# 1 PROTOCOL SYNOPSIS

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| Title | **Minimally Invasive Right Colectomy Anastomosis Study (MIRCAST):** A observational prospective multi-center 4-cohort study comparing robotic assisted and laparoscopic minimally invasive right colectomy, and intracorporeal anastomosis versus extracorporeal anastomosis |
| Study Objective | Comparison of the peri-operative complications after robotic assisted and laparoscopic minimally invasive right colectomy with intracorporeal anastomosis versus extracorporeal anastomosis.<br>Identify potential benefits of robotic assisted procedures for right colon resections. |
| Study Design | Observational, prospective, parallel cohorts, international, multi-center study |
| Study Endpoints | **Primary Endpoint:** Efficacy of surgical method defined as co-primary outcomes of surgical wound complications (infection) and postoperative complications as outline below:<br>- Surgical Site Infection.<br>- Clavien-Dindo[1] grade III-IV complications at 30 days postop.<br>**Secondary Endpoints:**<br>- Oncologic results at 2 years<br>  - Overall survival<br>  - Disease free survival (DFS)<br>  - Local recurrence<br>  - Metastases rate<br>- Rate of Unplanned Conversions to open surgery.<br>- Operative time (min)<br>- Complete mesocolic excision (CME).<br>- Number of Harvested Lymph Nodes<br>- R0 Resection<br>- Length of Stay (LOS, days)<br>- Ventral hernia (assessed 1&B 2 years after the right colectomy)<br>- Quality of life EORTC QLQ-C30 & QLQ-CR29<br>- SIRS (CRP) days 1 & 3 postoperative<br>- *[PCT days 1, 3 & 5 postoperative] (Optional)*<br>- *Medico-economic sub-study (Optional):*<br>  - *EQ-5D* |

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| | ○ *Time to ambulation, patient return to work/activity, pain evaluation, resource utilization for procedure and follow-up care* |
| Number of Patients | At least 1200 subjects will be enrolled in this study (300 per cohort).<br>All patients during the enrollment period shall be screened and recorded at sites in order to identify any selection bias. |
| Total Study Duration | Approximately 4 years:<br>□ Site start-up: 3-6 months<br>□ Study Enrollment: 24 months<br>□ Short term follow up: Discharge, 30 days and 3 months post procedure.<br>□ Long term follow up: 1 year and 2 years |
| Inclusion/ Exclusion Criteria | Study Inclusion:<br>1. 18 years or older.<br>2. Right colon tumor with indication for right colectomy (benign or malignant disease).<br>3. Patient has a life expectancy of at least 12 weeks.<br>4. Patients with adequate performance status (Eastern Cooperative Oncology Group Scale score of ≤2)<br>5. Patient has signed and dated the Informed consent before patient inclusion in the study.<br>Study Exclusion:<br>1. Patient with a comorbid illness or condition that would preclude the use of surgery.<br>2. Patients with cT4b tumors.<br>3. Patients unwilling to comply with all follow-up study requirements<br>4. Patient undergoing emergency procedures<br>5. Planned colonic surgery along with major concomitant procedures (e.g. liver resections, other intestinal resections).<br>6. Metastatic disease<br>7. Pregnant or suspected pregnancy<br>8. Inflammatory Bowel Disease (Crohn´s Disease or Ulcerative Colitis) |
| Human Subjects Protection | Full Ethics Committee (EC) approval, with all other country specific approvals, must be obtained for the study prior to study initiation at the |

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| | site. Subjects must sign an EC-approved Informed Consent Form (ICF) prior to enrollment into this study. |
| Data Collected | All patient assessments will be done according to the sites standard of care.<br>Data collected will include the following:<br>- Demographics, Patient Characteristics, and Pre-operative History: Gender, Age, BMI, cancer treatment and surgical history, comorbid conditions, indication for surgery, mechanical bowel preparation, Preop oral antibiotic, QoL (EORTC C30 & CR29).<br>- Intra-Operative Assessment: Type of Bowel recovery procedure (RC or Extended Right), Operative room time, Approach, Estimated blood loss (EBL), transfusion rate, concomitant procedures performed, complications, conversions, ICA/ECA, Lymphadenectomy (D2/D3), economic measures.<br>- Post-Operative Assessment through Discharge: Bowel recovery, complications, pathology, patient reported outcomes during post-surgical recovery period until discharge, ERAS protocol, economic measures *(Optional)*.<br>- Follow-Up Assessments: complications, procedure-related readmissions, pathological report (30d), procedure-related reoperations, patient reported outcomes, QoL and economic measures (Optional). Data will be collected at 30 days, 3 months, 1 year and 2 year. The visit will be performed as an inpatient visit or telephone call depending on the sites standard of care. |
| Data collection | Primary data collection will be performed by a study coordinator/designee in a study-specific Electronic Data Collection (EDC) system. |
| Statistical Analysis | Sample Size Considerations:<br>At the end of recruitment, primary endpoints will be presented with 95% confidence intervals, calculated with the use of standard methods based on a binomial distribution for each cohort.<br>Description analyses will be performed by cohort.<br>All analyses will be detailed in a SAP. |
| Finance | Research Grant Intutive Surgical Inc. |