DE NOVO CLASSIFICATION REQUEST FOR CONTAINOR

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **General laparoscopic power morcellation containment system**: A general laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign tissue that is not suspected to contain malignancy.

NEW REGULATION NUMBER: 21 CFR 878.4825

CLASSIFICATION: II

PRODUCT CODE: PZQ

BACKGROUND

DEVICE NAME: ContainOR

SUBMISSION NUMBER: DEN170075

DATE OF DE NOVO: September 29, 2017

CONTACT: Advanced Surgical Concepts
Unit 4 Sunnybank Centre
Upper Dargle Road
Bray, County Wicklow
Ireland

INDICATIONS FOR USE

The ContainOR is a bag containment system intended for use by qualified surgeons for tissue extraction and/or power morcellation during general laparoscopic procedures. The ContainOR is compatible with bipolar or electromechanical laparoscopic power morcellators that are between 15mm and 18mm in shaft outer diameter and 135mm and 180mm in shaft working length and which have an external component that allows for the proper orientation of the laparoscope to perform a contained morcellation**.**

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription use in

accordance with 21 CFR 801.109.

Contraindications

- Do not use for gynecological procedures.
- Do not use on tissue that is known or suspected to contain malignancy.
- Do not use this device on patients with known or suspected allergies to polyurethane.
- Do not use where the abdominal wall thickness is larger than 10 cm.

Boxed Warning

- Information regarding the potential risks of a procedure with this device should be shared with patients. The use of laparoscopic power morcellators may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk.

Warnings

- Do not cut, puncture or scrape the Bag with the morcellator tip, tenaculum/grasper or any sharp instrument.
- Do not use if package or printed information is damaged. The device is supplied sterile; inspect the package to ensure it is intact.
- This device is single-use only. Do not re-sterilize or reuse any portion of this device.
- Re-use or re-sterilization may create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Check for and remove adhesions that may inhibit proper placement of the device.
- The Bag must be fully inflated (12 – 15 mmHg) to minimize the risk of damage to the bag and adjacent organs during morcellation.
- At all times prior to morcellating, make sure the tenaculum/grasper is within view when grasping tissue, to prevent it contacting the Bag.
- The tip of the morcellator must be brought into view, prior to and during each activation to provide confirmation of the position of the morcellator tip and its proximity to the Bag.
- With the tip of the morcellator in view, prior to activating the morcellator, confirm that the tissue specimen is centered within the Bag.
- Do not bring the morcellator tip into contact with the Bag.
- Any abdominal incision introduces a risk of abdominal hernia.

Precautions

- Please read all instructions prior to use.
- Device should only be used with 5mm laparoscopes with ≥30° lens angle or deflectable tip.
- Only use an atraumatic grasper to manipulate the Bag.
- Appropriate pre-operative diagnostic testing should be completed prior to using this device.
- For procedures that contain stones, remove with an atraumatic grasper through the

large valve or incision. For large stones, 4-5 cm, an increase in incision size may be required. Use a surgical retractor to protect the bag if lengthening the incision.

- This device should only be used by surgeons with advanced training in laparoscopic techniques.
- This device should only be used by surgeons who have successfully completed the validated training program.
- Regarding the grasper/tenaculum used, teeth which are curved proximally to shield their sharp tips may help reduce the risk of damage to the bag from the grasper/tenaculum. However, a lower risk grasper does not alter the risk of damage to the bag from the morcellator tip. Careful adherence to the training provided and the Instruction for Use regarding placement and visualization of the tip remains critical.
- After use, the device is a potential biohazard. Handle and dispose of as required by hospital policy and applicable laws.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS AND PRECAUTIONS.

DEVICE DESCRIPTION

The ContainOR device consists of two main components:

- A laparoscopic multi-instrument port
- Tissue pouch (Bag) intended to provide a contained space in the abdomen for the safe morcellation of tissue.

Figure 1: ContainOR Device with labeled components

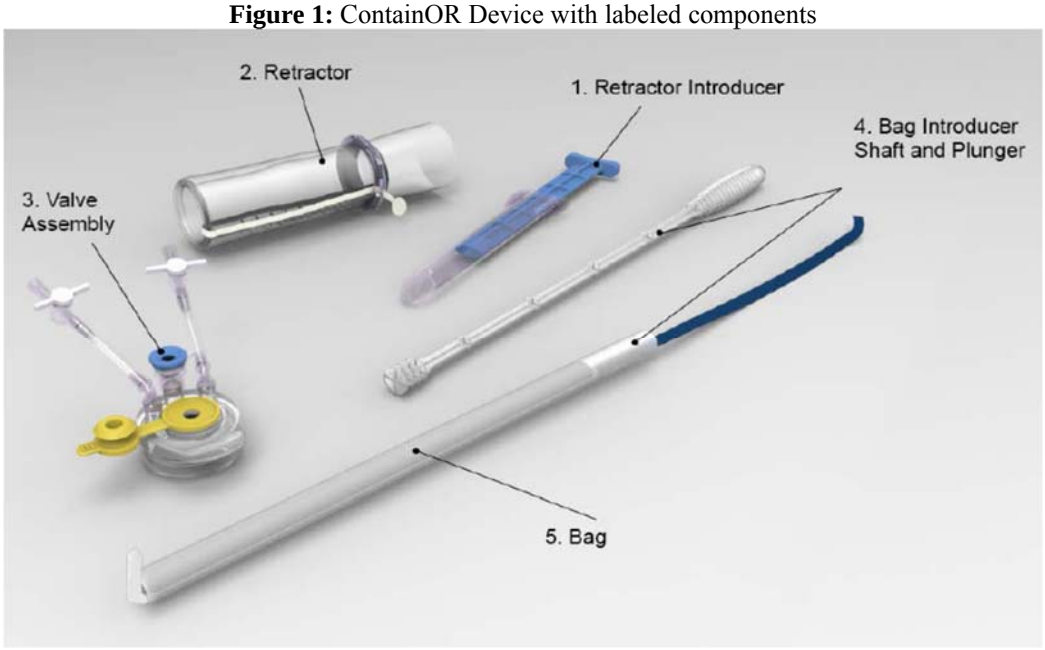

Figure 1 describes the sub-components of the device. The laparoscopic multi-instrument port consists of the Retractor, Retractor Introducer, and the Valve Assembly.

The *Retractor Introducer* is placed through the abdominal incision to deliver the distal ring on the *Retractor*. The Retractor retracts the incision to allow passage of laparoscopic instruments and provides an anchor for the *Valve Assembly.* The *Valve Assembly* consists of two insufflation ports and two instrument ports. The insufflation ports are used to maintain pneumoperitoneum and to vent smoke during the course of the procedure. The instrument ports consist of the large instrument valve port which allows the introduction for the Bag and Morcellator and a 5mm valve port that can accommodate a 5mm instrument such as a laparoscope or grasper. The large instrument valve includes a reducer than can reduce the valve opening to 5mm for smaller instruments.

The *Bag* is preloaded into the *Bag Introducer*, which is inserted through the Large Instrument Valve in the Valve Assembly. The *Bag Introducer Plunger* is depressed into the shaft, ejecting the Bag into the abdominal cavity.

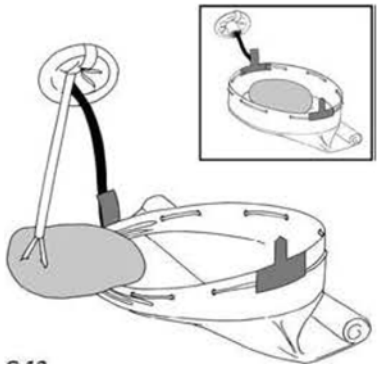

Figure 2. Tissue specimen being placed in Bag

In Figure 2, an opening ring on the neck of the Bag ensures the bag remains open. Once the specimen is placed in the bag, a tether closes the Bag and exteriorizes the collar section. The Valve Assembly can then be reattached inside the exteriorized Bag enabling inflation of the bag and re-establishing pneumoperitoneum. The multi-instrument port may now be used for power morcellation under direct visualization.

After morcellation is complete, the Bag is deflated and the Valve Assembly is removed. The Bag is removed followed by the Retractor.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The ContainOR system includes materials and colorants that have direct and indirect patient contact for duration of up to 6 hours. The complete device in its final, finished form was subject to an evaluation of biocompatibility in accordance with ISO 10993-1: Biological evaluation of medical devices, Part 1: Evaluation and Testing. The

ContainOR system is an externally communicating device, contacting tissue/bone/dentin for limited duration <24 hours. Given that the ContainOR is identical in its final finished form to the PneumoLiner (DEN150028), no additional testing from what previously evaluated in DEN150028 was required.

SHELF LIFE/STERILITY

The ContainOR is provided sterile for single use. The device is (b) (4) to achieve a sterility assurance level of 10^{-6}. It is packaged in a blister tray with a Tyvek lid. The sterilization validation was conducted in accordance with ISO 11137:2006.

Samples of the device were subjected to accelerated aging to simulate a 1 year shelf life. Device samples were evaluated for visual inspection and barrier properties (seal strength and bubble leak) in accordance with the following standards:

- Visual inspection per ASTM F1886: 2009 (2013)
- Bubble Leak testing per ASTM F2096:2011
- Seal Strength per ASTM F88:2009

Fifteen samples were used for the visual inspection and bubble leak tests. Sixty samples were used to assess seal strength. All samples passed.

Device functionality was assessed following 1 year of accelerated aging. Thirty-five samples representing the final, finished product were assessed using a protocol that mimics the design verification testing described in the bench testing section of this summary. In summary, the samples were put through the steps of a simulated use and assessed for leakage. At the completion of the simulated use, the ContainOR pouch was filled with (b) (4) water and inspected for leaks. This was followed by bond and material strength testing of the device components. The tested samples met the test acceptance criteria.

The information provided supports a 1 year labeled shelf-life for the ContainOR system.

PERFORMANCE TESTING – BENCH

Barrier Testing

The purpose of the Barrier Testing was two-fold:

- To demonstrate that the pouch material is impermeable to human cells through use of bacteria smaller than a human cell (filter test), i.e., *Brevundimonas diminuta*; and
- To demonstrate the integrity of the ContainOR pouch post-morcellation (immersion test).

Before performing the barrier testing, the sponsor validated the initial cleaning and sterilization step to ensure that bacterial cultures are not present at the beginning of the

tests. In addition, the sponsor determined the minimum concentration of *B. diminuta* that could be identified visually (i.e., (b) (4)).

Filter Testing

The first barrier test was a filter test. The method involved filtration of Tryptone Soya Broth (TSB) containing *B. diminuta* through sections (discs) of ContainOR pouch which included a seam.

In summary, the ContainOR pouch material was placed between two containers. The top container included TSB containing *B. diminuta,* and the bottom container contained sterile TSB. Vacuum was applied below the ContainOR pouch material to attempt to filter the "spiked" TSB through the ContainOR pouch material. Twenty five samples were tested.

The Sterile TSB collection container was incubated (b) (4) along with positive controls (ContainOR pouch with pinhole and "spiked TSB") and a negative control (TSB). There was no evidence of growth in the 25 samples and the positive and negative controls performed as expected.

The results of the testing are acceptable and validate the utility of this method.

The filter barrier testing was repeated on samples of ContainOR pouch that had undergone 1 year of accelerated aging. Each sample (b) (4) of the ContainOR pouch such that it included the seam. Thirty-three samples (32 test and 1 control) were tested. The 32 test samples all passed with no evidence of growth of bacteria when challenged with (b) (4) *B. diminuta*. The positive control sample, ContainOR pouch with pin hole, had evidence of growth.

The pass criteria for the filter barrier test required superiority against an 85% rate of passing the leakage test. Based on zero failures in this sample of 32, the estimated lower bound for passing the leakage test is 0.893, based on a 95% confidence interval.

The information provided on the filtration testing is sufficient to support the impermeability of the ContainOR pouch material including the seam to cells greater than the size of bacteria.

Immersion Testing

The second barrier test was an immersion test to assess ContainOR pouch permeability. The ContainOR pouch was filled with sterile TSB, (b) (4)

The ContainOR pouch was removed, then incubated for (b) (4), and checked for growth of bacteria. Positive controls (ContainOR pouch with a pinhole leak and ContainOR pouch with TSB inoculated with *B. diminuta*) and a negative control were tested as well.

There were issues with the heat sealing method used; however, twenty-five samples were tested with no evidence of (b) (4) following incubation.

The results of the testing are acceptable and validate the utility of this test method.

The testing was repeated with devices that had been subjected to powered morcellation. As a result of the issues with the (b) (4) noted during the validation testing, the sponsor revised the protocol to incorporate a check of the (b) (4) during the immersion test, including the following checkpoints:

- Post morcellation
- Post application of the (b) (4)
- Post initial incubation
- Post immersion

If a leak was noted at the (b) (4) the rest of the device was checked for a leak. If the only leak noted was at the (b) (4), the sample was excluded from the test results. If a leak was also discovered elsewhere in the device, the sample was included in the analysis. In addition, the sponsor also excluded any samples which showed the presence of bacteria other than the test bacteria explicitly included as part of the test environment.

In the first test group, the sponsor included 35 samples, 32 test and 3 controls. Six samples in the test group were excluded because they failed the initial leak test following (b) (4). Following immersion, no samples were excluded. Four samples in the test group were excluded due to the growth of aberrant bacteria. The remaining 22 samples in the test group were included in the analysis. All of these samples passed and the 3 samples in the control group performed as expected.

As a result of having to exclude a number of samples from further analysis due to the presence of other bacteria, the protocol was revised to require (b) (4) prior to the immersion test to rule out those samples in which aberrant bacteria were noted.

Since the number of samples available for analysis was smaller than the sample size calculated to test the hypothesis, additional samples were procured. An additional 24 samples were evaluated under the revised protocol, 3 samples were excluded for leaks following (b) (4). An additional six were excluded for contamination following the incubation period. Of the 15 samples remaining, 12 were designated as test samples and 3 as controls. These samples were immersed. Two of the test samples were excluded for leak following the incubation. There were a total of 10 test samples in the analysis and 3 controls. The 10 test samples all passed and the controls performed as expected

The immersion testing was designed to detect superiority against a set failure rate using a one sided significance level of 0.025 and 90% power. The maximum allowable failure rate was set at 0.125 (12.5%). Using these values, the calculated required sample size is

28 samples. Given that a total of 32 samples were tested without any failures, the upper bound on the 95% confidence interval was a failure rate of 0.107.

In summary, of the 59 total devices selected for immersion testing, only 38 samples were considered in the analysis (32 test samples and 6 controls.) While the number of test samples that had to be excluded from analysis was unexpected, the exclusions were defined *a priori* and were acceptable given the challenges posed by the test method and the test environment.

Overall, the barrier testing conducted supports that the ContainOR pouch materials are impermeable to bacteria, which are smaller than human cells, and the device following powered morcellation maintains its integrity when used in accordance with the parameters identified within the labeling.

Preliminary Bench Testing

The sponsor provided a set of initial tests intended to generate acceptance criteria for their design verification tests as well as to validate the surgical simulator and training rig developed specifically for the ContainOR system. The sponsor also performed some preliminary tests to profile the strength characteristics of the device. These tests, summarized below, did not include acceptance criteria:

- Laparoscope – evaluated the force required for the laparoscope to puncture the ContainOR pouch material. The minimum force to puncture (b) (4) 30 test samples.

- Tenaculum – evaluated forces required for grabbing the material and damaging the material using tenacula at different angles and forces. Each of 5 different tenacula was tested with 30 material samples. Two of the five tenacula were able to damage the material when open. The minimum force required (b) (4) Most of the tested tenacula caused damage to bags when scraped along them. (*As a result of this finding, a safety statement was added to the labeling.*)

- Powered Morcellation – Each of the available powered morcellators (5 different brands) was used once in a simulated use test rig with the ContainOR pouch insufflated to intentionally attempt to contact the liner with the tip. The volume in the rig was decreased using inserts. In all cases the morcellator could contact the ContainOR pouch, if it were pushed at an extreme angle to the side, which was not reflective of the expected use or even probable misuse, as the morcellator is used at an angle of 70° to 90^0 to the abdominal wall. (*As a result of this finding, additional safety statements were added to the labeling.*)

- Pressure/Burst Testing – Thirty ContainOR system samples were evaluated. The ContainOR pouch was insufflated (b) (4) intended pressure, (b) (4) a simulated use test rig (b) (4) No damage was noted. The ContainOR pouch samples were then attached to compressor and inflated to burst.

The minimum pressure recorded at failure (b) (4)

- Obstruction Testing – A large tissue specimen (one that cannot fit through the incision) was placed inside the ContainOR pouch. A force gauge was attached to the collar of the ContainOR pouch and the force required to remove the device from the incision was recorded. In the 30 samples tested, no failures were noted at the (b) (4) force of the gauge.

Design Verification

Design verification testing was conducted using various laparoscopic instruments including graspers, laparoscope, variety of tenacula (including representative samples of the different types of grasping jaws), and various morcellators. There were nine separate tests intended to assess device performance. Each of these tests included 30 or more device samples. Table 1 below includes the steps within each test that included quantitative acceptance criteria.

Table 1 – Design Verification

Test	Acceptance Criteria	Results
Test 1 Inspection of Components		
	Components match color and description, free from damage and no sharp edges, features	Pass
Test 2 Performance and Set-up of Retractor		
• Retract a section (b) (4) mm thick abdomen and maintain incision opening	Incisions remain retracted after 3 hours	Pass
• Removal Force	(b) (4)	Pass
• Time to set-up retractor		Pass
Test 3 Set-up and Use of Valve Assembly		
• Time to attach valve	(b) (4)	Pass
• Time to remove valve		Pass
• Flow Rate		Pass
• Time to attach Reducer from Large Instrument Valve		Pass
• Time to remove Reducer from Large Instrument Valve		Pass
• Leakage rate		Pass*
Test 4 Set-up and Use of ContainOR System		
• Time to insert ContainOR system	(b) (4)	Pass
• Time to remove ContainOR system	(b) (4)	Pass
Test 5 Inspection of components, assemblies, seams		

	No leakage when ContainOR filled with (b) (4)	Pass
Test 6 Base Retractor Assembly		
• Inner Proximal Ring to Retracting Sleeve Weld	(b) (4)	Pass
• Removal Ribbon to Inner Proximal Ring Weld	(b) (4)	Pass
• Retracting Sleeve Seam Weld, 25 mm section	(b) (4)	Pass
Test 7 Valve Assembly		
• Insufflation tubing to valve assembly	(b) (4)	Pass
• 5 mm valve to Valve bond		Pass
• Reducer valve to Large valve assembly	(b) (4)	Pass
• Large Valve to Valve Bond	(b) (4)	Pass
Test 8 ContainOR Pouch Assembly		
• Proximal tab to ContainOR pouch	(b) (4)	Pass
• Distal Tab to ContainOR pouch	(b) (4)	Pass
• ContainOR pouch tether to Opening Ring	(b) (4)	Pass
• Opening ring crimp	(b) (4)	Pass
• ContainOR pouch body weld at bottom end, 25 mm section	(b) (4)	Pass
• ContainOR pouch body weld at corner, 25 mm section	(b) (4)	Pass
• ContainOR pouch body weld at side, 25 mm section	(b) (4)	Pass
• ContainOR pouch weld between body and collar, 25 mm section	(b) (4)	Pass
Test 9 Forces required to use ContainOR system		
• Insert Distal Ring	(b) (4)	(b) (4)
• (b) (4)		(b) (4)
• Retract Sleeve		Pass
• Attach Valve		Pass
• Insert Introducer		Pass
• Eject ContainOR pouch		Pass
• Attach Reducer		Pass
• Remove Reducer		Pass
• Remove Opening Ring		Pass

• Remove Valve	(b) (4)		Pass
• Exteriorize pouch			Pass
• Open ContainOR pouch			Pass
• Remove ContainOR pouch			Pass
• Remove Retractor			Pass

**Due to one observation in which passage of a large instrument through the valve resulted in a leakage rate* (b) (4) *the diameter of the valve was decreased* (b) (4) *Testing repeated on the revised design met the acceptance criteria.*

Clinical Simulation of Morcellation

Simulated use testing was conducted to determine the ability of the ContainOR pouch to withstand morcellation using animal tissue, and to validate the test method for finding leaks/punctures following use. A total of 34 ContainOR pouches and 5 ContainOR system valve assembly and retractors were used for the testing along with the following laparoscopic instruments: graspers, trocars, laparoscope, variety of tenacula, and variety of morcellators (including electromechanical and bipolar). (All ContainOR pouches were initially checked for leaks as described in Test 2 below.)

In Test 1, simulated use was carried out in a surgical simulation test rig (SSTR). Of the 34 ContainOR systems used, the first ten tests were run using lamb heart as the tissue specimen, and the final twenty-four with beef tongue to assess different tissue characteristics. Morcellation was carried out in the insufflated ContainOR pouch using one of three different morcellators. Tissue specimen weights ranged from (b) (4) The time to morcellate ranged from (b) (4) Overall, morcellation time reduced as the operator performed more simulated use procedures. Lamb hearts took longer to morcellate compared to beef tongue when used as the tissue specimen. The weight of tissue morcellated ranged from (b) (4) and the weight remaining in the ContainOR pouch was between (b) (4)

The tissue remaining in the ContainOR pouch (b) (4) The largest force measured was 130N. This was below the 200N minimum force the bag can withstand.

Test 2 was a leak test. Each of the 34 samples above was cleaned and dried. (b) (4) Each inspection was carried out (b) (4) No bags were noted to have a leak. These samples were then used in the barrier testing previously described.

Additional Testing to support ContainOR use in General Laparoscopic Procedures

Additional testing was conducted to assess the safety and effectiveness of the device when used in tissue that may contain stones (e.g. kidney stones). The first test validated simulated kidney stones of various sizes, shapes, and composition for subsequent use in simulated use testing. These stones were molded (b) (4)
Two urologists confirmed that the simulant stones accurately mimicked the size and composition of actual kidney stones.

ContainOR performance was tested when morcellation is performed on tissue containing the artificial stones. The simulated use testing was performed using porcine kidneys with stones placed in the validated surgical simulator rig. Following morcellation of the tissue, the bag was tested for leaks using the validated water leak test cited above. Simulant stones typically remained intact and did not fracture or break unless directly applied with the morcellator. The fractured stones did not lead to any bag damage or leaks and were retrieved similarly to smaller stones. For larger stones, the sponsor observed that the incision size should be expanded to allow ease of removal. This led to additional changes to the labeled instructions for use.

Additional testing was performed to reaffirm the previously validated training program with general laparoscopic surgeons. The users set up and performed morcellation of a porcine kidney containing simulant stones in the surgical simulation test rig. The device was then tested for leaks post procedure to demonstrate that the inclusion of kidney stones did not adversely impact the containment function of the ContainOR. Five general surgeons were trained in the use of the device using the previously validated training for the PneumoLiner and the proposed ContainOR instructions for use. The general surgeons were able to use the ContainOR safely and effectively, and the stones were safely removed without compromising the bag integrity. There was no damage to the bag or leaks post morcellation.

PERFORMANCE TESTING – ANIMAL &/OR CADAVER

Testing in an animal model was used for training validation and design validation.

ContainOR System Training Validation

The training program developed by the device manufacturer was validated through testing in a porcine model, using participants with a range of experience in laparoscopic procedures. The training validation consisted of the following steps:

1. A study coordinator shows and describes use of the ContainOR system while participant reads the Instructions for Use (IFU).
2. Assisted device set up and use in which the coordinator assists the participant in set up and use of the ContainOR system in the training rig.
3. Participant sets up and uses the ContainOR system without assistance in the training rig.
4. Participant sets up and uses the ContainOR system in a porcine model (beef tongue

in various sizes used for morcellation specimen).

Thirty-four participants with a range of experience in laparoscopy were recruited. Each participant used at least 3 ContainOR systems in the training. Four different morcellators were used (2 bipolar and 2 electromechanical). The following table, Table 2, provides a breakdown of device usage by operator experience:

Table 2 – Training Validation: Operator Experience

	Experienced	Inexperienced
Mechanical Morcellators	8	5
Bipolar Morcellators	13	8
Total	21	13

Note: Experienced was defined as having previously performed at least 5 power morcellation procedures prior to training.

All users were able to successfully set up and use the ContainOR system. Following inspection with a water leak test, no ContainOR systems were observed to have a leak. The users reported that the IFU was clear and understandable; however, there were a few comments provided by the users that were incorporated into the training and a revised IFU for further clarity and emphasis.

With no failures noted in the 34 tests, the estimated lower bound on the 95% confidence interval for leakage is 0.898. This was greater than the 0.875 limit set for passing this test. (Note: A total of 102 ContainOR systems were used in total during this test with no evidence of leak.)

This testing demonstrates that both inexperienced and experienced users can be trained to perform a contained morcellation without compromising the ContainOR system and can successfully use the device.

Design Validation for ContainOR System

The purpose of the study was to show that the ContainOR system can be used safely and effectively. Specifically, the primary outcome was to assess whether surgeons in a clinical setting can damage the ContainOR pouch. The secondary outcomes are based on successful set up and use of the device, and that it meets user needs, e.g., it was effective in containing the tissue.

Participants from the training validation study participated in this study, with the exception of 3 subjects from the inexperienced cohort. Each participant (n=31) used one ContainOR system in a porcine model with beef tongue for the morcellation specimen. Specimen sizes tested ranged from approximately (b) (4) with three samples (b) (4) range. Table 3 provides a breakdown of morcellator type by experience level:

Table 3 – Design Validation: Operator Experience

	Experienced	Inexperienced
Mechanical Morcellators	8	5
Bipolar Morcellators	13	5
Total	21	10

Note: Experienced was defined as having previously performed at least 5 power morcellation procedures prior to training.

Each participant performed set up and use of the morcellator. Following removal, the test coordinator performed a leak test on the ContainOR pouch. The ContainOR pouch was filled with water (b) (4) and observed for leaks.

In all cases the users were successful in carrying out the procedure. There were no observed leaks following the procedure. There were a few comments from participants that were incorporated into the training and instructions for use for additional clarity.

With no device failures noted in 31 tests, the lower bound on the 95% confidence interval for success was 0.889. This exceeded the minimum value of 0.875 set in the sample size calculation. (As described above for the immersion test, a simple superiority test was set with a value of 0.875 with a 90% power and 0.025 alpha. The difference is that this was described as a test of success whereas the immersion test was described as a test of failure; therefore 0.875 was used here as opposed to the 0.125 used in the immersion test. The same method for determining the target success/failure was used.)

The nonclinical testing conducted on the bench and in an animal model demonstrates that the ContainOR system meets its design and performance specifications and can be successfully used by physicians without evidence of leakage.

Pediatric Extrapolation

In this De Novo request, existing data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling meets the requirements of 21 CFR § 801.109 for prescription devices.

The ContainOR Instructions for Use address the known hazards and risks of the procedure and incorporate safety statements to mitigate these risks. The labeling includes:

- Information on the types of morcellators, laparoscopes, graspers with which the device has been demonstrated to be compatible.
- The intended use population.
- Safety instructions intended to minimize the risk of contact of surgical instruments with the inside of the Bag.

- Safety instructions emphasizing the importance of visualization of the tenaculum/grasper and morcellator tip at all times.

- Precautions and instructions for the safe removal of tissue containing stones, (i.e. kidney stones)

- Risk information in a boxed warning that physicians should share with patients regarding the potential for a laparoscopic power morcellator to spread cancer and the lack of clinical demonstration of a reduction in risk when using a containment system.

- The use of the device requires training of the user. Clinicians using the ContainOR must be physicians who have familiarized themselves with the ContainOR Instructions for Use and have undergone training in the use of the device.

The contraindications identified in the ContainOR labeling contribute to the defined indications for use for the ContainOR. In accordance with 21 CFR 807.81(a)(3), removal or modification of any of the contraindications will require submission of a premarket notification [510(k)], which includes clinical performance testing to demonstrate that intended users can successfully use the device to contain the tissue specimen.

The information in the boxed warning is considered necessary for identifying the benefits and risks of the ContainOR.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the ContainOR and the measures necessary to mitigate these risks.

Table 4 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life testing Labeling
Intraperitoneal tissue dissemination • Material permeability • Improper function of containment device • Inadequate material strength • Physical trauma to liner caused by contact with morcellator or grasper/tenaculum • Damage to liner (intentional or accidental) from instrument inserted through secondary port • Tearing during removal with loss of contents into abdominal cavity	Non-clinical performance testing Animal performance testing Shelf life testing Labeling Training

Identified Risk	Mitigation Measures
• Tearing of the bag due to stones contained in tissue • Use error	
Traumatic injury to non-target tissue/organ • Active end of morcellator or grasper/tenaculum breaches liner • Loss of insufflation • Inadequate space to perform morcellation • Inadequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera • Use error	Non-clinical performance testing Animal performance testing Labeling Training
Hernia through abdominal wall incision	Labeling Training
Prolongation of procedure and exposure to anesthesia	Labeling Training

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the general laparoscopic power morcellation containment system is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Performance testing 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 intended shelf life.
4. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    a. Demonstration of device impermeability to tissue, cells and fluids.
    b. Demonstration that the device allows for the insertion/withdrawal of laparoscopic instruments while maintaining pneumoperitoneum.
    c. Demonstration that the containment system provides adequate space to perform morcellation and adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera.
    d. Demonstration that compatible laparoscopic instruments and morcellators do not compromise the integrity of the containment system.

e. Demonstration that users can adequately deploy the device, morcellate a specimen without compromising the integrity of the device and remove the device without spillage of contents.

5. Training must be developed and validated to ensure users can follow the instructions for use.
6. Labeling must include:
    a. A contraindication for use in gynecological procedures;
    b. A contraindication against use on tissue that is known or suspected to contain malignancy;
    c. The following boxed warning: "Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. The use of laparoscopic power morcellators may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk."
    d. A statement limiting use of device to physicians who have completed the training program; and
    e. A shelf life.

BENEFIT/RISK DETERMINATION

The probable benefits of the device are based on nonclinical laboratory studies (bench and animal). The benefits of the device include containment of tissue during laparoscopic power morcellation and the associated ability to perform a minimally invasive surgery. The nonclinical testing serves as a surrogate for clinical testing for establishing reasonable assurance that the ContainOR system will maintain its integrity and will not allow transit of cellular debris following laparoscopic power morcellation procedures.

The ContainOR system also offers the benefit of inflation of the containment system and visualization within the containment system. These two benefits allow for the creation of a working space around the specimen and visualization of the morcellator tip during morcellation. The single port design provides the additional benefits of single site surgery.

The risks associated with the use of the device include intraperitoneal tissue dissemination, traumatic injury to non-target tissue/organ, infection, hernia through abdominal wall incision, adverse tissue reaction and prolongation of procedure.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information, the data supports that when the ContainOR system is used in accordance with the intended population identified in the labeling for laparoscopic power morcellators, the probable benefits outweigh the probable risks. The device provides substantial benefits and the risks can be mitigated using general and the identified special controls.

CONCLUSION

The De Novo request for the ContainOR is granted and the device is classified under the following:

Product Code: PZQ
Device Type: General laparoscopic power morcellation containment system
Class: II
Regulation: 21 CFR 878.4825