessions it is recommended that the tissue viability personal, from within the hospital, be invited and that they are made aware of the potential for a medical adhesive-related skin injury (MARSI) to peri-ocular skin where the tissue has been compromised or is friable. A Tissue Viability Assessment should be carried out on Immuno-compromised patients, including those with autoimmune conditions, and especially those receiving corticosteroids or other immunosuppressant drugs.

3.2. For patients with compromised or friable skin in the peri-ocular region, Tissue Viability Assessments are highly recommended, as with the use of any type of adhesive dressing. Consideration to the use of skin barriers prior to applying adhesive products should be made, limit or avoid substances that increase the stickiness of adhesives and use proper application and removal techniques for adhesive patches.[1]

After the procedure gently remove the patch to prevent any possible localized damage. The same precaution should be observed with any adhesive dressing in this area.

3.3. The IFU has been updated to include procedural recommendations regarding the tissue viability issues highlighted in point 3.1 and 3.2. and the following comment has also has been added to the IFU: -

After the procedure, gently and slowly remove the patch to prevent any possible localized damage - never pull quickly as this will increase the adhesion strength. The same precaution should be observed with any adhesive dressing in this area. When removing the line fixation patch gently remove and never pull quickly.

Particular care should be taken when removing i-Loks from neonates children and the elderly due to the greater fragility of peri-ocular skin.

3.4. A link to the Global Component s Medical Limited web site for downloading of reference material has been added to the IFU and reference papers have placed on the web site.

4. Further Information and Support

4.1. The Tissue Viability Specialist within the hospital should be consulted whenever the skin integrity is suspected of being friable or compromised. This is absolutely necessary when it is

[1] '*Wound Care - Medical Adhesives and Patient Safety*', Laurie McNichol et al

known that the patient is immune supressed or compromised as a result of drug therapy or side effects.

4.2. Visit GCM web site for reference material - http://www.global-medical.co.uk/index.html

5. Report by Management - Regulatory Reviewer [Synopsis]

5.1. An extensive literature review and enquiries with the material manufacturer and convertor (sub-contract manufacturer) has been conducted and these enquiries indicates that there have been no technical issues with the acrylate adhesive used on the Nonwoven tape (equivalent to 3M Micropore) that is used for the eye shields. The review of this incident concludes that the company's Risk Analysis is to be reviewed and updated in light of the reported injury - that might have been caused by the adhesive at the time of the removal. The recommendations from the manufacturer, [3M] main reference document[2], on the uses of medical dressings should be highlighted in a revised IFU and users informed.

5.2. The material used in the manufacture of the eye protection device is referenced in the 3M Technical Information Sheet Product Number 1530L 3M TM Medical White Rayon Nonwoven Tape on Liner, this the material meets FDA and Medical Device 93/42 EEC directive regulatory requirements. This material and its adhesive have been in the market for over twenty years in this form and as an equivalent to the 3M product Micropore that was introduced in 1959.

5.3. The material and adhesive have been tested in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. The components of No. 1530-L have satisfied the requirements for devices in contact with intact skin for short term application (up to 29 days). All laboratory testing was conducted in accordance with the FDA Good Laboratory Practices Regulation of 1978. This is a statement by the manufacturer in their technical documentation.

5.4. Degree of stripping varies with skin condition, adhesive characteristics, and frequency of taping".

5.5. The reference data used for this evaluation is related to 3M Tegaderm which a transparent barrier is dressing using the same adhesive but with a similar bonding strength.

6. Key reference document

The recently published paper, *Medical Adhesives and Patient Safety: State of the Science Consensus Statements for the Assessment, Prevention, and Treatment of Adhesive-Related Skin Injuries* - Laurie McNichol, Carolyn Lund, Ted Rosen and Mikel Gray J Wound Ostomy Continence Nurs. 2013;40(4):365-380 is a main reference document in this review and can be accessed on the GCM web site - http://www.global-medical.co.uk/.

Medical adhesive-related skin injury (MARSI) is an atypical reaction within a normal healthy population. A consensus panel of 23 recognized key opinion leaders[3] convened to establish consensus statements on the assessment, prevention, and treatment of medical adhesive–related skin injury. The consensus summit was held in December 2012 and was made possible by an unrestricted educational grant from 3M. Panel members were in agreement that MARSI is far reaching and affects patients of all ages across all settings of care. The care of the skin, including its protection against MARSI, is a basic requirement for patient care. Healthcare providers should strive to prevent and reduce the incidence of MARSI but first must be made aware of the problem and its causes. They, as well as patients and caregivers, need to be provided with the knowledge and tools necessary for preventing and managing adhesive-related injury.

---

[2] *'Reducing the Risk of Superficial Skin Damage Related To Adhesive Use'* – 3M ~ 2001

[3] *Medical Adhesives and Patient Safety: State of the Science Consensus Statements for the Assessment, Prevention, and Treatment of Adhesive-Related Skin Injuries* - Laurie McNichol, Carolyn Lund, Ted Rosen and Mikel Gray J Wound Ostomy Continence Nurs. 2013;40(4):365-380.

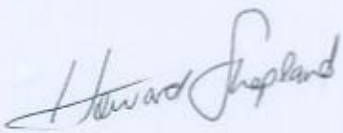
The consensus paper recommended that best practice guidelines are needed to assist those who use medical adhesives in using them appropriately, identifying patients at risk for skin injury, and implementing prevention and management strategies.

7. Notice to Staff

Please complete the attached reply form and return it to us by fax or email as per the instructions even if you have not had a problem and circulate this FSN to all colleagues within your organisation who need to be aware of the potential risk when using eye protection patches.

Global Components Medical Limited is committed to the highest level of service, product quality and reliability. We appreciate your understanding on this issue and should you need further assistance please do not hesitate to contact us,

Yours sincerely,



Howard Shapland

Director of Regulatory Affairs

GLOBAL COMPONENTS MEDICAL LTD
Watchmoor House, Watchmoor Road, Camberley Surrey, GU15 3AQ, UK.
Tel: +44 (0) 1276 679394
Fax: +44 (0) 1276 679055
E-Mail: info@global-medical.co.uk