TITLE: PercSac: A Device to Trap and Remove Kidney Stone Fragments Generated During Shock Wave Lithotripsy

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SUMMARY: During a percutaneous nephrolithotomy (PCNL) procedure, a telescope is passed directly into the kidney through a small incision in the flank to remove large kidney stones from the kidney. Often, large kidney stones need to be fragmented before they can be removed, and it is important to remove all resulting fragments in order to minimize the risk of stone recurrence. Small fragments of kidney stones, however, may migrate and drift into the renal calyces or down the ureter, requiring the surgeon to insert a flexible endoscope to search the entire kidney for residual fragments, which increases operative time and, thus cost of the procedure.

Occasionally, despite inspection of the kidney, fragments are missed and are detected on Computer Tomography (CT) scan only after the surgery. Removal of these residual fragments requires a second procedure in the operating room.

The new PercSac is a polyethylene bag that is placed over a rigid nephroscope and used to contain a stone during fragmentation with an ultrasonic lithotripter using either percutaneous nephrolithotomy (PCNL) or cystolitholapaxy. As the stone is contained within the PercSac during fragmentation, it prevents fragment migration making the surgical procedure more efficient. One end of the PercSac is a dome (diameter=32mm, height=40mm, circumference=100mm) that can contain a stone up to 2.5cm in size. There is a nitinol wire surrounding the circumference of the dome. The nitinol wire then exits the other end of the device through a stainless steel structural rod.

By pulling on the ends of this nitinol wire, the PercSac cinches closed around the stone. The structural rod allows for ease of advancement and retraction of the PercSac over a stone. A polyurethane flexible tube is attached to the distal end of the structural rod where the neck of the PercSac transitions into the dome-shaped pouch portion. This tube has an outside diameter of 2mm, an inside diameter of 1mm, and a length of 15mm. This polyurethane flexible tube allows the end of the PercSac to be soft so that it can be atraumatically advanced within a kidney or bladder.

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