

# Early Acute In-vivo Experience in Gynecology Oncology Applications with the SPORT Surgical System Technology

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## BACKGROUND

Laparoscopic surgery has been practiced for decades. Early laparoscopic surgery targeted a reduction in the morbidity associated with open surgery, as entry to the body via a few small incisions was surely less traumatic than a very large open incision. In fact, in many applications, the pain and complications associated with open surgery incisions for access to the body were much higher than the target surgery itself. Based on the demonstrated ability to produce improved patient outcomes including reduced operative time, lower intraoperative and postoperative complication rates, better cosmetic results, less pain and faster recovery times, multi incision laparoscopic surgery has evolved to become a standard of care.

Recently, and with focus on reducing the number of incisions, some surgeons have attempted Single Incision Laparoscopic Surgery (SILS) to minimize scars and, potentially, other complications. SILS is essentially surgery using the same laparoscopic instruments but through a single incision. Naturally, the working space is compromised in SILS procedures, which can further complicate the surgery. The intraoperative surgical and postoperative outcomes benefits of SILS have not been proven well enough for it to be widely adopted as the next frontier of laparoscopic surgery. The arrival of single-port robotically-assisted surgical systems may provide the opportunity to leap past some of the known challenges in performing more complex minimally invasive procedures with single incision surgery.

Today's robotic and laparoscopic surgeries predominantly involve a multi-port surgical approach. Both share the benefits of delivering instruments to the target tissue from multiple angles. The initial adoption of multi-port robotic surgery was facilitated by its similarity to how laparoscopic surgery is performed without changing procedural flow and surgical orientation for the surgeon. Recently, both laparoscopic and robotically-assisted single incision surgery have been proposed for procedures such as cholecystectomy and hysterectomy, where surgeons are exploring ways to perform surgeries without creating any visible scars (incision around the umbilicus hides the scar). Previous single incision surgical approaches including SILS as well as single port robotic surgery using curved, flexible instruments, have not been widely adopted due to limitations of the product offerings. Limitations include: lack of surgical precision, limited access, complicated setup and instruments with limited articulation, grasping and retracting capabilities.

While a leap forward for patient outcomes, laparoscopic surgery remains a suboptimal solution to solving the morbidity problem associated with open surgery. Robotic multi-port surgery has secured a place in the market by reducing some of the related limitations, such as tremor filtering and a more natural instrument interface, while offering similar benefits to open surgery such as dexterity and depth perception achieved through high-definition 3D visualization. Single-port robotic surgery shows promise for addressing the further limitations of laparoscopic surgery and open surgery, without significantly compromising on ergonomics, economics, and clinical capabilities. Furthermore, in many surgeries where specimen extraction is a vital and potentially time-consuming part of the procedure, single incision surgery, through an incision of approximately 25 mm, provides convenient access.

## TECHNOLOGY OVERVIEW

The SPORT Surgical System is a versatile single incision advanced robotic platform that features multi-articulated instruments with single-use replaceable tips, high-definition 3D visualization on a flat-screen monitor, an ergonomic open workstation and a single-arm mobile patient cart for ease of set up, enabling the broad applications of single and multi-quadrant surgeries.

The SPORT Surgical System is comprised of 2 main components: a surgeon workstation and a patient cart. A central unit (CU) is attached to the patient cart, a camera insertion tube (CIT) comprising the high-definition camera and light source at a distal end is attached to the CU, and two multi-articulated instruments are insertable through the CIT.

## SURGEON WORKSTATION

The surgeon workstation is where a surgeon operates the instruments using a natural handle interface and a 32" 3D high-definition flat-screen monitor, while sitting in an ergonomically comfortable chair with elbow supports.



## PATIENT CART

The patient cart has a single support boom that suspends the CU, to which the CIT is attached. It is used in the sterile field at the bedside and is positioned next to the OR table. The portability and ease of positioning along with a compact footprint and maneuverability are critical design aspects for efficient setup.

## CENTRAL UNIT

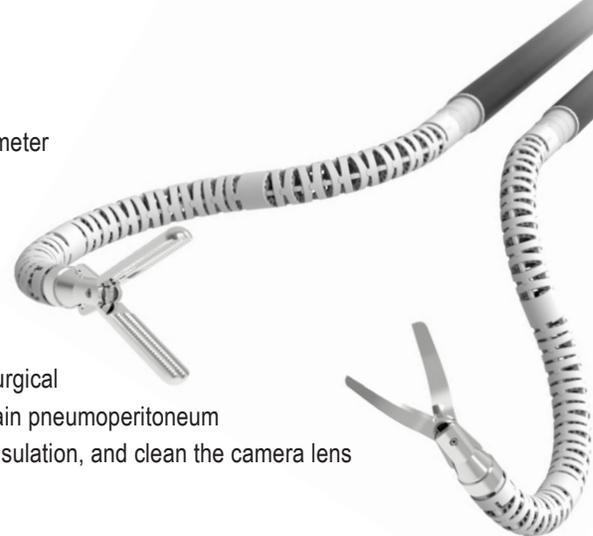
The central unit (CU) is the main drive unit that is attached to the patient cart support boom and is configured to receive the CIT during the docking process. It includes tracks to insert the left and right instruments through the CIT. It also has brake handles for positioning of the CU for a full range of motion during surgery, yet fixing it in position once the brakes are applied.

## CAMERA INSERTION TUBE

The Camera Insertion Tube (CIT) houses the high-definition 3D camera along with two 8 mm diameter instruments. The CIT's outer diameter is about 25 mm which is a critical parameter for minimizing the incision size of the single port approach.

## MULTI-ARTICULATED INSTRUMENTS

The multi-articulated instruments are capable of manipulation by the surgeon to perform critical surgical tasks. Accessories such as lumen seals, instrument boots and a lens wash accessory help maintain pneumoperitoneum during instrument exchanges, cover the articulating instrument architecture to provide electrical insulation, and clean the camera lens when occluded.



## EARLY IN-VIVO EXPERIENCE AND OBSERVATIONS

As with any new surgical technology, thorough testing of the technology can be complex and time consuming. Robotic surgery has come a long way and the possibility of performing complex procedures through a single incision appears closer than ever before. The basic requirements include excellent visualization in high-definition 3D, easy access to the body with minimal trauma and robust articulating arms that can approach the target tissue from multiple angles. This new robotic single port platform, SPORT Surgical System, appears to have solved even the most difficult problems of instrument strength, natural instrument movement and access to desired patient anatomy.

With availability of an advanced prototype, we set out to perform complex pelvic surgery in-vivo in a porcine model to assess feasibility and to explore the limits of the SPORT Surgical System. In a period of less than 30 minutes, familiarity with the operation of the system was quickly gained through some simple pre-operative dry-lab exercises. In the laboratory we performed successive surgeries in four live swine, which is an accepted model representative of the human anatomy for pelvic procedures. The surgery was divided into separate sub-procedures to evaluate as many aspects of the performance of the surgical platform as possible.

### ABDOMINAL ACCESS

The first step in each procedure was accessing the abdomen and introducing the SPORT system into the abdomen for single incision surgery. This was achieved by making a 25 mm incision just above the umbilicus and then placing a self-retaining retractor (Alexis® Wound Retractor by Applied Medical) attached to a gel access port (GelPOINT® by Applied Medical) into the incision and insufflating the abdomen with CO<sub>2</sub>. This option is similar to many other robotic and laparoscopic approaches and was easily accomplished in each of four surgical procedures.

### CAMERA INTRODUCTION AND DOCKING

The second step was to introduce the CIT into the abdomen, and this was achieved with some difficulty as the 25 mm diameter insertion tube acts as its own port and insufflation can be lost quickly. After practice during the first two procedures, this was more easily accomplished on the third and fourth procedures. An improved approach may include a valved port that allows easy entrance and exit of the CIT as needed without losing pneumoperitoneum. Although the CIT did not have to be removed once installed throughout any of the four surgical procedures, an access port that allows easy abdominal entry without loss of pneumoperitoneum would be ideal, as it would keep the high-intensity camera light off of the bowel and minimize the potential for trauma to internal organs during direct insertion with full visualization.

The CIT was introduced with the camera in non-deployed position during the insertion through the access port. Once the CIT was inserted and pelvic exploration completed, the CU was easily positioned near the CIT by the assistant and attachment of the CIT to CU was seamless. This is where the system is considered “docked” and ready for camera deployment and instrument introduction. One of the most common reasons for removing ports from the abdomen is to clean the camera, but we experienced very few incidents with debris on the camera during all four procedures, in which cumulative duration, represented about 10 hours of surgery. The few incidents of camera lens obstruction with body fluids were easily corrected with Lens Wash feature on the system. The CU and surgeon secondary screen had buttons for activation of the self-cleaning and drying feature, without having to remove the camera from the abdomen.

### SURGEON ERGONOMICS AND WORKSPACE

Each procedure began with the surgeon seated comfortably at the workstation, as the adjustable design allows for ergonomics to be optimized for each surgeon. The hand controls, clutches and foot pedals are slightly different than other robotic systems, but midway during the first case, the functions become obvious and surgeon muscle memory allowed the procedure to proceed without difficulty. The camera controls for pan, tilt and zoom are uniquely accessed on the hand controls, but were easy to adapt. Once docked, SPORT system provided adequate workspace to perform surgeries in the pelvis. The one limitation of the present design of the patient cart is that when accessing organs in multiple quadrants the CU is not under direct surgeon control for reorientation in a larger space. The surgeon needs to request the bedside assistant to pan or tilt the CU to reach any areas beyond the current workspace after the initial docking. The camera does tilt up and down as well as pan side to side, and the instrument arms can reach areas within the field of view. However, at the periphery, the instrument arms are stretched to their limit in developing adequate force, so the learning curve includes gaining familiarity with the “sweet spot” of operation, the volume in which movement of the multi-articulating arms feels natural, and the functions of tissue grasping, retraction and approximation, blunt and sharp dissection, cutting, coagulation and suturing are most easily performed.

## PRECLINICAL FINDINGS

The comfort and proficiency in operating the SPORT Surgical System improved with each procedure. The system seemed to overcome the problems of early single port robotic surgical systems, including lack of wristed instruments, limitation of near/far work space due to long access trocars, and lack of strength due to flexible instruments. The multi-articulating instrument arms that provided comprehensive instrument line up including monopolar scissors, bipolar Maryland graspers, atraumatic graspers and needle drivers, are strong, yet maneuverable in free space, and grip strength and torque were sufficient to approximate, grasp tissue and drive needles for suturing. In the first two subjects we initially performed two simple hysterectomies and bilateral salpingo-oophorectomies with pelvic lymphadenectomy. In the next two subjects, we performed two radical hysterectomies with pelvic and para-aortic lymphadenectomy with radically wide margins extending all the way to the side wall. In one of the procedures, we then continued to perform a radical cystectomy similar to that of an anterior exenteration. In all cases, the dissection was completed successfully with minimal blood loss and no difficulties encountered. Suturing at the end of the procedure was completed without difficulty and was performed on the vagina and the cervix, which is thicker to simulate the human tissue. Finally, in one of the procedures the ureters were intentionally transected and then dissected out completely and re-implanted into the bladder without difficulty. During the same procedure we also cut several large mesenteric vessels of 3 to 5 mm approximate diameter and we were able to achieve hemostasis with the bipolar Maryland grasper.

In all cases, the procedure was completed without difficulty and in a timely manner consistent with similar laparoscopic and single port robotic surgeries. The SPORT system's multi-articulating instrument arms performed consistently and predictably, other than an occasional user-induced error associated with gaining familiarity with clutching at the correct time. The surgeries were narrow in scope yet aggressive in complexity, and there were no difficulties encountered.

## OVERALL SUMMARY AND OPPORTUNITIES FOR IMPROVEMENT

Qualitatively, and based on this early experience, the SPORT system's instrument arms function efficiently and afford increased strength and dexterity over other available single port laparoscopic and single port robotic products. However, the system is presently in an advanced prototype state, useful for preclinical use as intended. Opportunities for improvement of the current design prior to clinical use include:

1. Initial Port of Access: Although we were able to safely gain access with minimal trauma, we believe that the CIT should not serve as its own port and a simple, short, valved port could allow easy entry and exit of the CIT without losing pneumoperitoneum. Losing insufflation during entry can lead to bowel injury or instrument damage. Utilized in its current state without a separate port, the CIT is difficult to move in or out when necessary during the procedure.
2. Camera Range of Motion: The camera itself pans 10-20 degrees laterally, but the field of work remains limited. Ideally, the surgeon should be able to pan the CIT at least 20-30 degrees to allow better lateral visualization.
3. Camera Profile: While the high-definition 3D camera functioned very well and required infrequent cleaning, it is significantly larger than those available in endoscopic systems. Reducing the size of the camera may facilitate an even smaller diameter CIT, and in turn, a smaller incision.
4. CIT length: In order for the bedside assistant to be least encumbered to help during single port surgery, clearance under the CU and CIT should be optimized. Adding a few inches in length to the CIT could be very helpful in improving clearance, without affecting the functionality of the instruments.

## CONCLUSION

In its current pre-production, first live procedure state, the SPORT Surgical System performed well above expectations. With minimal training and practice, we were able to access confined anatomy and perform essential surgical tasks including tissue grasping, retraction and approximation, blunt and sharp dissection, cutting, coagulation, suturing and reconstruction of structures including vessels. The procedures were all completed as scheduled and as our confidence grew, we ventured beyond the planned procedures and performed more challenging, complex procedures. The surgeon workstation control of multi-articulating instrument arm functionality in the patient cart was excellent under high-definition 3D visualization. With correction of the minor limitations noted above, we believe that the SPORT Surgical System can advance the state of single port surgery with its clinically-relevant functionality.

\*The SPORT Surgical System is currently not cleared and is not available for sale in the United States and European Union.