|  |  |
| --- | --- |
| **Inclusion Criteria:** | *Patients must meet ALL of the following criteria to be eligible for participation in the study:* * Patient is between 18 and 60 years of age
* Undergoing elective cholecystectomy due to:
* Cholelithiasis (Gallbladder stones < 2.5cm in diameter)
* Gallbladder polyps > 0.5mm in size as assessed by ultrasound
* Absence of non-correctable coagulopathy (INR < 1.4 or, platelet count of < 50,000/mcl)
* Patient has a body mass index (BMI) ≤ 35 kg/m2
* Patient, or authorized representative, signs a written Informed Consent form to participate in the study, prior to any study mandated determinations or procedure
 |
| **Exclusion Criteria:** | *Patients must be EXCLUDED from participation in this study if ANY of the following criteria are met:** Patients with metallic implants (such as pacemakers, prosthesis, etc)
* Has a biliary tract > 7mm in size as determined by ultrasound
* Biliary tract stones diagnosed before or during surgery
* History of endoscopic papillotomy (i.e: Preoperative indication of endoscopic retrograde cholangiopancreatography (ERCP)
* Previously diagnosed or suspected of having a history of choledocholithiasis based on any alterations in plasma hepatic enzymes
* Has a gallbladder wall thickness that is > 3mm
* Scleroatrophic gallbladder as shown by ultrasound
* Suspicion of biliary cancer
* Emergency presentation with acute gallbladder disease
* Gallbladder Empyema
* Patients with signs of gallbladder perforation diagnosed by ultrasound
* Patients with severe peritonitis
* Pancreatitis
* Jaundice
* Ongoing peritoneal dialysis
* Previous abdominal surgery or laparotomy (presence of any previous upper umbilical incision)
* Presence of umbilical hernia or previous umbilical hernia
* American Society of Anesthesiologists (ASA) score of III or IV
* Significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure)
* Contraindications to pneumoperitoneum
* Diabetic
* Blood coagulation issues
* Has signs of hepatic endocrinology (i.e: cirrhosis, liver failure, increase in liver enzymes, etc.)
* Patient has systemic infection or evidence of any surgical site infection (superficial or organ space)
* Patient has compromised immune system or autoimmune disease (WBC < 4000 or > 20,000), including prior or pending treatment for HIV or Hep. C
* Known allergy to paracetamol or piritramide or NSAID
* Patient is undergoing treatment for chronic pain with opiates
* Patient is pregnant or wishes to become pregnant during the length of study participation or lactation
* Patient is not likely to comply with the follow-up evaluation schedule
* Patient is participating in a clinical trial of another investigational drug or device
* Patient is mentally incompetent or a prisoner
* Known or suspected drug or alcohol abuse
* Patient intra-operatively needs an additional surgery while undergoing elective cholecystectomy
 |