U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Maquet Medical Systems, Tiger Paw System II - May Cause Tears and Bleeding in Heart Tissue

Recall Class: Class I

Date Recall Initiated: March 25, 2015

Device: TigerPaw System II

- **All Lots**
- **Part and Serial Numbers:**
  - C-TP-1507 (7 connectors)
  - C-TP-1509 (9 connectors)
- **Distribution Dates:** April 1, 2013 through March 23, 2015
- **Number of Units Distributed in the U.S**. 4,154
- **U.S. Distribution:** 223 Customers

Use: The TigerPaw II is a surgical staple used to close tissue in the left atrial appendage (LAA) of the heart.

Recalling Firm:
Maquet Medical Systems
45 Barbour Pond Drive
Wayne, New Jersey 07470

Manufacturer:
Laax, Inc.
151 Lindbergh Avenue, Suite I
Livermore, California 94551

Reason for Recall:

- Incomplete closure of the TigerPaw System II may result in tissue tears and/or bleeding.
- Possible tear on the left atrial wall (top left chamber) during use of the device

The firm received 51 reports of adverse events and one death.

Use of this recalled device may cause serious adverse health consequences, including death.

Public Contact: For further information about this recall, contact Maquet Customer Service at **CSsurgery@Maquet.com (mailto:CSsurgery@Maquet.com)** or at 1-888-880-2874, Monday - Friday from 6 a.m. - 5 p.m., Pacific Daylight Savings Time.

FDA District: San Francisco District Office

More Information about this Recall:

Maquet Medical Systems, on behalf of Laax, Inc., sent an "Urgent Medical Device Recall (Removal) Immediate Action Required" letter, dated March 30, 2015, to all affected customers. The letter described the product, problem, and actions to be taken.

Customers were instructed to:

- Immediately examine inventory for any TigerPaw System II recalled devices.
- Remove, quarantine, and place recalled devices in a secure location.
- Complete and return the Medical Device Recall (Removal) Response Form by emailing a scanned copy to **TigerPaw2015@maquet.com (mailto:TigerPaw2015@maquet.com)** or FAX to 1-(973)-396-3607.

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.

More in Medical Device Safety (/MedicalDevices/Safety/default.htm)

- Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)
- 2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)
- 2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)
- 2013 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384618.htm)
- Learn About Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm061973.htm)