MEETING OF THE HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE
Centers for Disease Control and Prevention
Meeting Date: February 12th- 13th, 2009
Meeting Location: Atlanta, Georgia

Liaison name: Sheila A. Murphey, MD

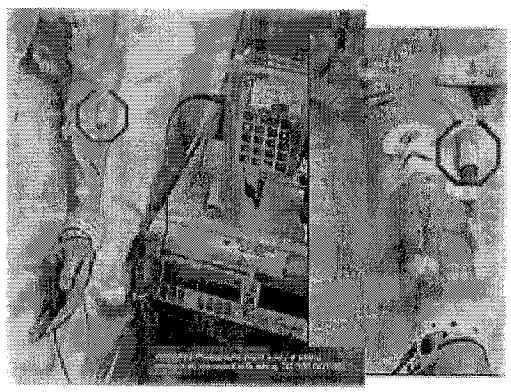
Organization represented: Food and Drug Administration

Interim activities and updates

Outbreak Activities:
• In conjunction with the CDCP and state/local Health Departments, the Recall and investigation of Salmonella typhimurium-contaminated bulk peanut butter used in the manufacture of a wide variety of foods continues.
Campaigns and Related Activities:
• **Luer Misconnections** FDA has published a 2009 Medical Device Safety Calendar (Luer Misconnections) which focuses on this very important safety issue. Misconnections can lead to patient injury, infection and even death. The entire Calendar is available at www.fda.gov/cdrh/luer. It contains important safety tips from the JCAHO. It is not copyrighted or restricted in any way; FDA encourages use of all or part of it in hospital safety efforts. See Attachment.
Public Health Advisory:
• Potential Hazards of Skin Products Containing Numbing Ingredients for Relieving Pain from Mammography and other Medical Tests and Conditions - Issued 1/16/09. See Attachment.
Recalls:
• Followup on 5/08 Warning Letter re the Steris System 1. A Customer Letter dated 1/20/09 has been issued by Steris agreeing to discontinue US sales of the Steris System 1 device. Existing devices will be supported for up to two years. See Attachments. Please notify FDA promptly of any issues related to these devices. • Stryker Craniomaxillofacial Custom Cranial Implant Kits - 4 lot numbers have been recalled because the firm is unable to assure sterility of the devices. See Attachments. Please notify FDA promptly of any infections related to these devices. • Update on Class I Recall 10/08 of lot UD30654 of Healon D viscoelastic material associated with eye surgery post-op inflammation including TASS. Most units have been accounted for, but not all. Please check inventory for any units. See Attachment.

Publications:
• CVM issued 1/09 "Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs". The guidance is available at www.fda.gov/cvm/Guidance/fguide187.pdf.
Other items of note:
FDA Unique Device Identification Public Workshop will be held 2/12/09 in Gaithersburg, MD. Comments may be posted to the Docket until 2/27/09. See Attachment.

Luer Misconnections



Patient injuries and deaths have occurred when different device delivery systems are mistakenly connected to each other. These errors are often facilitated by fittings called Luer connectors, which can allow different systems to be easily, but erroneously, connected.

The 2009 Medical Device Safety Calendar (Luer Misconnections) is one of FDA's efforts to help educate healthcare professionals about these dangerous misconnections. The calendar provides a graphic depiction of a variety of misconnection cases, coupled with recommendations from The Joint Commission (TJC) on ways to prevent these types of errors.

On this website, you can download or print the calendar, case studies, and additional resources about Luer misconnections and how to help prevent them.

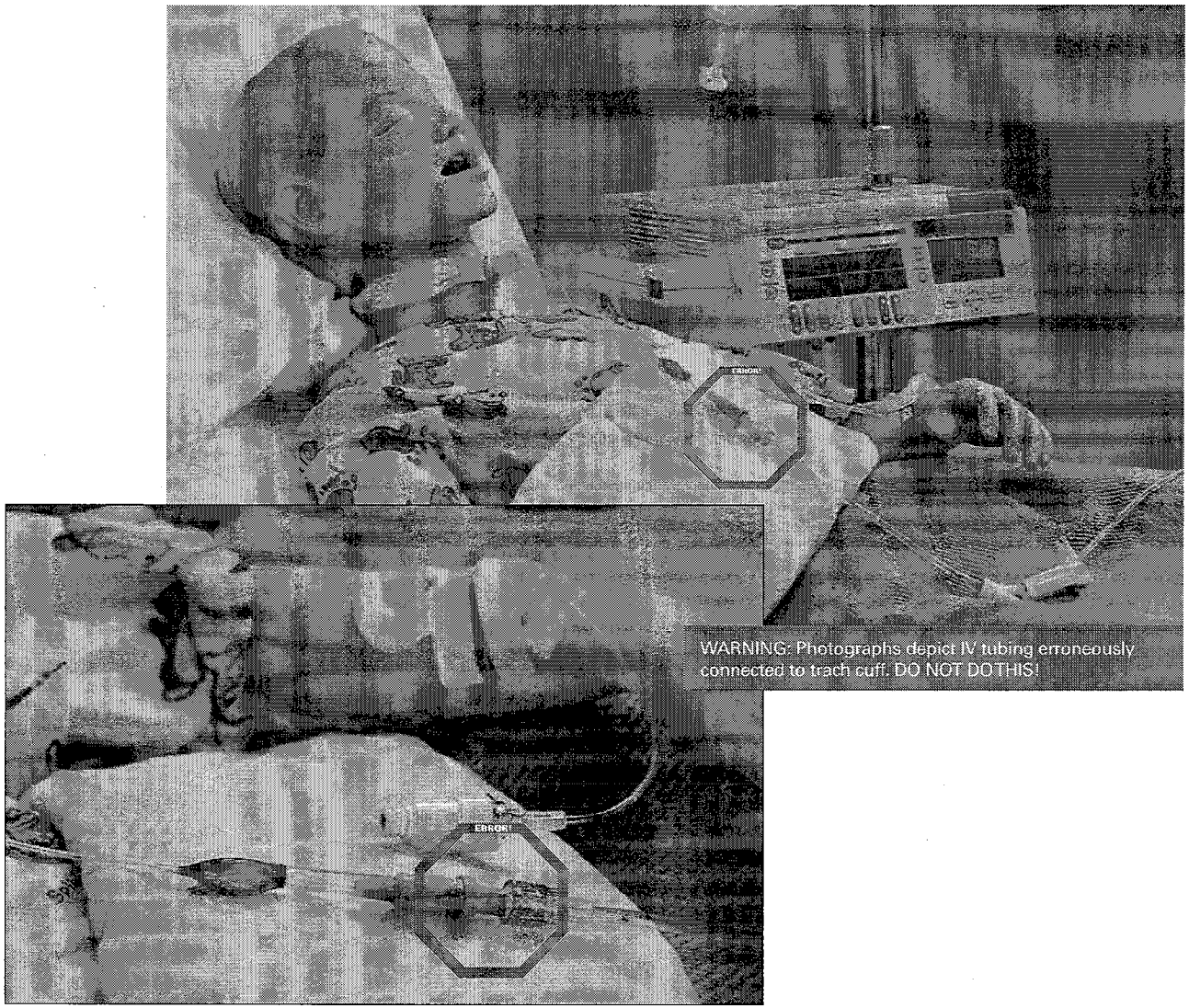
Updated January 28, 2009

Look.Check.Connect.

SAFE MEDICAL DEVICE CONNECTIONS SAVE LIVES

www.fda.gov/cdrh/luer

U.S. Food and Drug Administration



WARNING: Photographs depict IV tubing erroneously connected to trach cuff. DO NOT DO THIS!

EVENT

IV tubing erroneously connected to trach cuff

POTENTIAL FOR HARM

High

CASE STUDY

- A child in a pediatric intensive care unit had both an IV line and a trach tube
- The IV tubing was inadvertently connected to the trach cuff port
- The IV fluid over-expanded the trach cuff to the point of breaking and continuous IV fluids entered the child's lungs
- The child died

THE JOINT COMMISSION SAFETY TIP

Emphasize the risk of tubing misconnections in orientation and training curricula

FDA Public Health Advisory
Potential Hazards of Skin Products Containing Numbing Ingredients for Relieving Pain from Mammography and Other Medical Tests and Conditions

FDA is issuing this advisory to remind patients, healthcare professionals, and caregivers about potentially serious hazards of using skin numbing products, also known as topical anesthetics, for relieving pain from medical tests and conditions. In February 2007, FDA issued a *Public Health Advisory- Life-Threatening Side Effects with the use of Skin Products Containing Numbing Ingredients for Cosmetic Procedures* -that described the deaths of two young women who used topical anesthetics prior to laser hair removal [http://www.fda.gov/cder/drug/advisory/topical_anesthetics.htm]. Now, FDA is aware that lidocaine, a type of topical anesthetic, was studied to see if it may reduce discomfort during breast mammography[1].

During the study, the topical product was spread over a wide area and covered with plastic wrap. Although no serious side-effects were reported in this study, it was not large enough to evaluate whether uncommon but serious reactions could occur with this use. FDA remains concerned about the potential for topical anesthetics to cause serious and life-threatening adverse effects when applied to a large area of skin or when the area of application is covered.

Topical anesthetics work by blocking pain sensation in the skin. Some of the medication in a topical anesthetic can pass through the skin into the blood stream. More of the medication will pass into the blood stream if the topical anesthetic is applied over a large area of the skin, if a large amount is applied, if it is applied to irritated or broken skin, or if the skin temperature increases. Skin temperature can increase during exercise, by covering the skin with a wrap, or with use of a heating pad. Under these circumstances, the amount of anesthetic medication that reaches the blood stream is unpredictable and may be high enough to cause life-threatening adverse effects such as irregular heartbeat, seizures, breathing difficulties, coma and even death.

There are several topical anesthetics available by prescription and over-the-counter. When used appropriately, these products may provide safe and effective pain relief. Before recommending a topical anesthetic for any purpose, doctors should determine if the desired amount of pain relief can be achieved safely with a topical anesthetic, or if a different treatment would be more appropriate. If a topical anesthetic is determined to be the best choice, the lowest needed amount should be prescribed. Patients should speak with their doctor if they are considering using a

topical anesthetic before a mammogram. If a topical anesthetic is recommended then patients should:

- use a topical anesthetic that contains the lowest amount possible of medication that will relieve the pain;
- apply the topical anesthetic sparingly and only to the area where pain exists or is expected to occur;
- not apply the topical anesthetic to broken or irritated skin.
- ask their doctor what side effects are possible and how to lower their chance of having life-threatening side effects from anesthetic drugs.
- be aware that if wrapping or covering the skin with any type of material or dressing is recommended or considered, this can increase the chance of serious side effects, as can applying heat to the treated area while the medication is still present.

FDA is working with healthcare professional organizations and other media that distribute healthcare information to spread the message about the potential hazards and safe use of topical anesthetics.

[1]Lambertz CK et al. Premedication to Reduce Discomfort during Screening Mammography. Radiology 2008; 248 (3): 765-72.

Stakeholder Letter(PDF)

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PDF requires the free Adobe Acrobat Reader

Date created: January 16, 2009

STERIS

January 20, 2009

IMPORTANT NOTICE

Dear Valued SYSTEM 1 Customer:

On May 15, 2008, the United States Food and Drug Administration ("FDA") sent a warning letter to STERIS stating its view, among other things, that STERIS made changes or modifications to the STERIS System 1 requiring STERIS to submit to FDA a new premarket notification ("510(k)") and obtain marketing clearance for the changed device. Accordingly, FDA stated that the currently marketed device does not have a cleared premarket notification. The regulations require a new 510(k) when changes are made to a legally marketed device that "could significantly affect the safety or effectiveness of the device" (21 CFR 807.81(a)(3)(i)).

The changes or modifications identified in the warning letter occurred between 1988 and 2002, and are as follows:

- The centrifugal circulation pump's impeller was changed from a mechanically coupled to a magnetically driven impeller;
- The high pressure pump used to circulate sterilant to and through device lumens was changed: the original pump had a flow rate of 800 mls/min and the modified pump's flow rate was 3500 mls/min: also a pressure switch was added to monitor high pressure pump leakage;
- System 1 software was changed to limit the operation of the high pressure pump to avoid high pressure pump alarms related to low facility water pressure;
- The connector design was changed from separate components to groupings of tethered components intended for use with specified endoscopes, and new connectors were developed to facilitate the adaptation of the flow unit to the instrument intended for processing;
- The chamber size of the System 1 was made larger than the test chamber referenced in the original System 1 510(k), and the STERIS 20 sterilant formula was changed to maintain the FDA-cleared sterilant concentration to accommodate the larger chamber volume; and
- Additional inert ingredients were added to STERIS 20 sterilant, *i.e.*, water, sodium hydroxide, sodium polyacrylate, EDTA and NTA.

On July 31, 2008, STERIS provided a written response to FDA disagreeing with the agency's assessment that a new 510(k) was required under the agency's regulations. Subsequently, STERIS and FDA met to discuss the warning letter. Although the parties continue to disagree about the statements in the warning letter, STERIS agreed to submit a new premarket notification for an updated STERIS System 1, which includes the changes referenced above and other technology updates. STERIS submitted this new 510(k) to FDA on January 5, 2009.

In conjunction with the submission of the 510(k) for the updated STERIS System 1, STERIS is discontinuing sales in the U.S. of the System 1 Processor that is the subject of the warning letter, except for sales related to product replacement. STERIS will continue to support existing System 1 Processors for at least two years from the date of this notice. This support will consist of selling accessories and STERIS 20 sterilant, providing service and parts, and selling replacement units on a one-for-one basis. STERIS will work with customers on a timetable to transition to the purchase of a replacement for its System 1 product.

As always, Customers should report any serious adverse event that you suspect is associated with the use of the STERIS System 1 to STERIS 1-800-548-4873 and FDA (see http://www.fda.gov/medwatch/report/hcp.htm).

If you have any questions, please contact STERIS Customer Service at 1-800-548-4873 or www.steris.com.

Sincerely,

Rosemary Niewolak

Rosemary Niewolak
Product Manager, SYSTEM 1
STERIS Corporation

S67812

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

May 15, 2008

WARNING LETTER
CIN-08-5964-15

VIA FEDERAL EXPRESS

Walter M. Rosebrough
President and Chief Executive Officer
Steris Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: Steris System 1 Processor and Sterilant 20

Dear Mr. Rosebrough:

The Food and Drug Administration (FDA) has reviewed documents that were collected [redacted]. These records covered changes made to the Steris System 1 Processor (SS1), including the Sterilant 20, which is a liquid chemical sterilizer used to sterilize instruments such as endoscopes and bronchoscopes. The Steris System 1, including the Sterilant 20, is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

As explained below, our review of these documents and of agency records of premarket review decisions indicates that your device is adulterated under section 501(f)(1)(B) of the Act [21 U.S.C. 351(f)(1)(B)] because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the agency (21 U.S.C. 807.81(b)).

The kind of information you need to submit in order to obtain approval or clearance for your device is described on the internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Specifically, the device (Steris System 1 Processor and Sterilant 20) was cleared in 1989 for marketing under premarket notification (510(k)) submission number K875280. As discussed below, the documents collected [redacted] reveal that there have been significant changes or modifications in design, components, method of manufacture, or intended use, that require submission of a new premarket notification in accordance with 21 CFR 807.81(a)(3). Under that regulation, a new 510(k) must be submitted for a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. See 21 CFR 807.81(a)(3)(i). The changes described below are such significant changes. Therefore, until a 510(k) is submitted for the altered device and FDA issues a finding that this changed device is substantially equivalent to a legally marketed predicate, your device remains a class III device under section 513(f)(1) of the Act, 21 U.S.C. 360c(f)(1). Such devices are subject to the requirement of premarket approval under section 515(a) of the Act, 21 U.S.C. 360e(a).

Our investigation revealed the following changes that could significantly affect the safety or effectiveness of the device.

1. The cleared SS1's circulation pump was a [redacted] pump. In 1999, the pump was changed to a [redacted] pump. According to internal Steris documents, the original circulation pump failed for low flow performance and seal leakage that resulted in decreased SS1 reliability and consumer complaints. The change to a [redacted] pump altered the flow rate, the flow characteristics, and the flow through the lumen of the device. These changes significantly impact the function and delivery of the sterilant to and through an instrument.

2. The cleared SS1's high pressure pump was an [redacted] pressure pump with a flow rate of [redacted]. In 1992, you developed a new model SS1, Model 90. This new model had a [redacted] high pressure pump with a flow rate of [redacted] In 1995, as a result of consumer complaints of the Model 89 series high pressure pump leaking, your firm began installing pressure switches in the pumps to monitor the function of the high pressure pump. In 1998, your firm developed an "HP Pump Enhancement Kit," and in 1999, began replacing the [redacted] high pressure pumps in the Model 89A1 and 90B1 series with the new [redacted] high pressure pumps. The changes to the high pressure pump altered the flow rate and flow characteristics in the SS1 and through the lumen of the device. Therefore, these pump changes significantly impact the function and delivery of the sterilant to and through the device being processed.

3. In December 1996, your firm made changes to the original software used in the device as cleared in 1989, in response to reports that customers were receiving high pressure pump alarms due to low facility water pressure. In response, you changed the software program to limit the operation of the high pressure pump to the sterilant exposure phase and the final drain. Because of this software change, the high pressure pump no longer runs during the final rinse phase. This action may affect removal of chemical residues from the processed devices and may pose a risk to the patient.

4. On August 19, 2002, your firm sent correspondence to all of your customers stating that it had changed the connector design on the Quick Connect Kits from individual components to one unit, in which all of the components are tethered together. The design change was initiated following microbiological testing failures related to the older, individual-component connectors. Additionally, new connectors were developed to facilitate the adaptation of the flow unit to the

instrument to be processed. These changes to the connectors have a significant effect on the sterile fluid pathway and delivery of the sterilant.

5. The cleared SS1's chamber volume was [redacted]. After 510(k) clearance, your firm increased the chamber volume to [redacted] and then to [redacted]. Along with this large increase in the chamber volume, the Sterilant 20 formulation was altered, with the intent of maintaining the final peracetic acid (PAA) concentration given the larger chamber volume. This large increase in chamber volume, which apparently also prompted a change in sterilant formulation, could significantly affect the ability of the system to sterilize by altering how sterilant is delivered and the concentration of ingredients in the sterilant.

6. Following the clearance of the 510(k), your firm added five additional [redacted] ingredients ([redacted], and [redacted]) to the formulation of the Sterilant 20. This change to the sterilant formulation could significantly affect safety or effectiveness of the device, specifically, the effectiveness of the active ingredient and its ability to sterilize, and by altering the stability of the sterilant.

In addition to the changes above, each of which by itself would necessitate submission of a 510(k), the agency's review of the collected documents shows several additional changes to the SS1, including changes to the following: the sterile water filter housing; lid header block; material on the PV sleeves of the pinch valve; pressure relief added to the high pressure pump; the heater element changed from copper to stainless steel; and check valve on the drain block. These changes cumulatively result in a change in the overall device design that could significantly affect safety and effectiveness.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

In addition, we request that your response address the following. Our review of the documents collected [redacted] revealed actions (detailed below) that you have taken on the SS1 that appear to meet the definition of a correction under 21 CFR 806.2.(d). In your response to this letter, we request that you indicate whether or not your firm considers these actions to be corrections or removals under that regulation, and if you do not consider them to be corrections or removals, to provide your rationale for that conclusion. If your firm does consider any of these actions to be corrections or removals, please provide a copy of your documented rationale as to why each such correction or removal is not required to be reported under 21 CFR 806.10, Reports of Correction and Removals. Please provide this information for the following:

1. On August 19, 2002, you sent communication to your customers introducing the new "tethered quick connect kits" with a new "Quick Connect Card" and "Laminated Wall Chart" labeling. The correspondence states for the customers to convert their inventory to the new quick connects, because they will reduce operator assembly time and the potential for operators connecting the incorrect scope to a specific quick connect.

2. On May 23, 2001, you initiated Engineering Change Order #010189 to provide field service with a kit for replacing the SS1's circulation pump impellers due to premature impeller failure (cracking) in the field. On February 1, 2003, you issued a Service Bulletin addressing the issue of the impeller prematurely cracking and allowing the black substance inside the impeller to be circulated through the system (SS1).

3. Engineering Report #ER-0003, dated May 31, 2000 and June 1, 2000, states that all the [redacted] high pressure pumps in the Model 89A1 and 90B1 SS1s have been replaced with the [redacted] high pressure pumps during the 1999 Pump upgrade program, which began in February of 1999. According to your "510(k) Modification Analysis Memo," and Service Bulletins 98030-1, 97019-1, 97054-1 and 98025-1, between April 1997 and March 1998, your firm made several changes to the high pressure pump assembly in an effort to address reported problems with the high pressure pump and high pressure pump switch and to reduce high replacement rates of these parts.

4. On August 6, 1999, you issued a service bulletin stating that all [redacted] circulation pumps in the SS1 were to be replaced domestically by the [redacted] pump, and internationally by the [redacted] pump. According to an interoffice memorandum, dated January 23, 1998, you switched to the new pumps because of poor reliability and a low circulation pressure condition.

Your response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may send a facsimile to her at (513) 679-2773, or email her at gina.brackett@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Stryker Craniomaxillofacial Issues Nationwide Recall of its Custom Cranial Implant Kits; Catalogue Numbers 54-00101, 54-00102, 54-00103 and 54-00104, all lots shipped sterile

Contact:
Patrick Anderson, Stryker Corporation
(269) 385-7253
Patrick.Anderson@Stryker.com

Aaron Kwittken, Kwittken & Company
(646) 747-7144
AKwittken@Kwitco.com

FOR IMMEDIATE RELEASE -- Portage, Mich.,-- Dec. 23, 2008 --- Stryker's Craniomaxillofacial (CMF) business unit announced today that the U.S. Food and Drug Administration (FDA) concluded on Dec. 18, 2008 that its recall of the following Stryker CMF's Custom Cranial Implant Kits is a Class I recall, which means the product could pose an imminent hazard to health: Catalogue Numbers 54-00101, 54-00102, 54-00103 and 54-00104, all lots shipped sterile.

The notification relates to a nationwide voluntary recall initiated by Stryker CMF on Oct. 24, 2008 of 322 Custom Cranial Implant Kits after determining that the sterilization validation of the product was not performed according to appropriate standards. Because the company could not assure the sterility of the product, implantation could result in serious health problems including infection (e.g., meningitis), intracranial abscess, wound infection, sepsis, re-operation with revision of cranioplasty, long-term neurological deterioration, additional hospitalization, or long-term intravenous antibiotic treatment. Death can occur if an infection is not diagnosed quickly.

Physicians and hospitals who have product that corresponds to the catalogue numbers listed above should stop implanting the product immediately and return it to Stryker CMF. Stryker recommends that patients who have received these implants be monitored by their physicians for signs of infection for at least six months post-implantation.

Stryker CMF previously notified implanting surgeons, hospital risk managers and its sales representatives of the potential health risks associated with the kits and requested that they return any remaining products to Stryker CMF. Stryker CMF will again notify implanting surgeons, risk managers and its sales representatives of this recall and its potential health risk and request that physicians or hospitals return to Stryker CMF any of this product that has not been implanted.

Physicians and patients with questions related to this issue should contact Stryker CMF at 800-962-6558, Monday – Friday, 8 a.m. to 7 p.m. ET. Patients with questions are encouraged to speak with their surgeon. Any adverse events relating to this product should be reported to Stryker.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Stryker Corporation is one of the world's leading medical technology companies with the most broadly based range of products in orthopaedics and a significant presence in other medical specialties. For more information about Stryker, please visit www.stryker.com.

#

RSS Feed for FDA Recalls Information [what's this?]

Sign up for Recall email updates.

FDA Newsroom

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FDA Website Management Staff

This release was revised on January 9, 2009 to include changes to the fourth paragraph.

FDA News

FOR IMMEDIATE RELEASE
January 2, 2009

Media Inquiries:
Siobhan DeLancey, 301-796-4668
Consumer Inquiries:
888-INFO-FDA

FDA Announces Class I Recall of Ophthalmic Surgical Device

The U.S. Food and Drug Administration announced a Class I recall of lot no. UD30654 of Healon D, an ophthalmic viscosurgical device (OVD) manufactured by Advanced Medical Optics Inc. (AMO) of Santa Ana, Calif.

OVDs are viscoelastic materials used to maintain space in the eye during surgery. Typically, OVDs are pre-packaged in a syringe and are applied using a small tube.

On Oct. 30, 2008, AMO voluntarily recalled all 4,439 units of Healon D lot no. UD30654 of Healon D, due to complaints of inflammation after eye surgery, including Toxic Anterior Segment Syndrome (TASS). At that time, AMO informed customers of the number and nature of adverse event reports associated with OVD from that lot, and included a fax reply form for quick communication.

As of Dec. 3, 2008, AMO had retrieved 964 units and accounted for most of the 1,450 units that had been distributed in the United States.

AMO received 66 adverse event reports associated with the recalled products. Tests of this lot revealed elevated levels of endotoxin, which has been associated with post-operative intraocular inflammation and TASS.

TASS is a post-operative, acute inflammation of the anterior segment of the eye (the front third of the eye including the cornea, iris and lens). TASS has been linked to solutions and devices used during eye surgery, such as OVDs, intraocular lenses and irrigation solutions.

The FDA urges anyone in possession of any units from the recalled lot, whether units were purchased from the company or provided as a sample by a sales representative, to remove them from inventory, and contact AMO at 1-877-AMO-4Life to make arrangements for return. The lot number of the device is displayed on the side panel of each unit.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to AMO by calling 1-877-AMO-4LIFE and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm
Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787
Fax: (800) FDA-0178
Phone: (800) FDA-1088

FDA Unique Device Identification Public Workshop: February 12, 2009

Federal Register Notice

FDA has published a notice in the Federal Register announcing a Public Workshop on 12 February 2009 and requesting comments on a number of UDI related issues.

Please see Docket No. FDA-2008-N-0661, CDRH 200866. Unique Device Identification System; Public Workshop; Request for Comments (also available in PDF form).

Comments due February 27, 2009.

(NOTE: The registration link in the Federal Register notice is incorrect. Registration details are available here.)

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Date, Time and Location

The meeting will be held on 12 February 2009 from 9:00 a.m. to 5:00 p.m. at the following location:

Marriott Gaithersburg Washingtonian Center
9751 Washingtonian Boulevard
Gaithersburg, MD, 20878
(301) 590-0044
www.marriott.com/hotels/travel/waswg-gaithersburg-marriott-washingtonian-center

- Logistical information about other hotels, travel, and parking is also available.

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Agenda (preliminary)

Date/Time	Agenda
February 12, 2009 8:00 - 9:00am	Registration and Continental Breakfast
9:00– 9:15	Welcome and Introduction *Jay Crowley*
9:15 – 10:30	The Unique Device Identifier (standards, production identifier, small packages)
10:30 – 10:45	BREAK
10:45-12:00	Placement and Technology (kits, standards (1D and 2D), direct part marking, RFID)
12:00 – 1:00	LUNCH
1:00 – 2:15	The Unique Device Identifier Database (elements/attributes, development, use)
2:15– 2:30	BREAK
2:30 – 3:45	Implementation and Adoption (by stakeholders, e.g., distributors, hospitals, payors)
3:45– 4:45	Other presentations (time permitting)
4:45 – 5:00	Wrap-up and close

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Registration

Registration for the UDI Public Workshop is closed. You may send an email to cdrhudi@fda.hhs.gov requesting to attend the meeting, and we will let you know if space is available. Alternatively, the meeting is being simultaneously webcast; see below for details..

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Webcasting

We will also be providing real-time webcasting of the meeting. The link for the webcast will be posted to this site approximately one week prior to the meeting. Though you do not need to register for to use the webcast, we will send out information about the webcast to those who request it – please contact cdrhudi@fda.hhs.gov.

Webcast participants will also be able to submit questions and comments electronically.

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Contacts

The workshop organizer may be contacted at:

Jay Crowley
Center for Devices and Radiological Health
U.S. Food and Drug Administration
1350 Piccard Drive, HFZ-500
Rockville, Maryland 20850
240-276-2389
e-mail: jay.crowley@fda.hhs.gov

Updated February 2, 2009
