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RESEARCH ARTICLE

PRECLINICAL FEASIBILITY STUDY EVALUATING THE SAFETY AND PERFORMANCE OF THE COREVIVE™ COLONIC STENT SYSTEM IN A PORCINE MODEL

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ABSTRACT: Colonic stents are widely used to restore bowel patency in cases of obstruction, serving as both palliative treatment and a bridge to surgery. This feasibility study evaluated the safety and performance of the CoRevive™ Colonic Stent System in a porcine model. A single healthy male pig (n=1) underwent endoscopic- and fluoroscopic-guided colonic stent implantation under general anesthesia. Device deployment, lumen patency, and tissue response were assessed using fluoroscopy and endoscopy on Days 0, 14, and 44 post-implantations. The procedure was successfully completed with accurate stent placement and no complications. The animal remained clinically stable, with body weight increasing from 52.9 kg to 65.3 kg. Post-procedural pain was moderate and resolved within four days. Imaging demonstrated immediate luminal expansion with sustained patency at Day 44. Histopathological analysis showed mild inflammatory response and complete endothelialization, indicating favorable biocompatibility. These preliminary findings suggest that the device is feasible and demonstrates acceptable short-term safety and performance. Further studies in larger cohorts and disease-specific models are required to confirm these results.

Keywords: CoRevive™ (Colonic Stent System), Porcine Model, Radiography analysis, Endoscopy analysis and Histopathological.

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INTRODUCTION:

The CoRevive™ Colonic Stent System comprises a self-expanding metallic implant and a dedicated delivery mechanism. The implant is constructed from braided nitinol, forming a cylindrical structure with flared ends to enhance anchorage and minimize migration. It is preloaded in a constrained configuration within a flexible catheter and expands upon controlled release. The delivery system incorporates radiopaque markers to assist in accurate positioning and to account for foreshortening during deployment under fluoroscopic guidance. Self-expanding metallic stents (SEMS) are widely used in gastrointestinal interventions because of their flexibility, conformability, and ability to provide continuous radial force while adapting to luminal anatomy [1-5, 9].

Colonic obstruction is a serious gastrointestinal condition, most commonly associated with colorectal malignancies, resulting in impaired bowel transit and progressive luminal narrowing. If untreated, the condition may lead to bowel ischemia, perforation, electrolyte imbalance, sepsis, and death, necessitating urgent decompression and restoration of luminal patency. Emergency surgical management has traditionally been associated with significant morbidity, mortality, prolonged hospitalization, and frequent stoma creation [10-12].

Over the past decades, SEMS have emerged as a minimally invasive alternative to emergency surgery for malignant colonic obstruction. These devices provide immediate luminal decompression by exerting outward radial force after deployment, thereby restoring bowel patency and improving gastrointestinal function. SEMS are commonly used both for palliative treatment in unresectable disease and as a bridge to elective surgery, allowing patient stabilization, bowel preparation, and optimization prior to definitive surgical intervention. Clinical studies and systematic reviews have demonstrated high technical and clinical success rates, reduced need for emergency surgery, shorter hospital stays, and lower stoma formation rates following SEMS placement [13-16].

The clinical performance of colonic stents is highly dependent on device design characteristics, including radial force, flexibility, conformability, foreshortening behavior, and resistance to migration. Accurate deployment is essential to ensure adequate lesion coverage while minimizing complications such as perforation, migration, restenosis, and tissue injury. Modern delivery systems therefore incorporate radiopaque markers and controlled-release mechanisms to facilitate precise fluoroscopic placement and predictable expansion characteristics [17-19].

Malignant colorectal obstruction is a serious clinical condition that often requires urgent intervention to restore intestinal patency and relieve obstructive symptoms. In recent years, self-expanding metallic stents (SEMS) have gained significant attention as a minimally invasive alternative to emergency surgery, particularly in patients with left-sided colorectal malignancies. Clinical studies have demonstrated that colorectal stenting provides effective bowel decompression, reduces postoperative complications, and improves short-term patient outcomes. Systematic reviews and pooled analyses have further supported the safety and efficacy of SEMS in both palliative management and as a bridge to elective surgery. Additionally, multicenter prospective studies have confirmed the technical success and therapeutic reliability of metallic stents in managing malignant colorectal obstruction, highlighting their growing role in modern gastrointestinal and colorectal interventions. Nitinol has become the preferred material for SEMS fabrication because of its super elasticity, shape-memory behavior, corrosion resistance, and biocompatibility. Braided nitinol configurations provide enhanced flexibility and conformability, allowing the device to adapt to the tortuous anatomy of the colon while maintaining sufficient radial strength. Flared-end designs are frequently incorporated to improve anchorage and reduce migration risk during long-term implantation [20-27].

Preclinical evaluation is a critical component in establishing the safety and functional performance of gastrointestinal stent systems before clinical application. Such evaluations typically include

assessment of deployment accuracy, expansion behavior, radiographic visibility, migration potential, mechanical integrity, and local tissue response. The porcine model is widely accepted for gastrointestinal device studies because of its anatomical and physiological similarity to the human gastrointestinal tract, enabling clinically relevant assessment of procedural feasibility and short-term safety.

This feasibility study was therefore designed to evaluate the safety, deployment characteristics, and short-term performance of the CoRevive™ Colonic Stent System in a healthy porcine model. The study findings are intended to provide preliminary evidence supporting the continued development of the device and future investigation in larger preclinical and clinical studies.

The animal studies conducted in this research were performed in accordance with internationally accepted ethical and welfare guidelines for laboratory animals. All procedures complied with the requirements outlined in International Organization for Standardization ISO 10993-2:2006(E), which addresses animal welfare requirements for the biological evaluation of medical devices. Humane care and ethical treatment of experimental animals were ensured following the recommendations provided in the OECD guidance document ENV/JM/MONO (2000)7 on the recognition and use of clinical signs as humane endpoints in safety evaluation studies. In addition, the study adhered to the CPCSEA guidelines for laboratory animal facilities, as published in the Indian Journal of Pharmacology (2003), ensuring appropriate housing, handling, and monitoring practices throughout the experimental period [6-9].

MATERIALS AND METHODS

MATERIALS REQUIRED

Medication Details

This section delineates the drugs administered to the animals prior to, during, and following surgery, specified in **Table 1**.

Table 1: Details of medications used in the study

Drug name	Manufactured by	Batch / Lot No.	Expiry date
Ketamine	Themis Medicare Ltd	KME24005	Jan 2027
Xylazine	IIL India	FHK25001	Dec 2027
Isoflurane	Neon Laboratory Ltd	KPNP700029	Sep 2027
Atropine Sulphate	Pentagon Labs Ltd	23GAS002	Jun 2026
Thiopentone sodium	Neon Lab	172470	Dec 2026
Tramadol	Neon Lab	KP1568154	Oct 2026

The pain score for P1 was found to be 2 (Moderate) on day 0 (day of procedure) and on day 1, 2 and 3 pain score was 1 (Mild), from Day 4 till termination the pain score was found to be 0 (no pain).

Airway management equipment

- Laryngoscope
- Endotracheal tube

Monitoring and support

- Physiological monitor (for vitals)
- Electric clipper (for ECG patch sites)
- ECG patches (applied on thigh and shoulders of fore and hind limbs)

Endoscopic and interventional devices

- Endoscope (for visualization and insufflations)
- 260 cm guide wire
- Guide catheter
- Fluoroscopy unit with contrast media
- Delivery catheter (for stent deployment)
- **Test item**: CoRevive™ Colonic Stent System

DEVICE DESIGN

The CoRevive™ Colonic Stent System consists of a self-expanding metallic stent and a dedicated delivery mechanism. The implant is fabricated from braided Nitinol, forming a cylindrical structure with flared ends that enhance anchorage and help limit migration. Owing to the superelastic and shape-memory properties of Nitinol, the structure provides sustained outward force while adapting to luminal contours.

The implant is preloaded in a compressed configuration within a flexible catheter. Deployment is achieved by gradual withdrawal of the outer sheath, allowing controlled expansion against the colonic wall. The delivery mechanism includes three radiopaque markers indicating sheath position, deployment limit, and final placement to support accurate positioning under fluoroscopic guidance and to account for shortening during release.

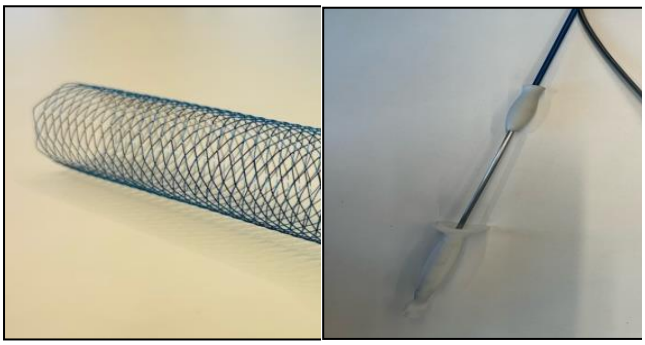
In comparison with conventional self-expanding metallic stents (SEMS), this system is designed to improve conformability and procedural control. The braided configuration enables an appropriate balance between outward force and flexibility, which may reduce localized stress on the tissue. Additionally, the controlled release mechanism facilitates precise placement and may enhance handling characteristics relative to currently available devices.

SIZE MATRIX

Table 2: Size matrix

Stent Body Diameter (mm)	Stent Flange Diameter (mm)	Stent Length (cm)	Delivery System Diameter (Fr)	Delivery System Length (cm)	Wire Guide Diameter (inch)
22, 25	27, 30	6, 9, 12	10	135, 230	0.035

PRODUCT IMAGE



(A) Colonic Stent System (B) Delivery System

Figure 1: Colonic Stent System and Delivery System

Table 3: Specification Component and materials

Sr. No.	Component	Material(s)
1	Stent	Nitinol wire
2	Catheter	Pebax (Outer layer) PTFE (Middle layer) SUS304 (Inner layer)
3	Inner Tube	PEEK 450G
4	Soft Tip	Pebax 3533 + 20% $BaSO_4$
5	Marker	Mix of Platinum – Iridium
6	Stent Locker	SS316L
7	Pusher Tube	PEEK 381G (Victrex)
8	Hub	PC-ABS
9	Handle	PC-ABS

EXPERIMENTAL DESIGN AND PROCEDURES

Fasting

The animal was administered a purgative 24 hours prior to implantation to facilitate clearance of the intestinal tract. Feed was withheld overnight before the procedure on Day 0, while water was made available ad libitum.

Animal Preparation:

The animal preparation process begins by weighing the subject to calculate precise medication levels, followed by anesthesia induction using an intramuscular combination of Ketamine, Xylazine, and Atropine. Once initial sedation is achieved, inhalational anesthesia with Isoflurane is administered via a face mask, with dosages carefully managed based on inspired concentration and alveolar pressure to maintain stable pharmacological effects in the blood and brain. For continuous electrocardiographic monitoring, hair is clipped from the thighs and shoulders using electric clippers to ensure proper patch application. Finally, after confirming the loss of glottis reflexes, the animal is endotracheally intubated with a laryngoscope and maintained under general anesthesia through a specialized workstation while a multi-parameter system continuously tracks physiological vitals throughout the study (**Table 4**).

Table 4: **Animal Body weights (Day 0 to Day 44)**

Body weights (kg) for Animal P1	
Day 0	**Day 44**
52.9 kg	65.3 kg

Table 5: Animal Clinical signs a (Pain score) observation

Animal Number	Acclimatization phase	Experiment Phase	Results
	07478	**P1**	**P1**
Sex	**Male**	**Male**	--
Day of Observations	Mortality/ Clinical Sign	Mortality/ Clinical Sign	--
Acclimatization Phase (Day 1- 3)	0/1	After acclimatization, the experiment was initiated	Survived
Experiment Phase (Day 0 - 44)	--	0/1	Survived

Pain assessment was performed using a modified composite pain scoring system adapted from validated veterinary pain scales for large animals (e.g., behavior-based observational scoring). The evaluation included parameters such as posture, activity level, vocalization, appetite, and response to handling. Each parameter was graded on a scale of 0–2, where 0 indicated no pain (normal behavior), 1 indicated mild discomfort (slight behavioral changes), and 2 indicated moderate pain (reduced activity, altered posture, or decreased feed intake). The cumulative score was used to classify overall pain severity.

The pain score for animal P1 was recorded as 2 (moderate) on Day 0 (day of procedure), which decreased to 1 (mild) on Days 1, 2, and 3. From Day 4 until the end of the study (Day 44), the score remained at 0, indicating no observable pain. These findings suggest that post-procedural discomfort was transient and resolved without complications (**Table 5**).

EXPERIMENTAL DESIGN OR ANIMAL TRIAL

On **Day 0**, the animal was positioned supine, and a colonoscopy was introduced via the rectal cavity to access the colon. Under endoscopic visualization, insufflation was performed to expand the lumen, followed by insertion of a 260 cm guide wire and navigation of a guide catheter under combined endoscopic and fluoroscopic guidance. Contrast radiography allowed accurate measurement of the proximal (27.3 mm) and distal (22.4 mm) lumen diameters for appropriate stent sizing. The colonic stent was then loaded onto a delivery catheter and advanced carefully to the target site. Deployment was achieved by withdrawing the catheter, enabling the stent to expand against the colonic wall. Proper positioning and patency were confirmed by fluoroscopy and endoscopy, after which the endoscope was withdrawn and the animal recovered uneventfully. Radiographic analysis was scheduled for Day 0, Day 14, and terminal Day 44 to assess stent length and diameter, while endoscopic imaging was performed at baseline, immediately post-implantation, and at termination to monitor the implantation site.

Throughout the 44-day study, the animal's health remained stable, with body weight increasing from 52.9 kg at Day 0 to 65.3 kg at termination, and no morbidity or mortality observed. Anesthesia was maintained intra-operative with 3% concentration isoflurane under endotracheal intubation, while ECG, respiration, heart rate, and oxygen saturation were continuously monitored. Clinical pathology included hematology and biochemistry analysis on Day 0 and Day 44, assessing standard parameters such as RBC, WBC, platelets, ALT, AST, ALP, electrolytes, creatinine, and BUN. At termination, the animal was euthanized with thiopental sodium, and a complete necropsy was performed. The stented colon was processed for histopathological evaluation, where resin-embedded sections were stained with H&E to assess endothelialization, inflammation, tissue injury, and implant integrity. Overall, the trial demonstrated successful stent deployment, stable performance over the study

period, and no adverse systemic or local pathological effects.

Monitoring During Procedure:
Electrocardiograms (ECG) 60–100 beats per minute, respiration rate 10–20 breaths per minute, oxygen saturation (Pulse Oximetry) 95%–100%, were monitored continuously during the procedure and was recorded in the raw data. Pigs are very sensitive to stress and handling, which can temporarily increase heart rate and respiration. During anesthesia or procedures, values may be slightly lower, but sudden drops or spikes are more concerning than mild deviations.

Pre-operative:
A purgative was administered 24 hours prior to implantation to ensure adequate intestinal clearance. Feed was withheld overnight before the procedure (Day 0), while water was provided *ad libitum*. On the day of the procedure, body weight was recorded, and the animal was prepared for intervention. Hair was clipped at designated electrocardiogram (ECG) electrode sites (thighs and shoulders of fore- and hind limbs) to facilitate monitoring. Physiological parameters, including ECG, heart rate, respiratory rate, and oxygen saturation, were continuously recorded throughout the procedure (**Table 6**).

Intra-operative and post-operative:
The animal was positioned supine under general anesthesia. A colonoscope was introduced via the rectum with controlled insufflation to visualize the colonic lumen. A guidewire and catheter were advanced under combined endoscopic and fluoroscopic guidance. Contrast imaging was used to measure luminal dimensions and determine appropriate stent size. The stent was deployed using a delivery system, allowing expansion against the colonic wall, with positioning and patency confirmed through imaging. Following the procedure, the animal was allowed to recover and received appropriate analgesic and antibiotic therapy. Daily monitoring included clinical status, feed intake, and body weight. Follow-up endoscopic and fluoroscopic evaluations demonstrated maintained device integrity, proper positioning, and sustained luminal patency, with no observed morbidity or mortality during the study period (**Table 6**).

Table 6: Pre intra and post operative

Purpose	Drug Name	Conc.	Dose	Route	Frequency
Anticholinergic	Atropine	1 mg/mL	0.05 mg/kg	IM	Once before Day 0 procedure and Day 44
Induction anaesthesia	Ketamine	50 mg/mL	15 mg/kg	IM	Once before Day 0 procedure and Day 44
	Xylazine	23.32 mg/mL	2.5 mg/kg	IM	Once before Day 0 procedure and Day 44
Maintenance of Anesthesia	Isoflurane	NA	3%	Face mask	Until intubation on Day 0 and day 44
Maintenance anaesthesia	Isoflurane	NA	3%	Endotracheal tube	Throughout procedure
Euthanasia	Thiopental sodium	303 mg/mL	100 mg/kg	IV	Day 44

Key: Conc. – Concentration; mg – Milligram; mL – Milliliter; kg – Kilogram; IM – Intramuscular; IV – Intravenous;

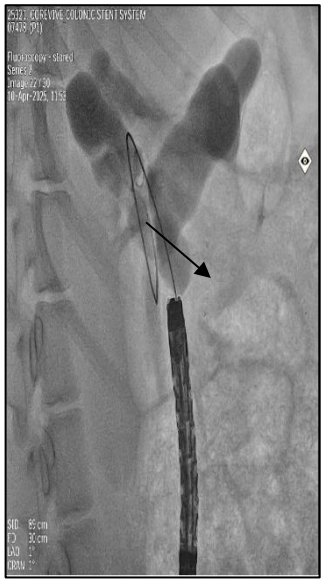
OBSERVATION
The animal demonstrated stable health throughout the study, with body weight increasing from 52.9 kg at Day 0 to 65.3 kg on Day 44, and no morbidity or mortality observed during acclimatization or the experimental period. Anesthesia was maintained with isoflurane (3%) via endotracheal intubation, and continuous intra-operative monitoring of electrocardiogram, respiratory rate, heart rate, and oxygen saturation confirmed stable physiological status. Performance assessment of the device indicated favorable trackability, handling, and

visualization of the delivery system, with reliable deployment, rapid and complete expansion of the colonic stent, and uncomplicated withdrawal of the delivery system. Fluoroscopic and endoscopic evaluations confirmed accurate positioning, patency, and structural integrity of the implant, while histopathological analysis of the explanted tissue demonstrated appropriate endothelialisation with mild inflammatory response and no evidence of adverse injury.

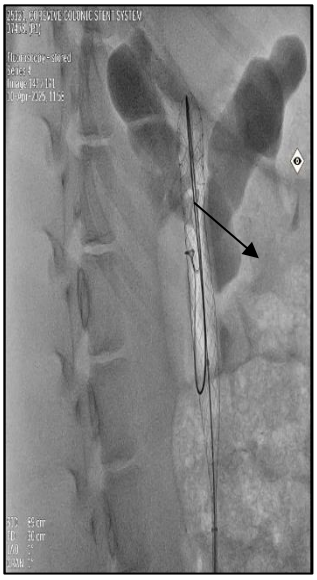
RADIOGRAPHY AND ENDOSCOPIC ANALYSIS

The study evaluated CoRevive™ Colonic Stent System, with the following results.

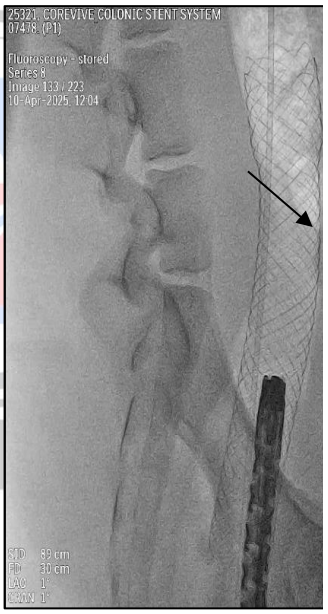
Evaluation of the CoRevive™ Colonic Stent System demonstrated consistent device performance and maintained colonic patency throughout the study period. Baseline fluoroscopic imaging performed prior to implantation established the mean colonic lumen length and diameter. Follow-up fluoroscopic assessments conducted on Day 0, Day 14, and at the terminal time point on Day 44 showed successful stent expansion and sustained lumen patency, with measurable changes in lumen length and diameter over time. Endoscopic evaluations performed pre- and post-implantation on Day 0 and at termination (Day 44) confirmed appropriate stent positioning and revealed no evidence of device-related complications at the implantation site. Representative radiographic and fluoroscopic images illustrating stent placement and luminal changes are shown in **Figure 2**.



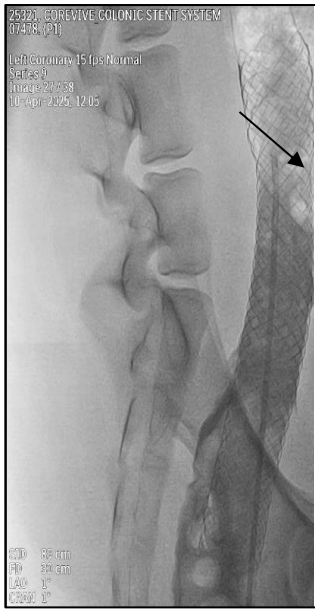
Day 0:Pre-implantation



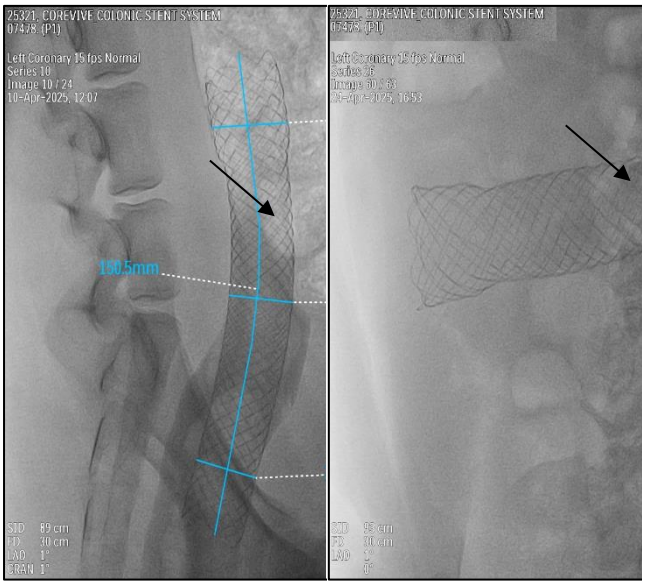
Day 0 :Pre-implantation of Colonic stent



Day 0:Post-implantation endoscopy

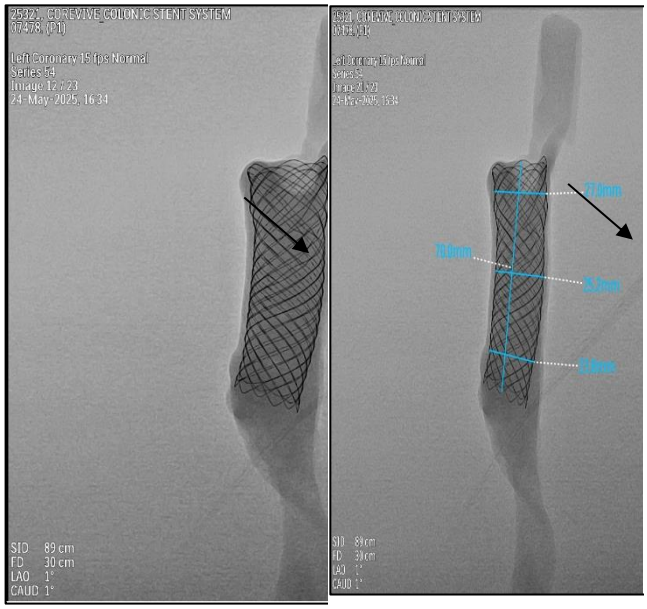


Day 0: Post implantation fluoroscopy



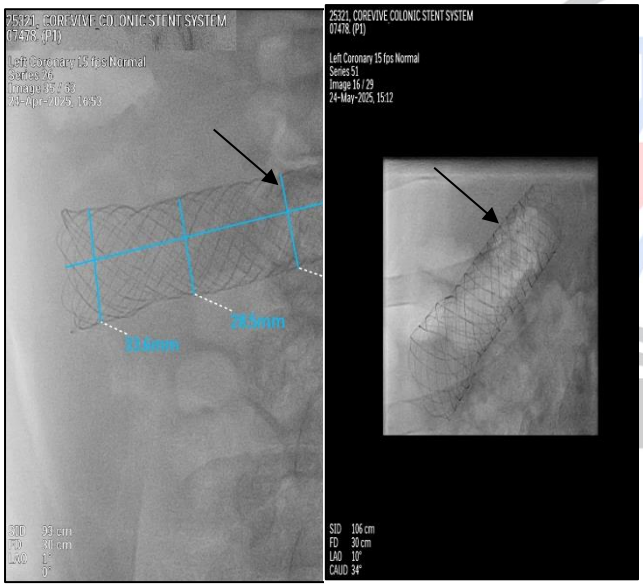
Day 0 :Post-implantation Colonic stent measurements

Day 14 :Stented colonic lumen



Day 44 :Harvested Colonic lumen Fluoroscopy

Day 44 :Harvested Colonic lumen Fluoroscopy Measurements



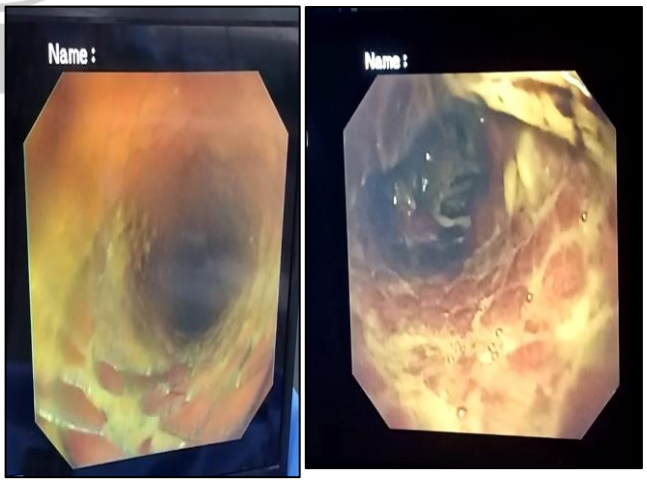
Day 14 :Stented Colonic lumen Measurements

Day 44 :Colonic lumen Fluoroscopy

Figure 2: Radiography and fluoroscopy

Endoscopy Analysis

Endoscopic images were recorded on day 0 pre, post-implantation and on termination (Day 44) for the implantation site are shown in **Figure 3**.



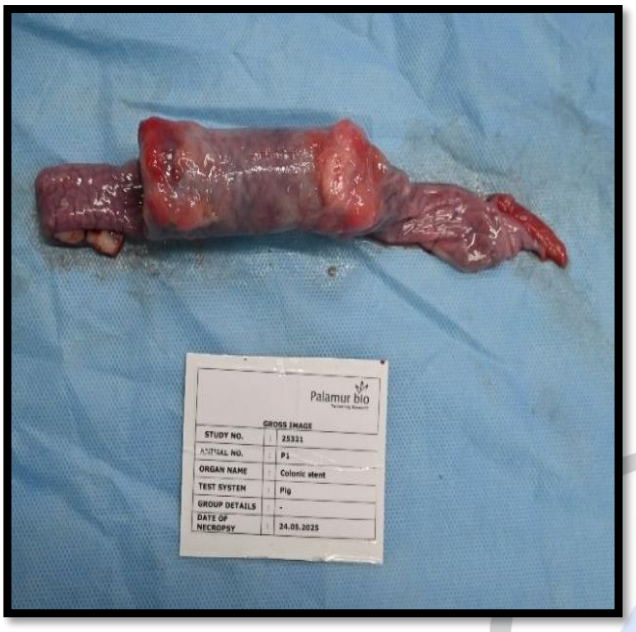
Day 0: endoscopy – After releasing the CoRevive™ Colonic stent system stent at target site of colon

Day 44: endoscopy after harvesting the colon implanted with CoRevive™ Colonic stent system

Figure 3: Endoscopy

Necropsy

A gross necropsy was done for all the organs after euthanasia. In addition, a detailed gross pathological examination was conducted on all the organs for abnormal lesions are shown in Figure 4.



Day 44: Stented Colonic lumen after necropsy

Figure 4: Necropsy

Pathology

Blood samples were collected from the test animal on Day 0 (pre-implantation) and on the terminal day (Day 44) to assess hematological and biochemical parameters. For hematology analysis, approximately 2 mL of blood was collected in K_2EDTA tubes, while 3 mL was collected in lithium heparin tubes for clinical biochemistry evaluations. Hematological assessments were performed using the ADVIA 2120i Hematology System (Siemens Healthcare Diagnostics Inc., NY, USA), and included a comprehensive panel of red and white blood cell indices, platelet counts, reticulocyte percentage, and differential leukocyte counts. Parameters analyzed comprised red blood cell (RBC) count, hemoglobin concentration (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), mean platelet volume (MPV), white blood cell (WBC) count, platelet (PLT) count, red cell distribution width (RDW), hemoglobin distribution width (HDW), and reticulocyte count (Retic). Additionally differential leukocyte count (DLC) included neutrophils, lymphocytes, monocytes, Eosinophils, basophiles, and large unstained cells (LUC).

Clinical chemistry analyses were conducted using the Beckman Coulter AU480 Chemistry Analyzer. Electrolyte measurements (sodium, potassium, chloride, and calcium) were performed using either the same analyzer or the ABG electrolyte analyzer ST200CC in plasma mode. The biochemical profile included assessments of hepatic enzymes—alanine aminotransferase (ALT), Aspartate aminotransferase (AST), alkaline phosphatase (ALP), and gamma-glutamyl transferase (GGT)—as well as renal function indicators such as creatinine (Creat), blood urea nitrogen (BUN), and creatine kinase (CK). Additional metabolic and nutritional markers included albumin (ALB), globulin (GLOB), total protein (T. Pro), glucose (Glu), triglycerides (Trig), cholesterol (HDL Chol), total bilirubin (T. Bill), lactate dehydrogenase (LDH), and inorganic phosphorus (Pi). The albumin/globulin ratio (A/G) was calculated to further assess protein balance.

All parameters were evaluated to monitor potential systemic effects of the implanted device and to ensure the physiological stability of the animal throughout the study period. Both pre- and post-implantation values remained within normal physiological ranges, indicating no evidence of systemic toxicity or organ dysfunction related to the test item.

Euthanasia

On the terminal day (Day 44), the animal was humanely euthanized in accordance with standard veterinary protocols. Euthanasia was performed via intravenous administration of Thiopental sodium at a dose of 100 mg/kg, delivered through the marginal ear vein. Successful induction of euthanasia was confirmed by the absence of cardiac electrical activity (a systole on ECG) and zero oxygen saturation, in accordance with accepted guidelines for confirming death in large animal models. This method ensured a rapid and painless termination, consistent with animal welfare

standards and ethical requirements for preclinical research.

Gross Necropsy

On Day 44, a gross necropsy was carried out to examine all major organs and tissues for potential abnormalities or adverse effects related to the implanted device. Both external and internal observations were made with attention to any pathological signs or morphological changes. No abnormalities were detected (NAD) in any organ system. The absence of visible lesions or structural deviations indicates that the CoRevive™ Colonic Stent System did not cause any gross pathological effects during the study period.

Histopathology

On terminal day 44, the animal was sedated with the combination of Xylazine and Ketamine followed by euthanized by an overdose of thiopental sodium and examined by Pathologist for external and internal gross pathological changes. The CoRevive™ Colonic Stent System along with colon were collected and preserved in 10% neutral buffered formalin. The stented colon of P1 was processed for resin embedding and sectioned around 100-to-200-micron thickness using Secotome cutting machine. Further, thickness will be reduced to the appropriate level needed for examination of slides by using Bainpol VTD Polishing machine. The tissue sections were stained by Haematoxylin and Eosin (H & E) and examined under the light microscope by the study pathologist for evaluation of histopathological lesions. **(Mention Figure 5)**

Histological analysis of Animal No. P1 following implantation of the CoRevive™ Colonic Stent System for a period of 44 days demonstrated a mild inflammatory response and evidence of complete endothelialization across all examined segments. The inflammatory profile was dominated by Polymorphonuclear cells, with scores of 2 (proximal), 1 (middle), and 2 (distal), indicating a mild acute response. Lymphocytic infiltration was observed at low to moderate levels (scores of 1–2), while plasma cells, giant cells, and necrosis were absent in all regions. Macrophages were detected only in the distal segment (score of 1). The subtotal inflammatory cell scores (multiplied by a factor of 2) were 6 for both proximal and middle, and 8 for the distal segment. Assessment of tissue response parameters revealed minimal neovascularization and fibrosis (score of 1 at all locations), and fatty infiltration limited to the proximal segment (score of 1). Total histopathological scores were 9 (proximal), 8 (middle), and 10 (distal), yielding an average score of 9, consistent with a low-grade host response. Notably, endothelialization was complete at all sites, with a score of 3 in the proximal, middle, and distal segments, indicating successful mucosal coverage of the stent and supporting the biocompatibility and tissue integration of the device over the 44-day implantation period.(**Tables 7 and 8**)

Table 7: Histopathology Scores

Animal No.	**P1**		
Location	**Proximal**	**Middle**	**Distal**
Inflammatory cells			
Polymorphonuclear	2	1	2
Lymphocytes	1	2	1
Plasma cells	0	0	0
Macrophages	0	0	1
Giant cells	0	0	0
Necrosis	0	0	0
Inflammatory cells (subtotal X 2) (A)	**6**	**6**	**8**
Tissue response			
Neovascularization	1	1	1
Fibrosis	1	1	1
Fatty Infiltrate	1	0	0
Tissue response subtotal (B)	**3**	**2**	**2**
Total (A+B)	**9**	**8**	**10**
Average		**9**	

Table 8: Endothelization Scores of CoRevive™ Stent in Porcine Colon at 44 Days

Animal No.	Stent Location	Duration	Location	Endothelization	Mean Score
P1	CoRevive™ Colonic Stent System	44 Days	Proximal	3	3
			Mid	3	
			Distal	3	

Histological analysis of the tissues surrounding the CoRevive™ Colonic Stent System in the Animal No. P1, 44 days post-implantation, demonstrated a mild inflammatory response with minimal tissue remodeling and complete endothelialization across all evaluated stent locations. The inflammatory cell population was dominated by Polymorphonuclear leukocytes, with scores of 2 in the proximal and distal segments, and 1 in the middle, corresponding to 5–10 cells per high-powered field (hpf), consistent with a mild acute inflammatory response. Lymphocytic infiltration was observed at low to moderate levels (scores: 1–2), indicating the presence of a limited chronic immune component. Macrophages were noted only in the distal region (score 1), while plasma cells, giant cells, and necrosis were absent in all segments, suggesting the absence of significant chronic, granulomatous, or necrotizing inflammation.

The calculated subtotal for inflammatory cells (with scores multiplied by a factor of two) was 6 in both the proximal and middle regions and 8 in the distal segment, indicating slightly higher reactivity at the distal end of the implant. Despite this, overall inflammatory cell infiltration remained within the mild range, with no evidence of tissue damage or adverse cellular accumulation. These findings align with an expected biocompatible host response to the stent material.

Tissue response parameters further supported the mild nature of the reaction. Neovascularization and fibrosis were consistently scored as 1 across all segments, corresponding to focal capillary proliferation (1–3 buds) and the presence of narrow fibrotic bands**,** respectively. Fatty infiltration was limited to the proximal segment (score 1), where minimal fat deposition associated with fibrosis was observed, while it was absent in the middle and distal regions. These findings reflect a limited foreign body response and minimal stromal remodeling, further supporting the inert nature of the device.

Notably, endothelialization was complete at all three anatomical locations, with a score of 3 in the proximal, middle, and distal segments. This outcome indicates full mucosal coverage of the stent surface, which is critical for reducing the risk of bacterial translocation, minimizing inflammation, and promoting tissue healing. The total histological scores were 9 (proximal), 8 (middle), and 10 (distal), yielding an average score of **9**, which is indicative of a low-grade host tissue response. Collectively, these results demonstrate that the CoRevive™ Colonic Stent System was well tolerated and exhibited favorable tissue integration within the colonic environment over the 44-day evaluation period, as summarized in **Tables 9, 10, and 11.**

Table 9: Histological evaluation system - Cell type/response

Cell type/response	Score 0	1	2	3	4
Polymorphonuclear cells	0	Rare, 1 to 5/hpf[a]	5 to 10/hpf	Heavy infiltrate	Packed
Lymphocytes	0				
Plasma cells	0				
Macrophages	0				
Giant cells	0	Rare, 1 to 2/hpf	3 to 5/hpf		Sheets
Necrosis	0	Minimal	Mild	Moderate	Severe

A hpf = high-powered (400×) field.

Table 10: Histological evaluation system - Tissue response

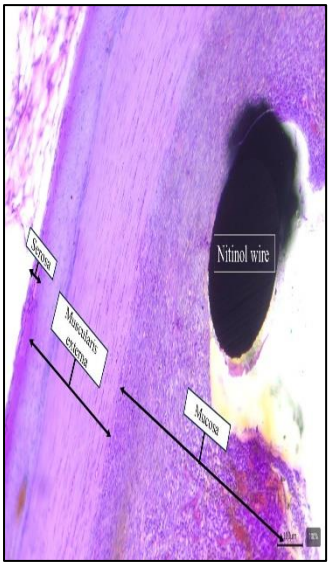
Response	Score 0	1	2	3	4
Neovascularization	0	Minimal capillary proliferation, focal, 1 to 3 buds	Groups of 4 to 7 capillaries with supporting	Broad band of capillaries with supporting fibroblastic	Extensive band of capillaries with supporting

			fibroblastic structures	structures	fibroblastic structures
Fibrosis	0	Narrow band	Moderately thick band	Thick band	Extensive band
Fatty infiltrate	0	Minimal amount of fat associated with fibrosis	Several layers of fat and fibrosis	Elongated and broad accumulation of fat cells about the implant site	Extensive fat completely surrounding the implant

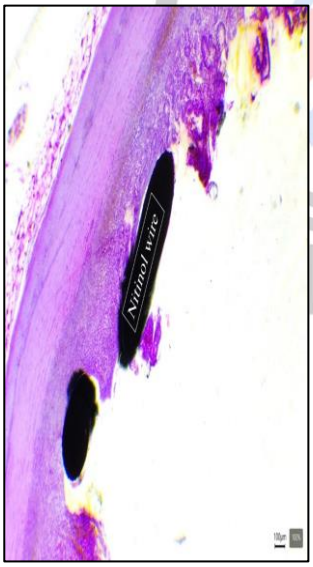
Table 11: Endothelization Scoring Criteria

Endothelization	Score
None	0
Mild Endothelization	1
Moderate Endothelization	2
Complete Endothelization	3

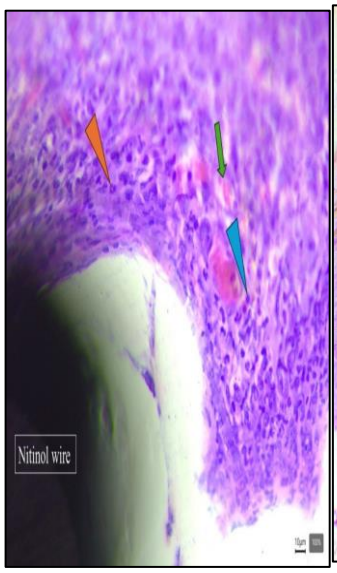
Histopathology Images:



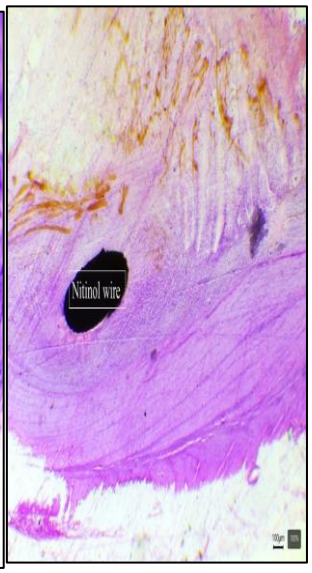
No. P1 (COREVIVE™), MID, H&E 10X (LABELLED IMAGE)



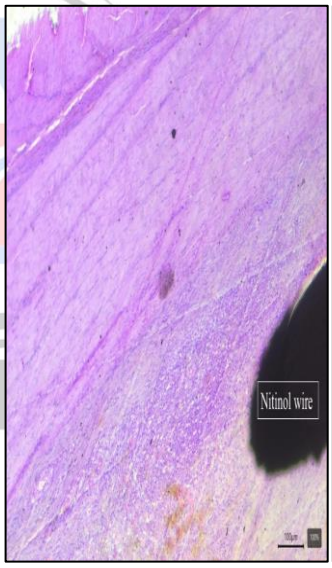
No. P1 (COREVIVE™), MID, H&E 4X



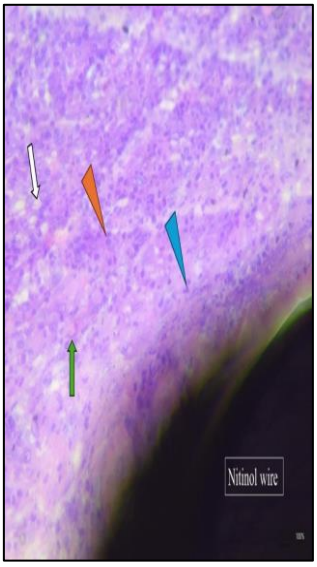
No. P1 (COREVIVE™), MID, H&E 40X



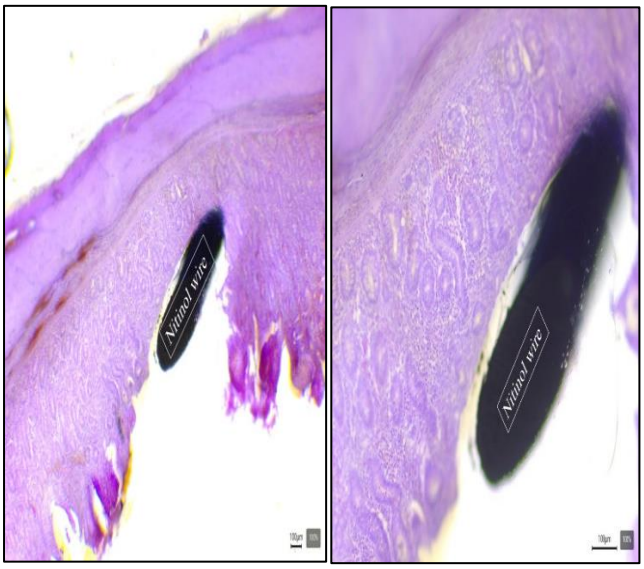
No. P1 (COREVIVE™), PROXIMAL, H&E 4X



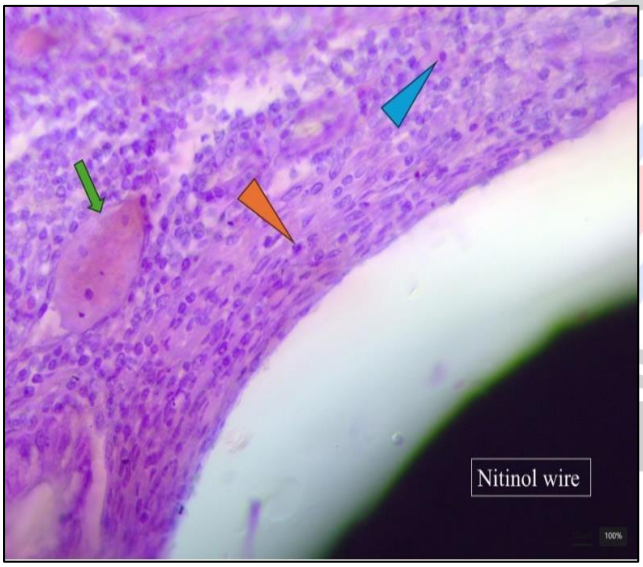
No. P1 (COREVIVE™), PROXIMAL, H&E 10X



No. P1 (COREVIVE™), PROXIMAL, H&E 40X



No. P1 (COREVIVE™), DISTAL, H&E 4X **No. P1 (COREVIVE™), DISTAL, H&E 10X**



No. P1 (COREVIVE™), DISTAL, H&E 40X

Neutrophils; Lymphocytes;
Neovascularization; Fatty Infiltration

Figure 5: Histopathology

RESULT:

The animal has maintained normal physiological and clinical status throughout the study period, with body weight increasing from 52.9 kg on Day 0 to 65.3 kg by Day 44. No morbidity or mortality was observed, and daily clinical observations remained normal. Post-implantation pain was moderate on Day 0, decreased to mild by Day 1, and fully resolved by Day 4, with no recurrence.

Clinical pathology parameters assessed on Day 0 and Day 44 remained within normal limits, with no clinically significant changes observed. Performance evaluation demonstrated successful delivery and deployment of the CoRevive™ Colonic Stent System, with smooth expansion, appropriate conformability, and maintained luminal patency. Fluoroscopic measurements showed effective dilation by Day 14 (28.2 mm proximal; 33.6 mm distal) and sustained patency at Day 44 (21.0 mm proximal; 24.5 mm distal), with no evidence of migration, collapse, or obstruction.

Gross pathological examination revealed no abnormalities. Histological evaluation at Day 44 showed minimal to mild inflammatory response, characterized by low scores for polymorphonuclear cells, lymphocytes, and macrophages, with no plasma cells, giant cells, or necrosis observed. Minimal neovascularization and fibrosis were present, limited fatty infiltration was noted, and complete endothelialization was observed across all segments. The mean histological score was 9, indicating a low-grade tissue response and favorable local biocompatibility.

DISCUSSION:

The present feasibility study evaluated the safety and short-term functional performance of the CoRevive™ Colonic Stent System in a healthy porcine model over a 44-day implantation period. Successful deployment of the device was achieved under combined endoscopic and fluoroscopic guidance, with maintained luminal patency and stable stent positioning throughout the study duration.

The animal remained clinically stable during the observation period, demonstrating normal behavior, regular feed intake, and progressive body weight gain. No morbidity, mortality, or clinically significant adverse events were observed, indicating acceptable procedural safety and tolerance of the implanted device.

Fluoroscopic and endoscopic evaluations demonstrated satisfactory stent expansion, conformability, and positional stability within the colonic lumen. The delivery system provided controlled deployment and accurate placement at the target site, supporting the functional performance of the device for colonic applications.

Histopathological examination demonstrated mild inflammatory cell infiltration with complete endothelialization across all evaluated segments. No evidence of severe tissue injury, necrosis, or excessive foreign body reaction was identified. These findings suggest favorable local tissue response and acceptable biocompatibility of the CoRevive™ Colonic Stent System within the colonic environment.

The braided Nitinol stent design and flexible delivery mechanism may contribute to effective lumen support, conformability to colonic anatomy, and stable tissue integration. Overall, the findings provide preliminary evidence supporting the feasibility and short-term safety of the device.

However, this study was limited by the use of a single healthy animal, absence of a disease-specific obstruction model, lack of a comparator group, and relatively short follow-up duration. Therefore, further preclinical investigations involving larger sample sizes, clinically relevant models, comparative assessment with commercially available self-expanding metallic stents (SEMS), and long-term evaluation are necessary to further establish device safety and performance prior to clinical application.

CONCLUSION:

A 44-day study of the CoRevive™ Colonic Stent System in a healthy porcine model confirmed the device's feasibility. The procedure was complication-free, maintaining both proper placement and an open lumen. Clinical health and weight gain remained on a positive trajectory. Histopathological results were encouraging, showing mild local tissue response and full endothelialization. To move toward human clinical trials, subsequent studies must address current limitations by utilizing larger sample sizes, disease-specific models, and comparative benchmarks against traditional metallic stents.

ABBREVIATION:

Abbreviation	Full Form
CoRevive™	Colonic Stent System
SEMS	Self-Expanding Metallic Stents
ECG	Electrocardiogram
IM	Intramuscular
IV	Intravenous
H&E	Hematoxylin and Eosin
RBC	Red Blood Cells
WBC	White Blood Cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
PLT	Platelets
MPV	Mean Platelet Volume
RDW	Red Cell Distribution Width
HDW	Hemoglobin Distribution Width
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
ALP	Alkaline Phosphatase
GGT	Gamma-Glutamyl Transferase
BUN	Blood Urea Nitrogen
CK	Creatine Kinase
ALB	Albumin
GLOB	Globulin
T. Pro	Total Protein
Glu	Glucose
Trig	Triglycerides
HDL	High-Density Lipoprotein
LDH	Lactate Dehydrogenase
Pi	Inorganic Phosphorus
A/G	Albumin/Globulin Ratio
Fr	French (Catheter Size Unit)
mm	Millimeter
cm	Centimeter
kg	Kilogram
mg	Milligram
mL	Milliliter

COI (Conflict of Interest)

All the authors are an employee of Meril Medical Innovations Private Limited, Vapi, Gujarat – India and declare no competing interests related to this study.

REFRENCES:

[1]. Hamad MA, Mentges B, Buess G. Laparoscopic sutured anastomosis of the bowel. Surg Endosc.

2003;17:1840–1844. doi: 10.1007/s00464-002-8618-z.

[2]. Karamanakos SN, Sdralis E, Panagiotopoulos S, Kehagias I. Laparoscopy in the emergency setting: a retrospective review of 540 patients with acute abdominal pain. Surg Laparosc Endosc Percutan Tech. 2010; 20:119–124.

[3]. Fan C, Ma J, Zhang HK, Gao R, Li JH, Yu L, Wu Z, Lv Y. Sutureless intestinal anastomosis with a novel device of magnetic compression anastomosis. Chin Med Sci J. 2011; 26:182–189.

[4]. Fok M, Ah-Chong AK, Cheng SW, Wong J. Comparison of a single layer continuous hand-sewn method and circular stapling in 580 oesophageal anastomoses. Br J Surg. 1991; 78:342–345.

[5]. Cohen SM, Clem MF, Wexner SD, Jagelman DG. An initial comparative study of two techniques of laparoscopic colonic anastomosis and mesenteric defect closure. Surg Endosc. 1994;8:130–134.

[6]. Biological Evaluation of Medical Devices - Part 2: Animal welfare requirements. ISO 10993-2:2006(E).

[7]. Guidance Document on the Recognition, Assessment and Use of Clinical signs as humane endpoints for Experimental Animals used in Safety Evaluation. ENV/JM/MONO (2000)7. OECD, December, 2000.

[8]. CPCSEA Guidelines for Laboratory Animal Facility. Indian Journal of Pharmacology. 2003; 35: 257-274.

[9]. Arezzo, A., Passera, R., Lo Secco, G., Verra, M., Bonino, M. A., Targarona, E., Morino, M., & Collaborative Study Group. (2017). Stent as bridge to surgery for left-sided malignant colonic obstruction: A systematic review and meta-analysis of randomized controlled trials. *Surgical Endoscopy, 31*(12), 524–533.

[10]. Baron, T. H. (2005). Colonic stenting: Technique, indications, and complications. *Gastrointestinal Endoscopy Clinics of North America, 15*(4), 757–771.

[11]. Baron, T. H., Rey, J. F., & Spinelli, P. (2002). Expandable metal stent placement for colorectal obstruction. *Endoscopy, 34*(10), 823–830.

[12]. Camúñez, F., Echenagusia, A., Simó, G., Turegano, F., Vazquez, J., Barreiro-Meiro, I., & Malignant Colorectal Obstruction Study Group. (2000). Malignant colorectal obstruction treated by means of self-expanding metallic stents: Effectiveness before surgery and in palliation. *Radiology, 216*(2), 492–497.

[13]. Cardoso, P. M., & Rodrigues-Pinto, E. (2025). Self-expandable metal stents for obstructing colon cancer and extracolonic cancer: A review of latest evidence. *Cancers, 17*(1), 87.

[14]. Cirocchi, R., Farinella, E., Trastulli, S., Desiderio, J., Listorti, C., Boselli, C., Noya, G., & Parisi, A. (2013). Safety and efficacy of endoscopic colonic stenting as a bridge to surgery in the management of intestinal obstruction due to left colon and rectal cancer: A systematic review and meta-analysis. *Surgical Oncology, 22*(1), 14–21.

[15]. De Gregorio, M. A., Mainar, A., Tejero, E., Tobío, R., Alfonso, E., Pinto, I., & Herrera, M. (1998). Acute colorectal obstruction: Stent placement for palliation and bridge to surgery. *Radiology, 209*(1), 117–120.

[16]. Dohmoto, M. (1991). New method: Endoscopic implantation of rectal stent in palliative treatment of malignant stenosis. *Endoscopia Digestiva, 3*, 1507–1512.

[17]. Fardanesh, A., George, J., Hughes, D., et al. (2024). The use of self-expanding metallic stents in the management of benign colonic obstruction: A systematic review and meta-analysis. *Techniques in Coloproctology, 28*, 85.

[18]. Fiori, E., Lamazza, A., De Cesare, A., Schillaci, A., Sterpetti, A. V., & Cangemi, V. (2004). Palliative management of malignant colorectal obstruction using self-expanding metallic stents. *The American Surgeon, 70*(8), 665–669.

[19]. Gupta, K., & Freeman, M. L. (2008). Enteral and colonic self-expanding metallic

stents. *Reviews in Gastroenterological Disorders, 8*(2), 83–97.

[20]. Jung, D. Y., Lee, Y. K., & Yang, C. H. (2014). Status and literature review of self-expandable metallic stents for malignant colorectal obstruction. *Clinical Endoscopy, 47*(1), 65–73.

[21]. Kim, J. H., Song, H. Y., Shin, J. H., et al. (2008). Metallic stent placement in benign and malignant colorectal strictures. *RadioGraphics, 28*(7), 1867–1880.

[22]. Khot, U. P., Lang, A. W., Murali, K., & Parker, M. C. (2002). Systematic review of the efficacy and safety of colorectal stents. *British Journal of Surgery, 89*(9), 1096–1102.

[23]. Mainar, A., De Gregorio, M. A., Tejero, E., Tobío, R., Alfonso, E., Pinto, I., & Herrera, M. (1996). Colorectal obstruction: Treatment with metallic stents. *Radiology, 198*(3), 761–764.

[24]. Pirlet, I. A., Slim, K., Kwiatkowski, F., Michot, F., & Millat, B. (2011). Emergency preoperative stenting versus surgery for acute left-sided malignant colonic obstruction. *Surgical Endoscopy, 25*(6), 1814–1821.

[25]. Repici, A., De Caro, G., Luigiano, C., et al. (2012). WallFlex colonic stent placement for management of malignant colonic obstruction. *Gastrointestinal Endoscopy, 75*(6), 1268–1275.

[26]. Saito, S., Yoshida, S., Isayama, H., et al. (2011). A prospective multicenter study on colorectal stenting for malignant colorectal obstruction in Japan. *Gastrointestinal Endoscopy, 74*(5), 108–115.

[27]. Sebastian, S., Johnston, S., Geoghegan, T., Torreggiani, W., & Buckley, M. (2004). Pooled analysis of the efficacy and safety of self-expanding metal stenting in malignant colorectal obstruction. *The American Journal of Gastroenterology, 99*(10), 2051–2057.

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