Laurie Lenkel
Ombudsman (HF-7)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

May 15, 2006

Reference: Request for Correction of Information – FDA Patient Safety News Alert "Preventing Bleeding with Vacuum-Assisted Wound Closure"

Dear Ms. Lenkel:

BlueSky Medical Group, Inc. ("BlueSky"), located at the address and phone numbers listed below, requests correction pursuant to "Federal Data Quality Act," *OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 FR 8452 (Feb. 22, 2002) and the Food and Drug Administration's (FDA's) own implementing guidance, which is part of the Department of Health and Human Services *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, September 30, 2002 concerning the Food and Drug Administration's (FDA's) Patient Safety News – Safety Alert titled "Preventing Bleeding with Vacuum-Assisted Wound Closure" and dated November, 2005. The following documents are involved with the requested correction and are available at http://www.accessdata.fda.gov/psn/transcript.cfm?show=45:

1. FDA Article – Malli, S. "Keep A Close Eye On Vacuum-Assisted Wound Closure" *Nursing2005* 35(7) (the "Article"), included as Attachment 1;

2. FDA Patient Safety News – Safety Alert - "Preventing Bleeding with Vacuum-Assisted Wound Closure" (the "Transcription"), included as Attachment 2; and

3. FDA Patient Safety News – Video Webcast - "Preventing Bleeding with Vacuum-Assisted Wound Closure" (the "Video"), included as Attachment 3.

The Article, Transcription, and Video ("Documents") misrepresent the relative safety of different products used for Negative Pressure Wound Therapy (NPWT). The Documents continue to negatively influence BlueSky by falsely representing BlueSky and its products to its distributors and end users. BlueSky requests that FDA take the following actions to rectify the situation:

1. Remove the Documents noted above from the FDA website;

2. Correct the Documents to reflect a complete interpretation of the different methods and safety concerns involved with NPWT; and

5924 Balfour Ct. • Suite 102 • Carlsbad, CA 92008
Phone (760) 603-8130 • Fax (760) 760-8331
http://www.blueskymedical.com

3. Disseminate corrected Documents to the public to create an accurate and unbiased presentation.

The documents at issue in this request purport to be objective, authoritative information intended to influence clinicians and patients. This information is expected to maintain objectivity, utility, and integrity in both substance and presentation. The following aspects of the Documents require correction to conform to the standards of quality endorsed by FDA:

1. Terminology

   The Transcription and Video use inconsistent terminology for the therapy commonly known as Negative Pressure Wound Therapy and abbreviated "NPWT". The terms "vacuum-assisted wound closure," "vacuum-assisted closure therapy", and "vacuum-assisted wound closure therapy" are used throughout the Transcription and Video. The term "V.A.C® Vacuum Assisted Closure" refers to a specific, commercialized device and is avoided by clinicians and publications for this reason.

   Remedy: We request that the term "Negative Pressure Wound Therapy" or "NPWT" be used whenever generalizing about, or referring to, the field as a whole.

2. Description

   The Transcription and Article describe NPWT as using a "special foam dressing" packed into the wound cavity or over a flap. The Versatile 1™ Wound Vacuum System (K042134, cleared November 1, 2004), intended for use in NPWT, utilizes the Chariker-Jeter® Wound Sealing Kit that does not utilize foam dressings. The Video images focus exclusively on methods for NPWT that utilize foam.

   Furthermore, the Transcription and Article associate a case of "serious bleeding" and death with NPWT. There have been no reported incidents, as substantiated by FDA M.A.U.D.E. data, of tissue ingrowth, subsequent bleeding as a result of tissue ingrowth, or death using the Versatile 1™ Wound Vacuum System with Chariker-Jeter® Wound Sealing Kits.

   Remedy: We request that distinction be made regarding the available technologies (e.g. foam, Chariker-Jeter®, etc.) for NPWT.

3. Warnings

   The Transcription and Article recommend the use of "petrolatum-impregnated, non-adherent" (non-adherent) layers. Chariker-Jeter® Wound Sealing Kits are provided with non-adherent gauze and instructions for the use of non-adherent gauze during NPWT.

   The use of non-adherent layers is mentioned in the Video, however there are no images of non-adherent layers or images of their application in a clinical or other setting.

Remedy: Please clarify how the above warnings apply to users of the Versatile I™ Wound Vacuum System and Chariker-Jeter® Wound Sealing Kits.

Remedy: Please confirm device labeling should include, as part of the NPWT protocol, the use of a separate, non-adherent layer for protection of the wound bed.

BlueSky agrees with the intent of the Documents, however the Chariker-Jeter® method for NPWT has been wrongly associated with other techniques for NPWT that may be inherently more dangerous than the Chariker-Jeter® method for NPWT. The Documents do not show the specificity that is characteristic of information typically disseminated by FDA.

Consequently, current and potential users have wrongly associated and misunderstood BlueSky's products. Such confusion causes BlueSky's distributors and users to misconstrue the products as misbranded or adulterated in violation of the Federal Food, Drug, and Cosmetic Act.

I appreciate your urgent attention towards this matter. Please feel free to contact me at 760-603-8130 x209 (voice), 760-603-8331 (fax), or jasper@blueskymedical.com if you have any additional questions.

Sincerely,

/s/

Vice President, Quality and Regulatory Affairs
BlueSky Medical Group, Inc.

Cc: Les Weinstein
CDRH Ombudsman (HF-5)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Attachment 1

Keep a close eye on vacuum-assisted wound closure

BY SUZANNE MALLI, RN, BSN

AFTER BEING SERIOUSLY injured in a fall, a patient had his leg amputated. During his recovery, he was prescribed anticoagulants to prevent venous thromboembolism. Two weeks after the amputation, he began treatment with negative-pressure wound therapy (NPWT) to promote healing. During a dressing change while undergoing NPWT, he experienced serious bleeding from several areas in the wound. He later died, reportedly from severe hemorrhage and possible acute myocardial infarction. Further follow-up revealed that complications associated with bleeding initially started at surgery, before the NPWT was used.

What went wrong?

A noninvasive mechanical wound care therapy, NPWT assists in wound healing by applying controlled localized negative pressure to a wound's surface and margins. As specified in the device labeling, NPWT is applied to a special foam dressing packed in the wound cavity or over a flap or graft. Vacuum pressure helps remove fluids and infectious material from the wound, which encourages healing.

If a patient is undergoing NPWT, closely monitor him for signs and symptoms of overt and occult bleeding if he meets any of these criteria:

- He's actively bleeding.
- He's receiving anticoagulant therapy.
- He has weakened, irradiated, or sutured blood vessels or organs in proximity to the wound.

The patient in this case was especially vulnerable to hemorrhage during NPWT because he was actively bleeding from the surgical site and he was undergoing anticoagulant therapy.

What precautions can you take?

If NPWT is prescribed for your patient, take these steps to protect him from bleeding.

- Assess him for preexisting bleeding disorders or use of anticoagulants or other medications or herbs that prolong bleeding times, such as nonsteroidal anti-inflammatory drugs, aspirin, or gingko biloba.
- Carefully observe him for unusual or excessive bleeding after surgery.
- Make sure you know the contraindications and precautions for NPWT, including difficult wound hemostasis.
- Use protective barriers (such as gauze impregnated with petrolatum) to protect weakened, irradiated, or sutured blood vessels or organs that are close to areas being treated with NPWT.
- Know and follow your facility's policy and procedure for using NPWT.
- Review and follow the device manufacturer's instructions for use, including the appropriate negative-pressure setting recommended for the type of wound.
- Monitor patient for complications while device is in use.

SELECTED REFERENCE

Mendez-Eastman S. Using negative-pressure wound therapy for positive results. *Nursing2005*. 35(5):48-50, May 2005.

Although you need to support the adverse event–reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services.

Beverly Albrecht Gallauresi, RN, BS, MPH, is a nurse-consultant at the Center for Devices and Radiological Health at the Food and Drug Administration in Rockville, Md., and coordinates Device Safety.

Suzanne Malli is a nurse-consultant at the Center for Devices and Radiological Health.

Attachment 2

Return to Top Return to FDA Patient Safety News Home

November 2005 | FDA Patient Safety News

Preventing Bleeding with Vacuum-assisted Wound Closure

Vacuum-assisted wound closure, also known as negative pressure wound therapy, can help heal certain non-healing wounds by removing fluids and infectious material from the site. The therapy is applied to a special foam dressing packed in the wound cavity or over a flap or graft. A recent FDA article in Nursing2005 highlights the importance of carefully selecting and monitoring patients being treated with this therapy.

The article describes a patient who had his leg amputated after being seriously injured in a fall. During his recovery, he was prescribed anticoagulants to prevent venous thromboembolism. Two weeks after the amputation, he began treatment with vacuum-assisted wound closure to promote healing.

During a dressing change while undergoing the therapy, he experienced serious bleeding from several areas in the wound. He later died, reportedly from severe hemorrhage and possible acute myocardial infarction. Further follow-up revealed that complications associated with bleeding had begun at the time of surgery, before the vacuum-assisted closure therapy was started.

The article lists several precautions to help prevent this kind of bleeding in patients undergoing vacuum-assisted wound closure therapy. For example, certain patients should be closely monitored for overt and occult bleeding. This includes those who are actively bleeding, on anticoagulants, or who have weakened, irradiated, or sutured blood vessels or organs that are close to the wound.

Use protective barriers such as gauze impregnated with petrolatum to protect vulnerable blood vessels or organs. And follow the device manufacturer's instructions for use, including selecting the correct negative pressure recommended for that type of wound.

Additional Information:

Malli, S. "Keep A Close Eye On Vacuum-Assisted Wound Closure" Nursing2005 35(7)
http://www.fda.gov/cdrh/psn/048_devicesafe.pdf

Return to Top Return to FDA Patient Safety News Home

November 2005 | FDA Patient Safety News

Updated Cardiotoxicity Data for Herceptin

Genentech is notifying healthcare professionals about updated cardiotoxicity information related to Herceptin (trastuzumab). Herceptin is used to treat patients with metastatic breast cancer whose tumors over-express the HER2 protein.

The labeling for Herceptin already contained a boxed warning that use of the drug can result in ventricular dysfunction and congestive heart failure in some patients. Genentech's letter now provides additional information about that risk based on a preliminary analysis of data from the National Surgical Adjuvant Breast and Bowel Project. The new information includes how often these adverse events occur and when they occur in relation to starting treatment.

Additional Information:

FDA MedWatch Safety Alert - Herceptin (trastuzumab)
http://www.fda.gov/medwatch/safety/2005/safety05.htm#Herceptin

Return to Top Return to FDA Patient Safety News Home

Preventing Medical Errors

November 2005 | FDA Patient Safety News

Caution on Accidentally Giving Nimodipine Intravenously

In a recent Medication Safety Alert, ISMP warns about inadvertently administering nimodipine or Nimotop intravenously. This has resulted in patient deaths and serious injuries. Nimodipine is a calcium channel blocker that's used to prevent vasospasm in patients with subarachnoid hemorrhage.

Nimodipine capsules are given by mouth, but for patients who can't swallow, the contents of an oral capsule can be extracted into a syringe

Attachment 3