

May 10, 2010



FDA Safety Announcement: Weck Hem-o-Lok Ligating Clips: Contraindicated for Ligation of Renal Artery During Laparoscopic Living-Donor Nephrectomy

AUDIENCE: Urology, Transplant Surgery, Risk Manager

ISSUE: The FDA has notified health care providers that Weck Hem-o-Lok Ligating Clips should not be used for the ligation of the renal artery during a laparoscopic living-donor nephrectomy because of serious risks to the donor. There is the potential for the clips to become dislodged, which can lead to uncontrolled bleeding, additional surgery, or death of the donor. In 2006, the manufacturer added this contraindication to the Instructions for Use after receiving 15 reports of 12 injuries and three deaths which occurred between 2001 and 2005. Since the contraindication issued in 2006, there have been three more kidney deaths, all associated with the contraindicated use.

BACKGROUND: The Weck Hem-o-Lok Ligating Clip is a V-shaped clip made from a non-absorbable material that comes in various sizes. It is used to permanently close bleeding vessels or tissue structures.

While there are published journal articles that appear to endorse the continued use of Weck Hem-o-Lok Ligating Clips for ligating the renal artery during laparoscopic living-donor nephrectomies, the Organ Procurement and Transplantation Network (OPTN) and the American Society of Transplant Surgeons issued separate safety notifications reinforcing the contraindication to their members and to all OPTN-approved living-donor kidney transplant programs.

RECOMMENDATION: See the FDA [safety communication](#) for a listing of affected model numbers, and recommendations for healthcare providers, hospital staff, and patients.

To help the FDA learn as much as possible about the adverse events associated with Hem-o-Lok Ligating Clips, please include the following information in your reports:

- Manufacturer's name
- Device name (brand name)
- Date device was manufactured
- Distributor's name
- Details of adverse event and medical and/or surgical interventions
- Complete and submit the report online: www.fda.gov/MedWatch/report.htm

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm254363.htm>

www.kcercoalition.com/alerts.htm