

**DE NOVO CLASSIFICATION REQUEST 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 manual percutaneous surgical set assembled in the abdomen is a prescription 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: 21 CFR 878.4805

CLASSIFICATION: II

PRODUCT CODE: OXT

BACKGROUND

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

SUBMISSION NUMBER: DEN110016 (K110431)

DATE OF DE NOVO: September 20, 2011

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

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

Do not use excessive force.

Once partial entry has been accomplished, very little pressure may be required to complete entry. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.

To prevent damage to trocar seals, do not insert the exposed obturator through the seals of the trocar.

Do not attempt to bend the percutaneous shaft. Forcefully bending the shaft could lead to device damage and the inability to disconnect the attachment from the shaft.

Do not attempt to remove the percutaneous shaft from the body with attachment still connected. This could lead to enlargement of initial percutaneous defect.

After removing the percutaneous shaft from the cavity, always inspect the site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.

Do not introduce or withdraw the loader in the articulated position through a trocar.

Do not use the device to crush or crimp other surgical instruments or foreign bodies.

Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.

Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.

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 VD_{max}25.

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

The sponsor provided descriptions about how the device functions as well as videos, including 25 surgeons performing 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 attachment 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.

Based on the findings of the simulated use testing, no clinical testing was determined to be necessary.

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 labeling bears the following: "Caution: Federal law restricts this device to sale by or on the order of a physician."

The labeling includes a shelf life and instructions for instrument assembly, disassembly, and removal.

RISKS TO HEALTH

Table 1 below 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.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Device failure	Non-clinical performance testing, Sterilization validation, and Shelf life testing
User error	Non-clinical performance testing, Simulated use testing, and Labeling
Abdominal cavity damage	Non-clinical performance testing, Simulated use testing, and Labeling
Infection	Sterilization validation, and Shelf life testing

SPECIAL CONTROLS

In combination with the general controls of the Food, Drug & Cosmetic Act, the manual percutaneous surgical set assembled in the abdomen is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Performance data must demonstrate the sterility of patient-contacting components of the device.
3. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.
4. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - a. Dimensional verification testing must be conducted.
 - b. Force verification testing must be conducted. The force testing must demonstrate the forces necessary to insert and operate each component of the device during use as intended.
 - c. Functional verification testing of the device components must be conducted.
5. Simulated use testing in an anatomically relevant animal model must demonstrate the device's ability to penetrate soft tissue, be assembled *in situ*, and to grasp, hold and manipulate soft tissues in the intended treatment area.
6. The labeling must include the following:
 - a. Instructions for use, including detailed instructions for instrument assembly, disassembly, and removal.
 - b. A shelf life.

CONCLUSION

The De Novo request 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 878.4805