COOK INCORPORATED
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PHONE: 812.339.2235 TOLL FREE: 800.457.4500
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# Recall Communication
## Updated Instructions for Use

Affected Products: Cook LapSac® Surgical Tissue Pouch

May 20, 2015

Dear Health Care Provider:

Cook Medical is recalling the Instructions for Use (IFU) for the LapSac® Surgical Tissue Pouch to **remove morcellation** from the **Intended Use**, **Warnings and the Instructions and to add a Contraindication**. This recall is to correct the IFU; the IFU is being recalled and updated to reflect these changes. Though, this is a recall notification of the IFU, neither device nor IFU need to be returned to Cook Medical. Additional updates to the IFU are being made to emphasize best practices in conjunction with the November 24, 2014 Updated Laparoscopic Uterine Power Morcellation in Hysterectomy or Myomectomy: FDA Safety Communication discouraging use of laparoscopic power morcellation in cases where the presence of cancerous tissue cannot be ruled out.

Modifications made to the IFU are as follows:

The **intended use** for the device is being modified from "Used to isolate tissue during, or prior to, surgical removal and/or morcellation" to "Used to isolate tissue during, or prior to, surgical removal".

A **contraindication** being added is as follows:

- Not for use with power morcellators.

The **warnings** are being modified to read as follows:

- The LapSac Surgical Tissue Pouch is not intended for use with sharp surgical instruments.
- Care should be taken to avoid damaging, puncturing or tearing the LapSac Surgical Tissue Pouch.
- Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.

The **instructions for use** are being modified to read as follows:

1. Following aseptic technique, introduce the LapSac Surgical Tissue Pouch into the abdominal cavity.
2. Place tissue to be removed from the body into the pouch.

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**Recall Communication (continued)**
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3. Using the drawstring, carefully close the LapSac Surgical Tissue Pouch. Please note that if excess force is used, the drawstring may break or tear the LapSac.
4. Remove the LapSac Surgical Tissue Pouch from the body, taking care not to spill contents of the bag.

Refer to the attached Recall Response Form listing for specific product identifiers. Your facility has received shipment(s) of at least one of these products. Please complete this attachment and return as instructed on the bottom of the form.

Please report any Adverse Event to Cook Medical Customer Relations (800) 457-4500 or 1-812-339-2235. Monday through Friday between 7:30 a.m. and 5:00 p.m. Eastern Daylight Time or email at CustomerrelationsNA@cookmedical.com

Adverse events or quality problems experienced with the use of this product may also be reported to FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail) or
- Call FDA 1-800-FDA-1088

This notice must be passed on to appropriate personnel within your organization or to any organization where the potentially affected devices have been transferred.

If you have further questions regarding labelling changes for this device, please contact your Cook Sales Representative or Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339-2235.

Sincerely,

COOK MEDICAL

[redacted]

Rita A. Harden
Director, Customer Relations and Regulatory Reporting