

**EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) FOR  
PERCUTANEOUS SURGICAL SET WITH 5 MM OR 10 MM ATTACHMENTS**

**REGULATORY INFORMATION**

FDA identifies this generic type of device as:

Manual Percutaneous Surgical Set Assembled in the Abdomen. A device consisting of a percutaneous surgical set and accessories used as a means to penetrate soft tissue to access certain areas of the abdomen. The device's effectors or attachments are provided separately from the percutaneous shaft and are introduced to the site via a traditional conduit such as a trocar. The attachment or effectors are connected to the shaft once the tip of the shaft is inside the abdomen. Once inside the abdomen, the surgical set is used to grasp, hold, and manipulate soft tissues.

A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

**NEW REGULATION NUMBER:** Sec. 878.4790 Manual Percutaneous Surgical Set Assembled in the Abdomen

**CLASSIFICATION:** II

**PRODUCT CODE:** OXT

**BACKGROUND**

**DEVICE NAME:** Percutaneous Surgical Set with 5 mm or 10 mm Attachments

**510(K):** K110431

**DATE OF 510(K) NSE DECISION:** August 26, 2011

**DATE OF DE NOVO PETITION:** September 21, 2011

**PETITIONER CONTACT:**  
Ethicon Endo-Surgery, Incorporated  
4545 Creek Road  
M/L 131  
Cincinnati, Ohio 20993

**PETITIONER'S RECOMMENDED CLASSIFICATION:** II

### **PETITIONER'S RECOMMENDED CONTROLS:**

- The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109.
- The labeling includes specific instructions regarding the proper assembly/disassembly and use of the device.
- The device has been demonstrated to be biocompatible and sterile.
- Preclinical and bench testing has demonstrated that assembling and disassembling the device inside the body can be appropriately achieved.
- General controls

### **INDICATIONS FOR USE**

The Percutaneous Surgical Set with 5 mm or 10 mm Attachments is indicated for the means to penetrate soft tissue to access certain areas of the human abdomen and used to grasp, hold and manipulate tissue.

### **LIMITATIONS**

Please refer to the labeling for a more complete list of warnings, precautions and contraindications.

### **DEVICE DESCRIPTION**

The Percutaneous Surgical Set with 5mm or 10mm Attachments is a family of minimally invasive devices that can penetrate soft tissue, be assembled *in situ*, and allow access to certain areas of the abdomen. The Set is designed for assembly within the abdomen to grasp, hold or manipulate soft tissue. There are three attachments (or end effectors): a 5 mm grasper, 5 mm Maryland dissector and a 10 mm Babcock grasper. The attachments can be mounted individually to the 3 mm percutaneous metal shaft.

The device is for single use only and is disposable.

### **SUMMARY OF NONCLINICAL/BENCH STUDIES**

#### **BIOCOMPATIBILITY/MATERIALS**

All components of the Percutaneous Surgical Set are made of surgical grade stainless steel, with exception of the loader end, which is comprised of a polycarbonate. These are commonly used materials for surgical instruments.

The patient-contacting components of the Percutaneous Surgical Set were evaluated with respect to their intended use per ISO 10993-1:2003. Testing was performed on finished, sterilized devices. The Percutaneous Surgical Set was evaluated for cytotoxicity (ISO 10993-5), irritation and sensitization (ISO 10993-10), and systemic toxicity (ISO 10993-

11). All patient-contacting devices were shown to be biocompatible per ISO 10993-1:2003 with respect to their intended uses.

### **SHELF LIFE/STERILITY**

The Percutaneous Surgical Set is packaged as one unit. Each surgical set is placed in a polyethylene terephthalate glycol-modified (PETG) tray with lid, then heat sealed with a Tyvek® lid to form the sterile barrier. Each sealed tray is placed inside a carton. Each carton contains only one tray. The single pouch is placed in an outer carton along with the instructions for use (IFU). The Percutaneous Surgical Set attachment with attachment cartridge is placed in a plastic insert, packaged in a Tyvek® pouch and heat sealed to form the sterile barrier.

The Percutaneous Surgical Set is sterilized by cobalt irradiation. The sterilization process validation and routine monitoring comply with ISO 11137:2006 and ISO 11137:2007, using the method VDmax.

The shelf life of one year has been established through testing of devices and packaging exposed to a combination of accelerated and real-time aging in accordance with ASTM F 1980-07: Standard Guide for Accelerated Aging of Sterile Medical Device Packages.. All test devices and packages underwent environmental testing in a climate controlled area for the full shelf-life duration.

### **PERFORMANCE TESTING – BENCH**

Comprehensive bench testing has been successfully completed on the Percutaneous Surgical Set. Testing included functional, dimensional and force verification, as summarized below. Testing was performed on finished, sterile devices. All devices were shown to meet pre-determined acceptance criteria. These tests were conducted using six devices to show that the mechanical design is able to be used in the abdomen.

A summary of each test is provided below:

- Functional Verification – Test developed to determine whether the device could be assembled or disassembled in the abdomen. Additionally, this test was used to demonstrate that the device could grasp, hold and manipulate soft tissue.
- Dimensional Verification – Test developed to determine whether the dimensions of the device are adequate for use in the abdomen, including items such as working length, overall length, and ability to fit through a trocar.
- Force Verification – Test developed to measure the pressure applied to the grips each time the device is in use.

### **SIMULATED USE TESTING**

To demonstrate the device's ability to penetrate soft tissue, to be assembled *in situ*, and to grasp, hold, and manipulate soft tissues, the sponsor conducted testing in a porcine model (1 pig was used), with 3 Percutaneous Surgical Sets. Comparison testing with alternative

surgical instruments that are not designed for assembly/disassembly *in situ* to ensure that the Percutaneous Surgical Set could penetrate, grasp, hold and manipulate soft tissue without inadvertent device disassembly was also conducted. Multiple insertion sites were conducted on the animal. Also, testing on 3 devices not requiring in situ assembly already cleared for a similar indication were used as the control device.

The sponsor provided descriptions about how the device functions as well as videos, including having 25 surgeons perform the test procedure in the insufflated porcine abdomen. There were a total of 75 attempts with 2 attempts resulting in an unsuccessful attachment (the unsuccessful attachments occurred during the users' first attempt with the device). Total assembly/disassembly times averaged slightly over 80 seconds for the first test procedure, decreasing to 60 seconds by the third test procedure.

### **ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY**

Electromagnetic and electrical concerns do not apply to this manual surgical device. Mechanical properties are provided in bench testing.

Note: It is envisioned that the Agency will be able to rely upon well-designed bench and/or animal testing rather than clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies may not be needed for most manual percutaneous surgical sets assembled in the abdomen, FDA may recommend that you collect clinical data for the following situations:

- indications for use dissimilar from a legally marketed system of the same type; or
- different technology; designs dissimilar from this design or subsequent designs that may be cleared under a premarket notification.

New intended uses or technology differences that raise different questions of safety or effectiveness may be grounds for not reviewing the device through the 510(k) pathway.

### **LABELING**

The Percutaneous Surgical Set complies with the labeling requirements under 21 CFR 807.87(e) and prescription device requirements under 21 CFR § 801.109. The device is exempt from having adequate directions for lay use. The device labeling bears the following: "Caution: Federal law restricts this device to sale by or on the order of a physician."

### **RISKS TO HEALTH**

The following table identifies the risks that may be associated with the use of a manual percutaneous surgical set assembled in the abdomen and the measures recommended to mitigate these risks.

## Risks to Health and Recommended Mitigation Measures

<b>Identified Risk</b>	<b>Recommended Mitigation Measures</b>
Adverse Tissue Reaction	Biocompatibility Testing
Device Failure	Performance Testing Sterilization and Shelf Life Testing
User Error	Performance Testing Simulated Use Testing Labeling
Abdominal Cavity Damage	Performance Testing Simulated Use Testing Labeling
Infection	Sterilization and Shelf Life Testing

### **SPECIAL CONTROLS**

The special controls for the Percutaneous Surgical Sets are contained in the special controls guidance document entitled: “Class II Special Controls Guidance Document: Manual Percutaneous Surgical Set Assembled in the Abdomen.”

### **CONCLUSION**

The *de novo* petition for the Percutaneous Surgical Set with 5 mm or 10mm Attachments is granted and the device is classified under the following:

Product Code: OXT

Device Type: Manual Percutaneous Surgical Set Assembled in the Abdomen

Class: II

Regulation: 21 CFR 878.4790