International Journal of Advanced Research in Science, Engineering and Technology

Vol. 12, Issue 11, November 2025

ISSN: 2350-0328

IMPACT FACTOR 7.150

Evaluation of safety and performance of the EsoRevive™ Esophageal Stent System in a porcine model

Minocha Dr. Pramodkumar, Kothwala Dr. Deveshkumar, Khusboo Shah, Pandya Kamna, *Shinde Divya, Solanki Himanshu , Desai Digvijaysinh

Meril Medical Innovations Private Limited, Bilakhia House, Survey no.879, Muktanand Marg, Chala, Vapi, Dist-Valsad, Gujarat, 396191.

ABSTRACT: A preclinical investigation was carried out to analyze the safety, efficacy, and biological reaction of the EsoRevive™ Esophageal Stent System—a self-expanding metallic stent that is meant for esophageal strictures treatment and gastroesophageal reflux prevention. The goal was to investigate its in-vivo functionality and biocompatibility through the usage of a pig model. Two bypigs were created with surgical induction of esophageal strictures, followed by stent placement under combined fluoroscopic and endoscopic guidance. The total observation period for the animals lasted 30 and 95 days, and the assessments were conducted on the basis of clinical signs, hematological and biochemical parameters, and outcomes related to the stent. The stent displayed favorable deployment characteristics and stable placement in the esophagus, and it was able to keep the lumen open for 30 days without any adverse tissue reactions happening The slight caudal displacement and partial blockage of the lumen due to excessive tissue growth were noticed at 95 days; however, the stent did not fail and its integrity was maintained. The investigation of the tissue samples indicated very little inflammation at the beginning that gradually disappeared over time, thus the biocompatibility of the stent was good. No unusual signs of clinical toxicity in the system were recognized, and blood values were in normal ranges. The study results indicate that the stent provides good short-term esophageal support and mid-term outcomes that are acceptable, with little tissue irritation. The light tissue overgrowth seen at the study's conclusion indicates the necessity for further long-term studies to better the stent's surface properties and anchoring mechanisms. To sum up, the present research indicates that the large animal model for the esophageal stenting system has a safety and efficacy profile that is good enough to support its use in the treatment of esophageal strictures.

KEYWORDS: Esophageal stent, Preclinical study, Porcine model, Biocompatibility, Tissue overgrowth, Esophageal stricture

International Journal of Advanced Research in Science, Engineering and Technology
ISSN: 2350-0328
Vol. 12, Issue 11, November 2025

I.INTODUCTION

An Esophageal Stent System EsoRevive™ is fitted with a specially designed stent for easy installation by a flexible delivery system. The stent is constructed using Nitinol wire and is either partially or completely coated with silicone polymer to prevent tumor infiltration through the wire mesh and to close off concurrent esophageal fistulas. [1,2]. A suture is threaded through the proximal end of the stent and is intended to aid in removal during the initial placement procedure, especially in cases of incorrect deployment [3]. The stent has flares at both ends to minimize migration post-placement [4]. It includes four radiopaque (RO) markers to assist in deployment using fluoroscopy. RO marker bands on the inner tube of the delivery system identify the stent ends when constrained, while an additional band marks the point beyond which reconstrainment is not possible. A fourth RO marker on the distal end of the outer tube indicates the extent of stent deployment [5]. The interior tube includes a central lumen for a 0.038 in (0.97 mm) guidewire.

For the sake of safety and efficacy, esophageal stents are required to perform strict preclinical testing under physiological conditions. The porcine model is commonly used in gastroenterology and medical device assessment because it is anatomically and functionally similar to the human esophagus. [6,7]. The porcine esophageal model is thus considered suitable for assessing stent performance, biocompatibility and tissue response over time [8].

The present preclinical study was designed to assess the performance and biological response of the Esophageal Stent System, a self-expanding metallic stent, in a porcine model over 95-day duration. The primary objectives of this study were to:

- Evaluate the stent's ability to maintain esophageal patency and support normal esophageal function
- Determine its effectiveness in alleviating symptoms typically associated with esophageal strictures
- Monitor for any local or systemic complications arising from stent implantation over an extended in vivo period [9]

Two healthy male swine were selected for fluoroscopic and endoscopic stent implantation. During the experiment, different clinical signs, deaths, and illnesses were observed in the animals and they also had their blood and plasma tested in order to provide thorough assessment of the device's safety and efficacy. [10].

II.MATERIALS AND METHODS

MEDICATION DETAILS

The drugs administered to the animal pre-operative, intra-operative and post-operatively were recorded in the raw data and described in table no. 1 below,

Table 1: Details of medications used during the study

Drug name	Manufactured by	Batch / Lot No.	Expiry date
Ketamine	Themis Medicare Ltd.	KME24002	Sep 2026
Xylazine	IIL India	FHK24005	Feb 2027
Isoflurane	Troikaa Pharmaceuticals Ltd.	I30250	July 2027
Tramadol	Neon Lab	KP949131	Nov 2024
Atropine	Pentagon Labs Ltd.	23GAS002	Jun 2026
Thiopentone	Neon Lab	173288	Feb 2026
Tramadol	Neon Lab	KP1568007	Feb 2025
Enrofloxacin	Pharmanza (India) Pvt. Ltd.	CM4433013	June 2026

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IMPACT FACTOR 7.150

III.MATERIALS REQUIRED

1. Esophageal Stent

2. Delivery System

DEVICE DESIGN

Details of the Esophageal Stent System are as follows:

Name of the test item	EsoRevive™ Esophageal Stent System
Intended Use of the Device	Esophageal Stent System is used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistulas.
Total Surface area/ Dimensions (Length, Inner Diameter, Outer Diameter, Width, Radius etc.)	22610.26 mm^2 / 20 mm×120 mm
Manufactured by	Meril Life Sciences Pvt. Ltd., Muktanand Marg, Chala, Vapi - 396191, Gujarat, India.
Lot No.	EESAts12
Manufacturing date	12.04.2024
Expiry date	11.04.2026
Safety of handling	Protective gloves face masks, aprons/ protective suits, and goggles will be used to ensure the health and safety of the personnel.

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

SIZE MATRIX

Table 2: Size Matrix of Esophageal Stent System

Sr. No.	Type	Stent Body Diameter (mm)	Stent Flange Diameter (mm)	Stent Length (mm)	Delivery System Length (cm)	Delivery System Diameter (Fr)	Guidewire Diameter (Inch)
1.	Partially Covered & Fully Covered	18	23	80	80	18	0.035
2.		18	23	100	80	18	0.035
3.		18	23	120	80	18	0.035
4.		18	23	150	80	18	0.035
5.		20	25	80	80	18	0.035
6.		20	25	100	80	18	0.035
7.		20	25	120	80	18	0.035
8.		20	25	150	80	18	0.035

PRODUCT IMAGE

The schematic diagram of Esophageal Stent System is as follows;

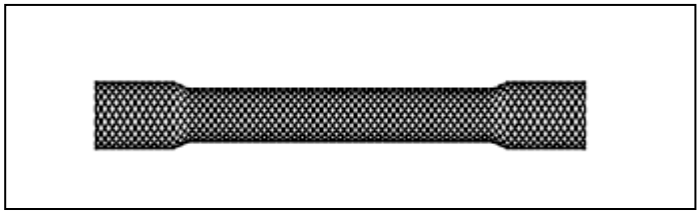


Figure 1: Schematic diagram of EsoRevive™ Esophageal Stent System

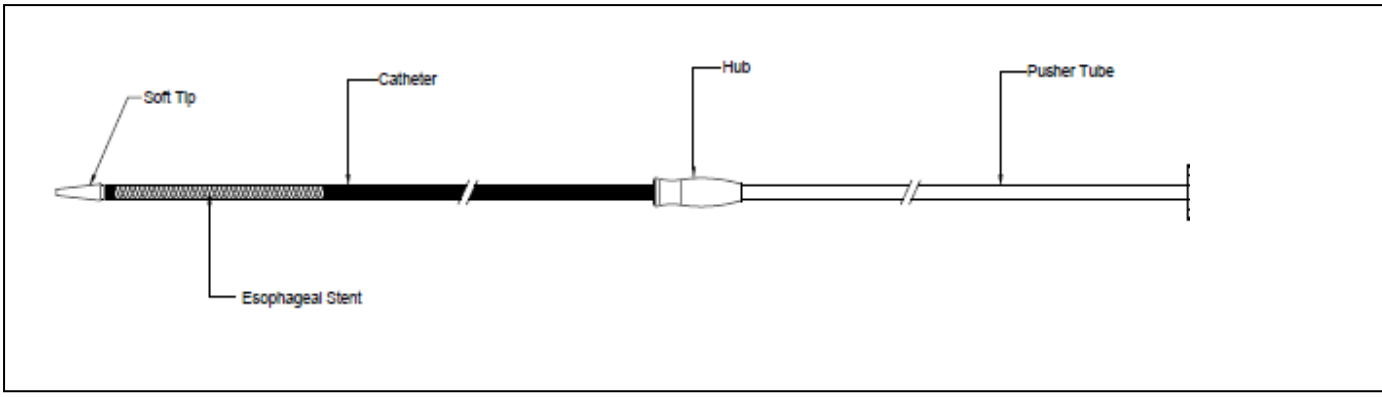


Figure 2: Schematic diagram of EsoRevive™ Esophageal Delivery System

The actual image of Esophageal Stent System is as follows;

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

Figure 3: Actual Image of EsoRevive™ Esophageal Stent System

Figure 4: Actual Image of EsoRevive™ Esophageal Delivery System

DEVICE COMPONENT DESCRIPTION

Table 3: Device Component Description of EsoRevive™ Esophageal Stent System

Sr. No.	Component	Raw Material
1.	Esophageal Stent	Nitinol Wire & Silicone
2.	Delivery System	
i)	Catheter	Pebax, PTFE, SUS304
ii)	Pusher Tube	HDPE
iii)	Peek Tube	PEEK 450 G
iv)	Stent Locker	SS316
v)	Soft Tip	Pebax 3533
vi)	Radiopaque Marker	Platinum/Iradium

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

EXPERIMENTAL PROCEDURE

Fasting: The animals were fasted overnight before procedure (day 0) and before anesthesia whenever animals were taken for follow-up while water was provided *ad libitum*. Feed was further withheld for a period of minimum 4 hrs after recovery of the animals from anesthesia.

Animal Preparation: Animal was prepared and draped for aseptic procedure. The animal was weighed and anesthetized with pre-anesthetic, Atropine at a dose of 0.05 mg/kg (IM), Xylazine 2.5 mg/kg (IM), and Ketamine 15 mg/kg (IM) followed by inhalation anesthesia of 1-4% through facemask. **Tramadol** (4 mg/kg, IM) as an analgesic was administered to the animal once prior to the procedure.

Animal hair was clipped free of hair on the electrode placing sites, neck region, chest and flank area. Once the glottis reflexes were checked, animal was intubated with an endotracheal tube.

Table 4: Drugs for Swine during Pre, Intra and Post-operative care

Sr. No.	Purpose	Drug name	Conc.	Dose	Route	Frequency
1.	Anti-Cholinergic	Atropine	1 mg/mL	0.05 mg/kg	IM	Day 0, 9, 16, 23, 30, 36, 44, 51, 58, 65, 72, 79, 86 and 95
2.	Induction Anesthesia	Ketamine	50 mg/mL	15 mg/kg	IM	
		Xylazine	23.32 mg/mL	2.5 mg/kg	IM	
		Isoflurane	NA	1-3%	Face mask	Until intubation, on day 0, 9, 16, 23, 30, 36, 44, 51, 58, 65, 72, 79, 86 and 95
3.	Maintenance Anesthesia	Isoflurane	NA	1-3%	Endotracheal tube	Throughout during the procedure
4.	Analgesic	Tramadol	50 mg/mL	4 mg/kg	IM	For 5 days from day 0 procedure
5.	Antibiotic	Enrofloxacin	100 mg/mL	7 mg/kg	IM	For 5 days from day 0 procedure
6.	Euthanasia	Thiopental sodium	303 mg/mL	100 mg/kg	IV	Day 30 and day 95

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IMPACT FACTOR 7.150

EXPERIMENTAL DESIGN

OBSERVATIONS

Body Weights: Body weights were taken on acclimatization start day, on procedural day (day 0) and on termination day. In addition, body weights were taken on follow up days.

Clinical Signs

1. Acclimatization

Morbidity/Mortality: Animals were examined twice daily for Morbidity/Mortality (once daily on holidays).

Cage Side Observations: Cage Side Observations of the animals were performed for pain score together with any signs of illness/any deviations of health.

2. Pre-operative

Morbidity/Mortality: Animals were examined for Morbidity/Mortality.

Cage Side Observations: Cage Side Observations of the animals were performed for pain score together with any signs of illness/any deviations of health.

3. Intra-operative

Electrocardiography (ECG), heart rate, respiratory rate, and oxygen saturation were monitored and documented in the operation notes.

4. Post-operative (day 1 to till termination)

Morbidity/Mortality: Electrocardiography (ECG), heart rate, respiratory rate, and oxygen saturation were monitored and documented in the operation notes.

Cage Side Observations: Cage Side Observations of the animals were performed for pain score together with any signs of illness/any deviations of health.

PATHOLOGY

1. Clinical Pathology

Blood samples were taken on day 0 (before the procedure) and on the last day.

Table 6: Blood Collection details

Collection Tube	Volume (mL)	Purpose	Time Points
K_2EDTA	2	Hematology	On day 0, prior to procedure and on termination day
Lithium Heparin	3	Clinical Chemistry	On day 0, prior to procedure and on termination day

Following hematology and clinical biochemistry parameters were analyzed using Hematology analyzer (Siemens Advia2120i) and Clinical Biochemistry (Beckman Coulter AU480). Electrolyte parameters were performed using Electrolyte analyzer (Starlyte 3/ABG electrolyte analyzer-ST200CC) in plasma mode.

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

Table 7: Hematology Parameters evaluated

Sr. No.	Hematology Parameters	Abbreviations	Units
1.	Red Blood Corpuscles	RBC	10^{12}/L
2.	Haemoglobin	HGB	g/L
3.	Haematocrit	HCT	L/L
4.	Mean Corpuscular Volume	MCV	fL
5.	Mean Corpuscular Haemoglobin	MCH	pg
6.	Mean Corpuscular Haemoglobin Concentration	MCHC	g/L
7.	Mean Platelet Volume	MPV	fL
8.	Reticulocytes Counts	Retic	%
9.	White Blood Corpuscles	WBC	10^{9}/L
10.	Platelets	PLT	10^{9}/L
11.	Red Cell Distribution Width	RDW	%
12.	Haemoglobin Distribution Width	HDW	g/L
13.	Differential Leucocyte Count[2]	DLC	%

Table 8: Clinical Biochemistry Parameters evaluated

Sr. No.	Clinical Biochemistry Parameters	Abbreviations	Units
1.	Alanine Aminotransferase	ALT	U/L
2.	Alkaline Phosphatase	ALP	U/L
3.	Aspartate Aminotransferase	AST	U/L
4.	Gamma Glutamyl Transpeptidase	GGT	U/L
5.	Albumin	ALB	g/L
6.	Globulin	GLOB	g/L
7.	Albumin/Globulin ratio (calculated value)	A/G	Ratio

International Journal of Advanced Research in Science, Engineering and Technology
ISSN: 2350-0328
Vol. 12, Issue 11, November 2025

8.	Potassium	K	mmol/L
9.	Sodium	Na	mmol/L
10.	Calcium	Ca	mmol/L
11.	Chloride	Cl	mmol/L
12.	Inorganic Phosphorous	Pi	mmol/L
13.	Creatinine	Creat	µmol/L
14.	Creatine Kinase	CK	U/L
15.	Blood Urea Nitrogen	BUN	mmol/L
16.	Glucose	Glu	mmol/L
17.	Cholesterol	HDL Chol	mmol/L
18.	Total Plasma Protein	T. Pro	g/L
19.	Triglycerides	Trig	mmol/L
20.	Total Bilirubine	T. Bil	µmol/L
21.	Lactate Dehydrogenase	LDH	U/L

2. Euthanasia

The animals were euthanized on follow-up time points (P1-day 30, P2-day 95) with a thiopental sodium injection (100 mg/kg, IV). The death was confirmed via observation of a systolic ECG and zero oxygen saturation.

3. Gross Necropsy

A gross necropsy was done for wound areas and all the organs after euthanasia. In addition, a detailed gross pathological examination was conducted on all the organs for abnormal lesions.

4. Histopathology

At scheduled sacrifice dates, the male P1 (day 30) and P2 (day 95) animals were euthanized by thiopental sodium and examined by pathologist for external and internal gross pathological changes. As per study plan, the EsoRevive™ Esophageal Stent System along with esophagus were collected and preserved in 10% neutral buffered formalin. The stented esophagus of P1 and P2 were processed for resin embedding and sectioned around 100 to 200 micron thickness using Secotom Cutting Machine. Further, thickness was 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.

RESULTS

1. **Body weights:** Body weights of the animals were taken on acclimatization start day (P1-50.1 kg, P2-54.0 kg), on procedural day (P1-50.1 kg, P2-54.2 kg), and on termination day (P1-55.8 kg, P2-61.9 kg) as shown in table no. 9,
2.

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IMPACT FACTOR 7.150

Table 9: Body Weight of the animals

Day	Date	Body Weight (Kg)	
		P1	P2
Acclimatization day 1	23/08/24	50.1	54.0
0	26/08/24	50.1	54.2
9	04/09/24	50.6	55.1
16	11/09/24	51.3	56.2
23	18/09/24	52.2	57.4
30	25/09/24	55.8	59.1
36	01/10/24	The P1 animal was euthanized on Day 30; therefore, no further data or observations were collected after this point.	58.2
44	09/10/24		58.5
51	16/10/24		58.8
58	23/10/24		59.2
65	30/10/24		59.6
72	06/11/24		59.9
79	13/11/24		60.8
86	20/11/24		61.5
95	29/11/24		61.9

2. Morbidity/Mortality: There was no morbidity/mortality observed throughout the study duration from acclimatization start day to till termination day (P1-day 30, P2-day 95) as shown in table no. 10,

Table 10: Morbidity/Mortality of the animals

Animal Number	Acclimatization Phase		Experiment Phase	
	41122	40406	P1	P2
Sex	Male	Male	Male	Male
Day of acclimatization	Mortality/Incidences		Mortality/Incidences	

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IMPACT FACTOR 7.150

Acclimatization Phase (day 1 to 3)	0/2	--	
Experiment Phase (P1: day 0 to 30)	--	0/2	--
Experiment Phase (P2: day 0 to 95)	--	--	0/2

3. Clinical Sign: In the cage side observations, animals were observed for behavior, posture, movements, skin and secretions from the orifices. No abnormal clinical signs were observed throughout the study duration from acclimatization start day to till termination day (P1-day 30, P2-day 95).

Along with the clinical signs, the pain was assessed on the scale of 0-3 (0-no pain, 1-mild pain, 2-moderate pain and 3-severe pain) from day 0 to till termination day (P1-day 30, P2-day 95).

Both the animals (P1&P2) showed moderate pain (2) on day 0 and day 1, mild pain (1) from day 2 till day 4 which subsided on day 5 and there was no sign of pain (0) from day 5 to till the terminal day (P1-day 30, P2-day 95) for both the animals.

4. Performance Evaluation of Test Item

4.1. Ease of deployment at the target site: The test item demonstrated excellent ease of deployment, with a smooth and efficient process in both animals P1 & P2. The device accurately placed at the target site

4.2. Accuracy of deployment including migration of the device: The device was deployed accurately, with no significant instances of migration observed throughout the study in both animals P1 & P2.

4.3. Position and functionality of the implant at post-implantation

Day 30 (P1): The position of the implant was optimal with no significant displacements. The stent maintained its intended placement within the esophageal lumen, with good patency observed on fluoroscopy and endoscopy. The functionality was deemed excellent, with no signs of obstruction, and the esophageal walls showed little vegetative endothelial growth.

Day 95 (P2): At terminal time point, the stent remained well-positioned, with around 5-7 mm caudal migration observed. The fluoroscopic examinations confirmed well expanded esophageal segment with material integrity conserved except one of the strut sites, a partial endothelialization was observed. The stent appears in the target position under endoscopic examinations, with partial occlusion noted due to vegetative growth.

Vegetative Growth:

- Irregular, friable, and exophytic vegetative growth observed along the stented segment
- The growth was partially obstructing the lumen, leading to narrowing
- Mucosal irregularity and ulceration noted over the growth
- Contact bleeding present on probing

These results demonstrate that the esophageal stent functionally appeared performing well up to day 30 but the vegetative growth observed with the mucosal irregularity and fragility for bleeding makes it difficult to keep the esophageal lumen patent without obstruction.

The fluoroscopy and endoscopy images for P1 and P2 animals are provided in below section.

5. Pathology

5.1. Clinical Pathology: Blood samples were collected on day 0 (prior to the procedure) and on the terminal day. On day 0, the baseline hematology and clinical biochemistry parameters were within normal range and there were no abnormal findings. On terminal day (P1-day 30, P2-day 95), hematology and clinical biochemistry parameters were within normal range and there were no abnormal findings compared to the baseline.

International Journal of Advanced Research in Science, Engineering and Technology
ISSN: 2350-0328
Vol. 12, Issue 11, November 2025

The results of clinical biochemistry and hematology parameters are tabulated in tables 11 & 12.

Table 11: Clinical Biochemistry Data

Parameters	P1		P2	
	Baseline	Terminal	Baseline	Terminal
ALB (g/L)	29.10	32.50	33.80	31.30
ALP (U/L)	103.00	79.00	63.00	81.00
ALT (U/L)	37.00	23.00	12.00	32.00
AST (U/L)	131.00	25.00	24.00	26.00
Ca (mmol/L)	2.00	2.66	2.47	2.51
CK (U/L)	2793.00	652.00	280.00	248.00
Creat (µmol/L)	87.00	92.00	101.00	114.00
GGT (U/L)	60.00	54.00	37.00	48.00
Glu (mmol/L)	6.28	4.22	5.32	4.50
HDL-C (mmol/L)	0.73	1.49	0.71	0.75
Pi (mmol/L)	2.45	2.15	1.67	1.92
LDH (U/L)	925.00	364.00	495.00	427.00
T. Bil (µmol/L)	2.91	3.48	5.43	3.54
T. Pro (g/L)	69.60	68.50	84.60	86.10
Trig (mmol/L)	0.67	0.35	0.21	0.27
BUN (mmol/L)	4.66	5.72	5.53	2.16
GLOB (g/L)	40.50	36.00	50.80	54.80
A: G Ratio	0.72	0.90	0.67	0.57
Sodium (mmol/L)	152.00	143.60	151.60	146.60
Potassium (mmol/L)	3.19	4.26	4.16	3.66

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IMPACT FACTOR 7.150

Chloride (mmol/L)	113.00	112.20	112.60	114.30

Table 12: Hematology Data

Parameters	P1		P2	
	Baseline	Terminal	Baseline	Terminal
WBC (10^9/L)	18.65	5.16	13.32	9.58
RBC (10^{12}/L)	4.41	5.42	4.93	7.25
HGB (g/L)	90.00	108.00	97.00	149.00
HCT (L/L)	0.29	0.36	0.31	0.44
MCV (fL)	65.20	66.40	62.80	61.30
MCH (pg)	20.50	20.00	19.70	20.50
MCHC(g/L)	314.00	301.00	314.00	335.00
RDW (%)	16.80	17.30	15.40	15.90
HDW (g/L)	26.50	20.10	16.50	18.90
PLT(10^9//L)	307.00	433.00	495.00	327.00
MPV (fL)	8.20	7.30	8.00	7.60
Neut (%)	72.40	58.40	33.10	50.20
Lymp (%)	23.50	36.50	57.60	45.00
Mono (%)	0.90	2.70	6.80	3.90
Eosi (%)	1.90	0.10	0.20	0.30
Baso (%)	0.10	0.00	0.20	0.10
LUC (%)	1.10	2.30	2.10	0.50
Retic (%)	3.79	5.91	1.23	1.19

International Journal of Advanced Research in Science, Engineering and Technology
ISSN: 2350-0328
Vol. 12, Issue 11, November 2025

5.2. Gross Histopathology

External Findings: External examination of male animals P1 (day 30) & P2 (day 95) did not reveal any lesions of pathological significance.

Internal Finding: The distal part of the Esophageal Stent System implanted site was occluded on internal examination of P2 (day 95) male animal whereas internal examination of P1 (day 30) male animal did not reveal any lesions of pathological significance.

5.3. Histopathology

The esophagus in which the Esophageal Stent System was implanted showed the following histopathological findings:

Pig 1 (day 30): A total of 1 (rare, 1 to 5 per high powered field) polymorphonuclear cells were found in the animal P1 (distal), whereas animal P1 (proximal) exhibited score 2 (5 to 10 per high powered field) polymorphonuclear cells. Lymphocytes score 1 (rare, 1 to 5 per high powered field) were found in animal number P1 (proximal, middle and distal). Neovascularization score 1 (1 to 3 buds) was detected in animal number P1 (proximal, middle and distal). Fatty infiltration score 1 (minimal) was observed in animal number P1 (proximal, middle and distal).

Pig 2 (day 95): Polymorphonuclear cells score 2 (5 to 10 per high powered field) was observed in animal number P2 (distal). Lymphocytes score 1 (rare, 1 to 5 per high powered field) were observed in animal number P2 (distal). Neovascularization score 1 (1 to 3 buds) were observed in animal number P2 (middle). Neovascularization score 2 (4 to 6 capillaries) observed in animal number P2 (distal).

Table 13: Individual Animal Inflammatory Cells and Tissue Response Score

Animal No.	P1 (Day 30)			P2 (Day 95)		
Location	**Proximal**	**Middle**	**Distal**	**Proximal**	**Middle**	**Distal**
Inflammatory Cells						
Polymorphonuclear	2	0	1	0	0	2
Lymphocytes	1	1	1	0	0	1
Plasma Cells	0	0	0	0	0	0
Macrophages	0	0	0	0	0	0
Giant Cells	0	0	0	0	0	0
Necrosis	0	0	0	0	0	-
Inflammatory Cells (subtotal × 2) (A)	6	2	4	0	0	6
Tissue response						
Neovascularization	1	1	1	0	1	2
Fibrosis	0	0	0	0	0	0

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IMPACT FACTOR 7.150

Fatty Infiltrate	1	1	1	0	0	0
Tissue response subtotal (B)	2	2	2	0	1	2
Total (A+B)	8	4	6	0	1	8
Sum of Total Scores	18			9		

Table 14: Histopathological Scoring System

Histological Evaluation System- Cell Type/ Response

Response	**Score**				
	0	**1**	**2**	**3**	**4**
Polymorphonuclear Cells	0	Rare, 1 to 5/hpf	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

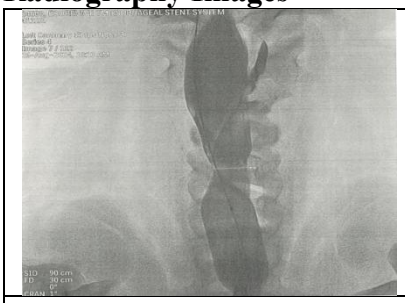
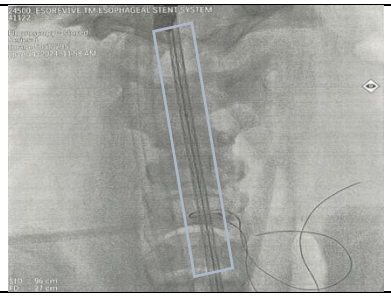
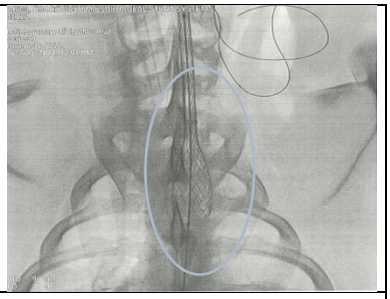
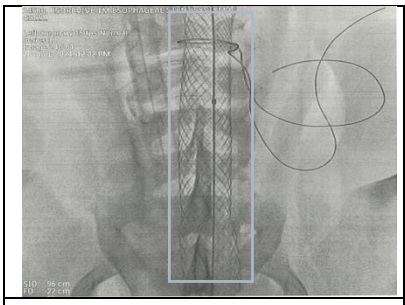
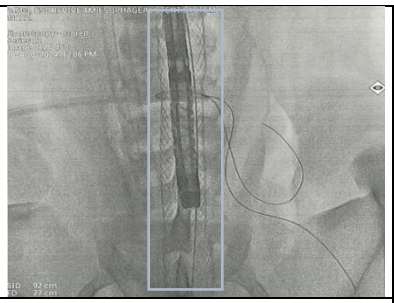
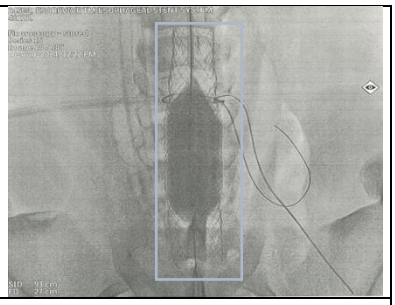
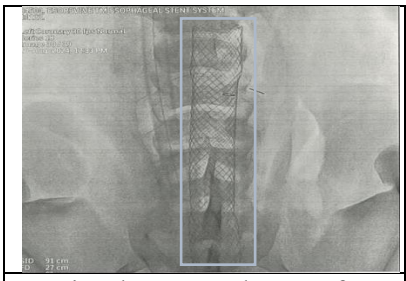
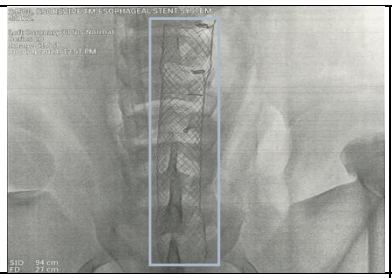
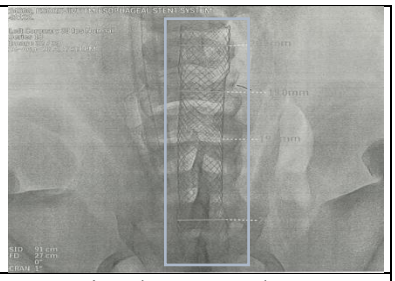
Table 15: Histological Evaluation System- Tissue Response

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 fibroblastic structures	Broad band of capillaries with supporting fibroelastic structures	Extensive band of capillaries with supporting fibroelastic structures
Fibrosis	0	Narrow band	Moderately thick band	Thick band	Extensive band

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

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

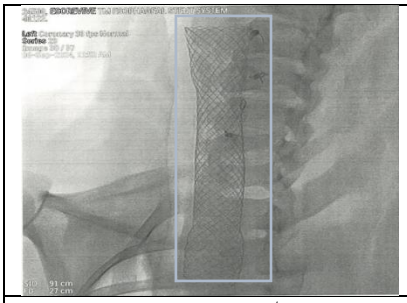
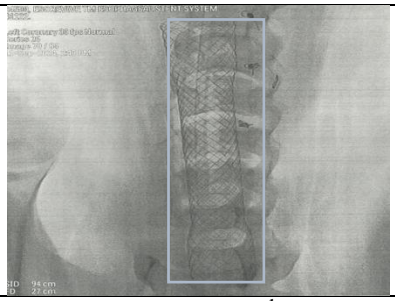
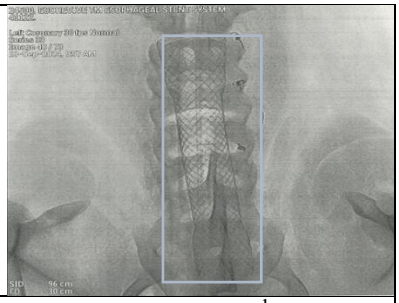
Radiography Images

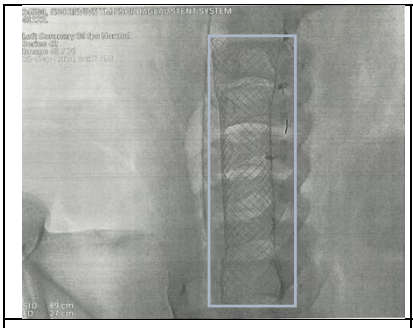
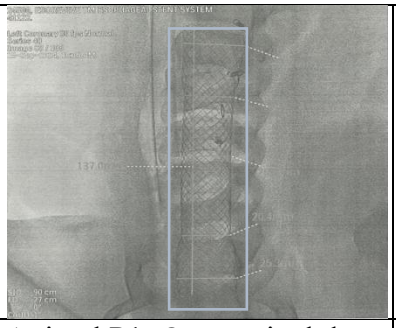
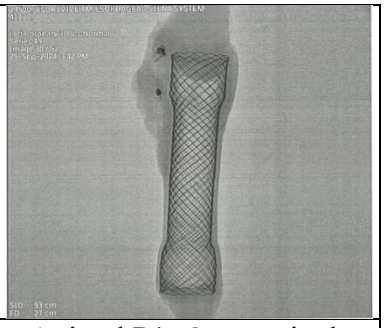
		
Animal P1: On day 0, esophagus diameter was 16.0 mm	Animal P1: On day 0, esophageal stent positioned in the esophagus	Animal P1: On day 0, esophageal stent released in the esophagus
		
Animal P1: On day 0, esophageal stent released in the esophagus	Animal P1: On day 0, esophageal stent endoscopy done	Animal P1: On day 0, esophageal stent post-dilation performed
		
Animal P1: On day 0, after post dilation esophageal stent fluroscopy	Animal P1: On day 0, after post dilation esophageal stent fluroscopy	Animal P1: On day 0, esophageal stent diameter and length measurements

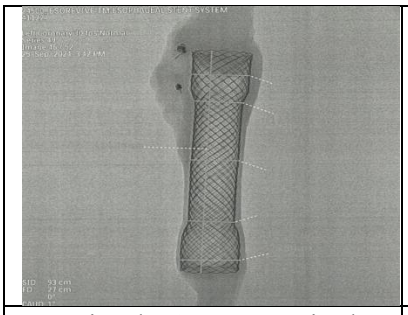
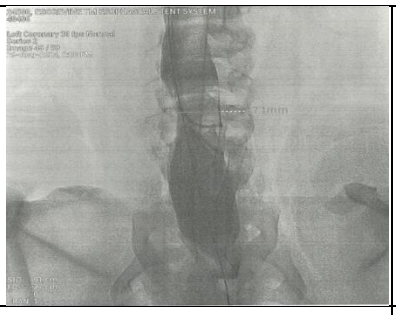
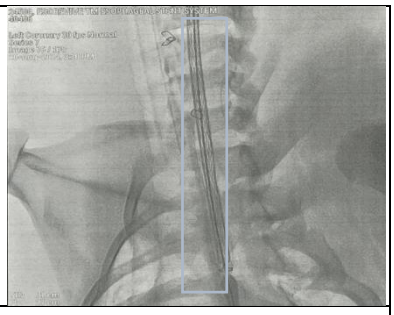
International Journal of Advanced Research in Science, Engineering and Technology

ISSN: 2350-0328

Vol. 12, Issue 11, November 2025

		
Animal P1: On 1st week, esophageal stent fluoroscopy	Animal P1: On 2nd week, esophageal stent fluoroscopy	Animal P1: On 3rd week, esophageal stent fluoroscopy

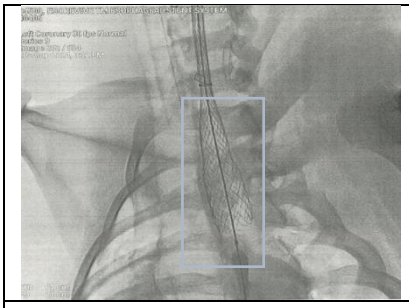
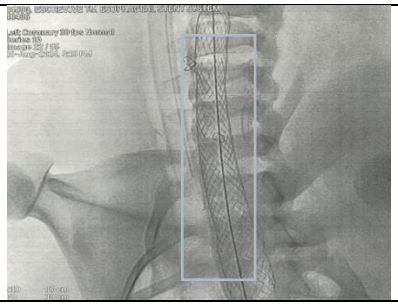
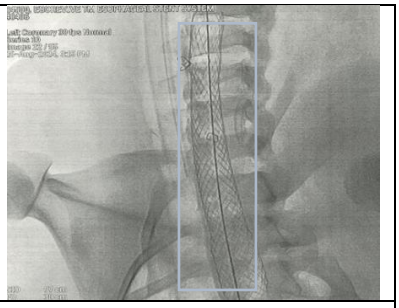
		
Animal P1: On terminal day, esophageal stent fluoroscopy	Animal P1: On terminal day, esophageal stent diameter and length measurements	Animal P1: On terminal day, harvested esophagus with stent

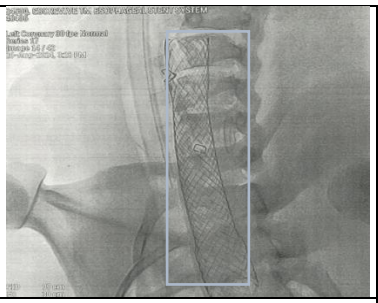
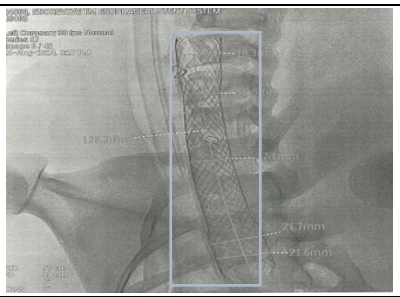
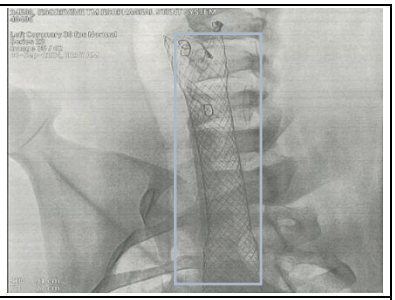
		
Animal P1: On terminal day, harvested esophagus with stent diameter and length measurements	Animal P2: On day 0, esophagus diameter was 17.1 mm	Animal P2: On day 0, an esophageal stent positioned in the esophagus

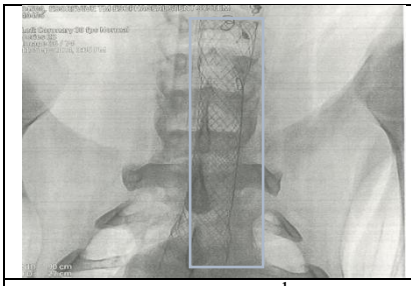
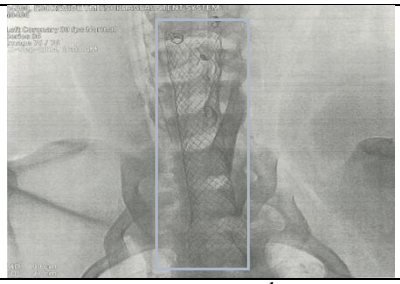
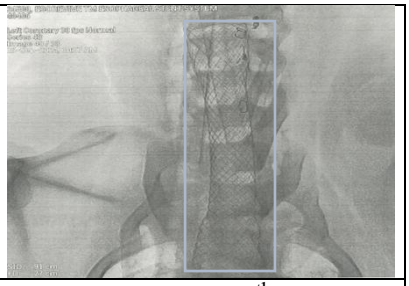
International Journal of Advanced Research in Science, Engineering and Technology

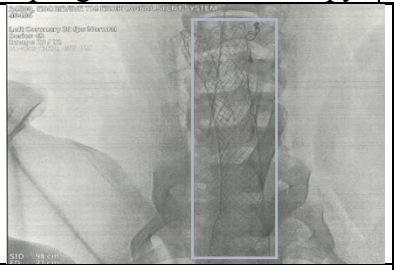
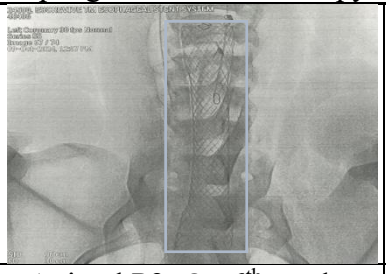
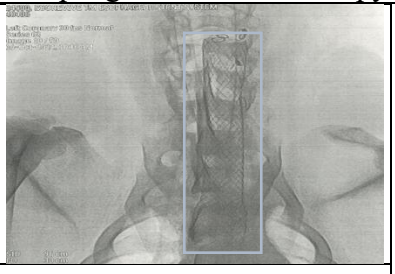
ISSN: 2350-0328

Vol. 12, Issue 11, November 2025

		
Animal P2: On day 0, an esophageal stent released in the esophagus	Animal P2: On day 0, an esophageal stent released in the esophagus	Animal P2: On day 0, an esophageal stent endoscopy done

		
Animal P2: On day 0, post stenting esophageal stent fluoroscopy	Animal P2: On day 0, esophageal stent diameter and length measurements	Animal P2: On 1st week, esophageal stent fluoroscopy

		
Animal P2: On 2nd week, esophageal stent fluoroscopy	Animal P2: On 3rd week, esophageal stent fluoroscopy	Animal P2: On 4th week, esophageal stent fluoroscopy

		
Animal P2: On 5th week, esophageal stent fluoroscopy	Animal P2: On 6th week, esophageal stent fluoroscopy	Animal P2: On 7th week, esophageal stent fluoroscopy

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

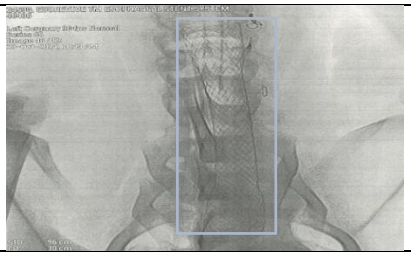
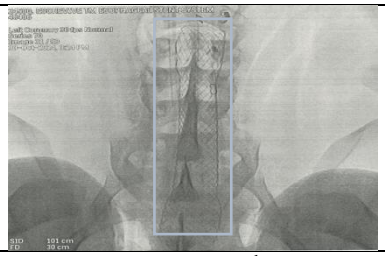
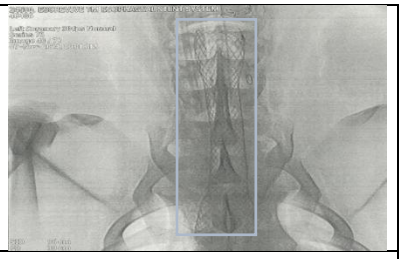
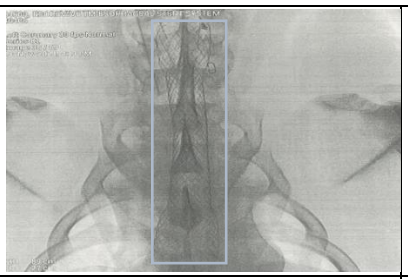
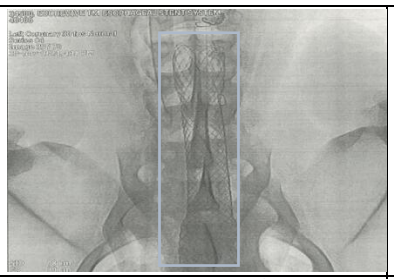
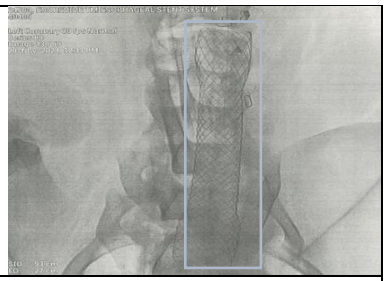
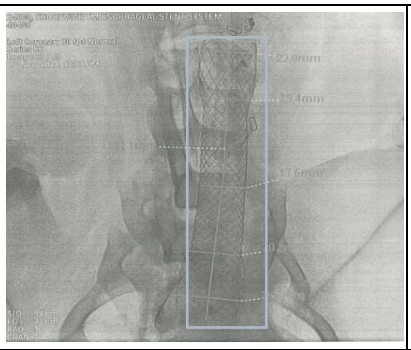
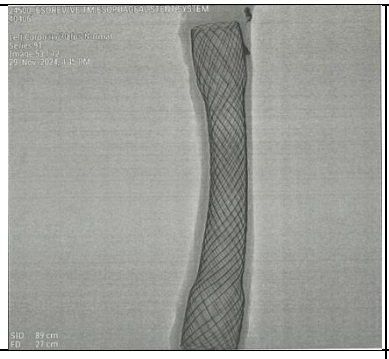
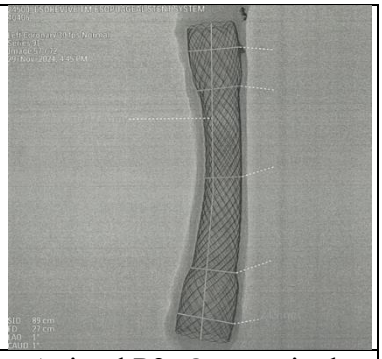
		
Animal P2: On 8th week, esophageal stent fluoroscopy	Animal P2: On 9th week, esophageal stent fluoroscopy	Animal P2: On 10th week, esophageal stent fluoroscopy
		
Animal P2: On 11th week, esophageal stent fluoroscopy	Animal P2: On 12th week, esophageal stent fluoroscopy	Animal P2: On terminal day, esophageal stent fluoroscopy
		
Animal P2: On terminal day, esophageal stent diameter and length measurements	Animal P2: On terminal day, harvested esophagus with stent	Animal P2: On terminal day, harvested esophagus with stent diameter and length measurements

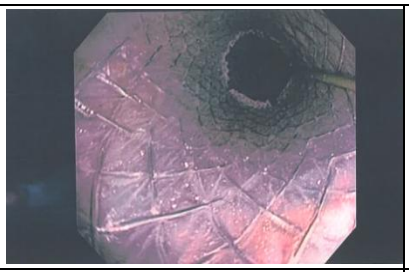
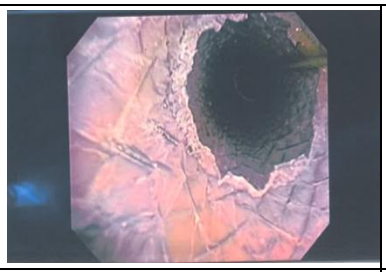
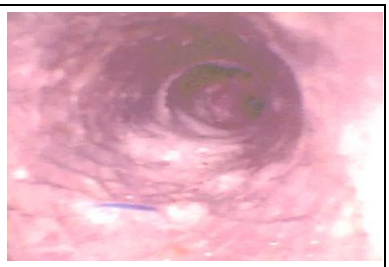
Figure 5: Radiography Images of EsoRevive™ Esophageal Stent System Endoscopy Images

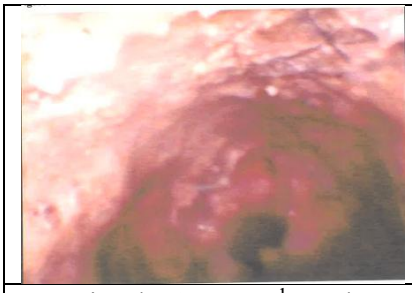
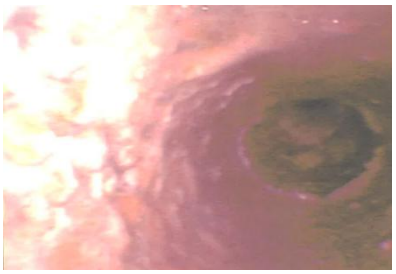
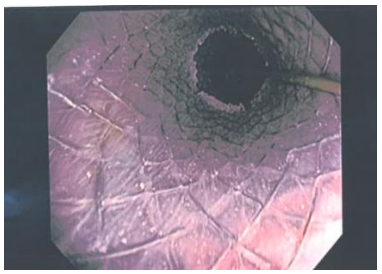
International Journal of Advanced Research in Science, Engineering and Technology

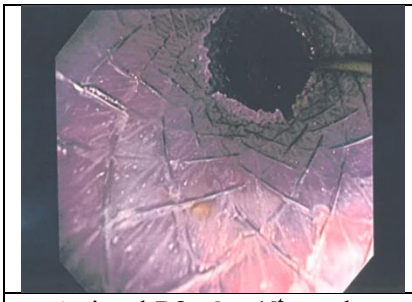
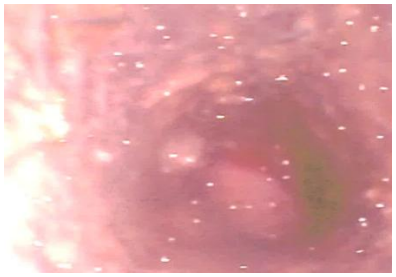
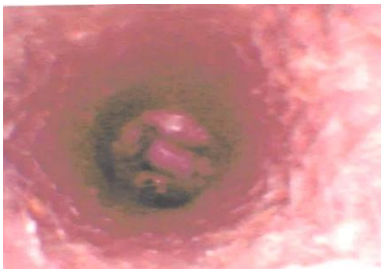
Vol. 12, Issue 11, November 2025

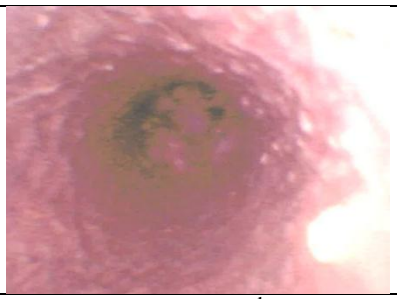
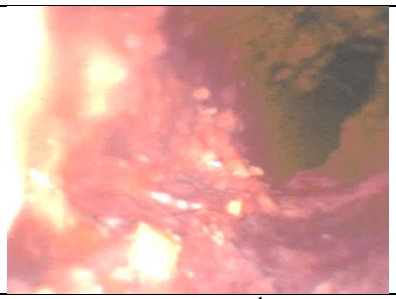
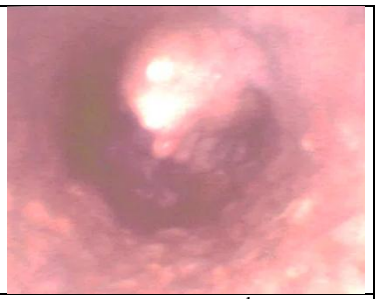
ISSN: 2350-0328

IMPACT FACTOR 7.150

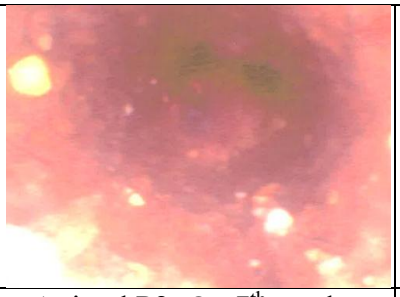
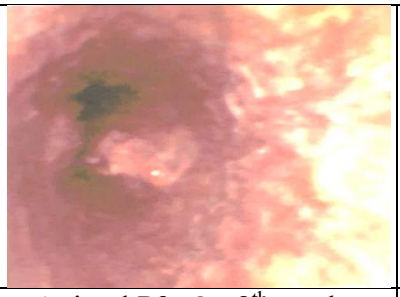
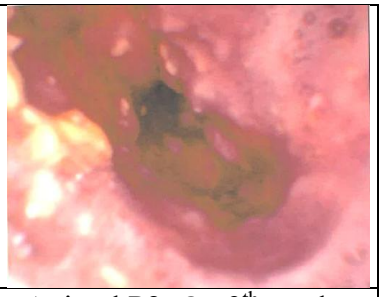
		
Animal P1: On day 0, endoscopy image	Animal P1: On 1st week, endoscopy image	Animal P1: On 2nd week, endoscopy image

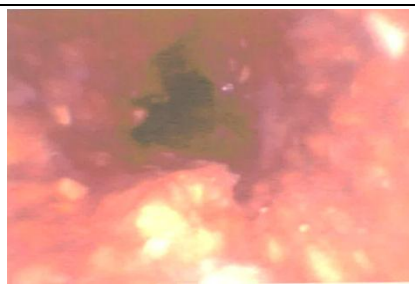
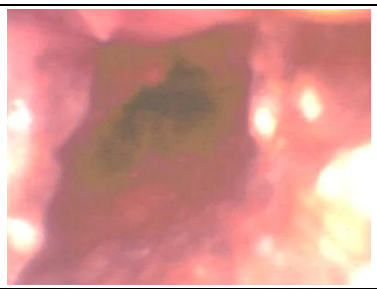
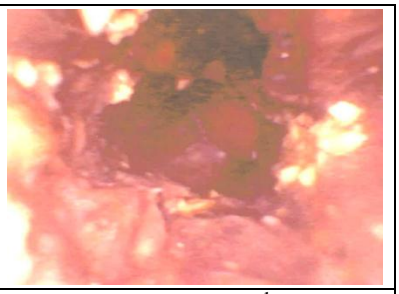
		
Animal P1: On 3rd week, endoscopy image	Animal P1: On follow up day, endoscopy image	Animal P2: On day 0, endoscopy image

		
Animal P2: On 1st week, endoscopy image	Animal P2: On 2nd week, endoscopy image	Animal P2: On 3rd week, endoscopy image

		
Animal P2: On 4th week, endoscopy image	Animal P2: On 5th week, endoscopy image	Animal P2: On 6th week, endoscopy image

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

		
Animal P2: On 7th week, endoscopy image	Animal P2: On 8th week, endoscopy image	Animal P2: On 9th week, endoscopy image

		
Animal P2: On 10th week, endoscopy image	Animal P2: On 11th week, endoscopy image	Animal P2: On 12th week, endoscopy image

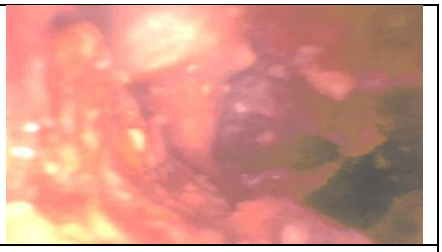
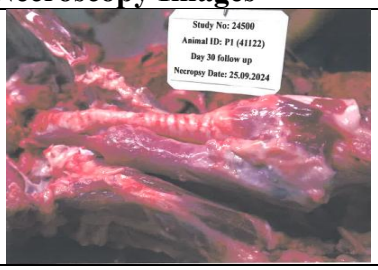
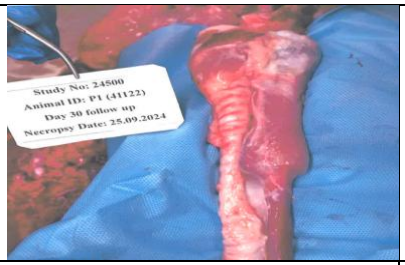

Animal P2: On terminal day, endoscopy image

Figure 6: Endoscopy Images of EsoRevive™ Esophageal Stent System

Necroscopy Images

		
Animal P1: On follow-up day, the esophageal stent is in place with the esophagus	Animal P1: On follow-up day, the esophageal stent is in place with the esophagus	Animal P1: On follow-up day, the harvested esophagus with esophageal stent

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150

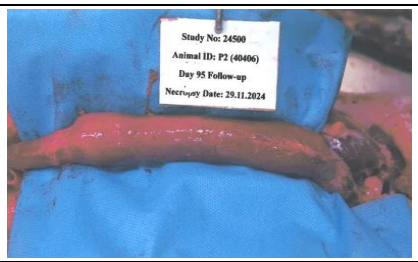
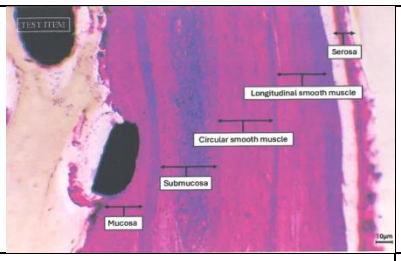
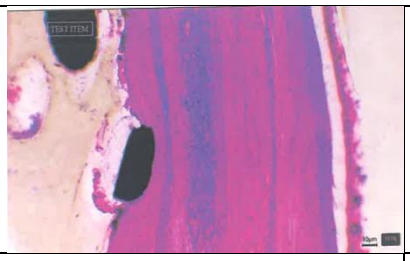
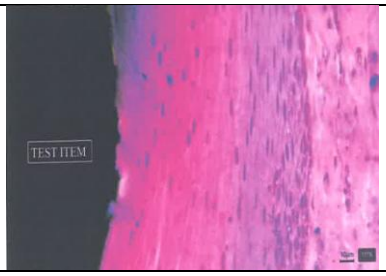
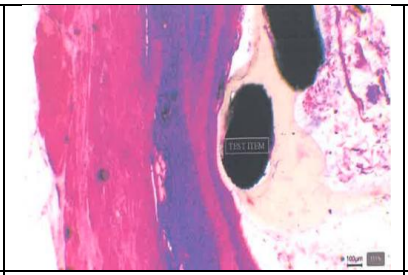
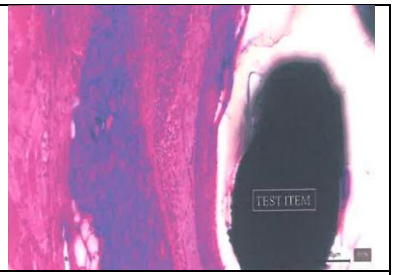
		
Animal P2: On follow-up day, the esophageal stent is in place with the esophagus	Animal P2: On follow-up day, the esophageal stent is in place with the esophagus	Animal P2: On follow-up day, the harvested esophagus with esophageal stent

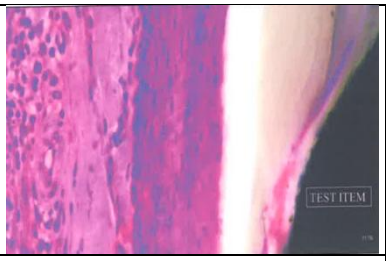
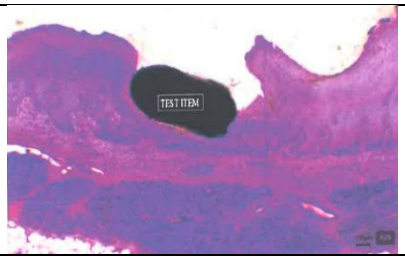
Figure 7: Necroscopy Images of EsoRevive™ Esophageal Stent System

Histopathology Images

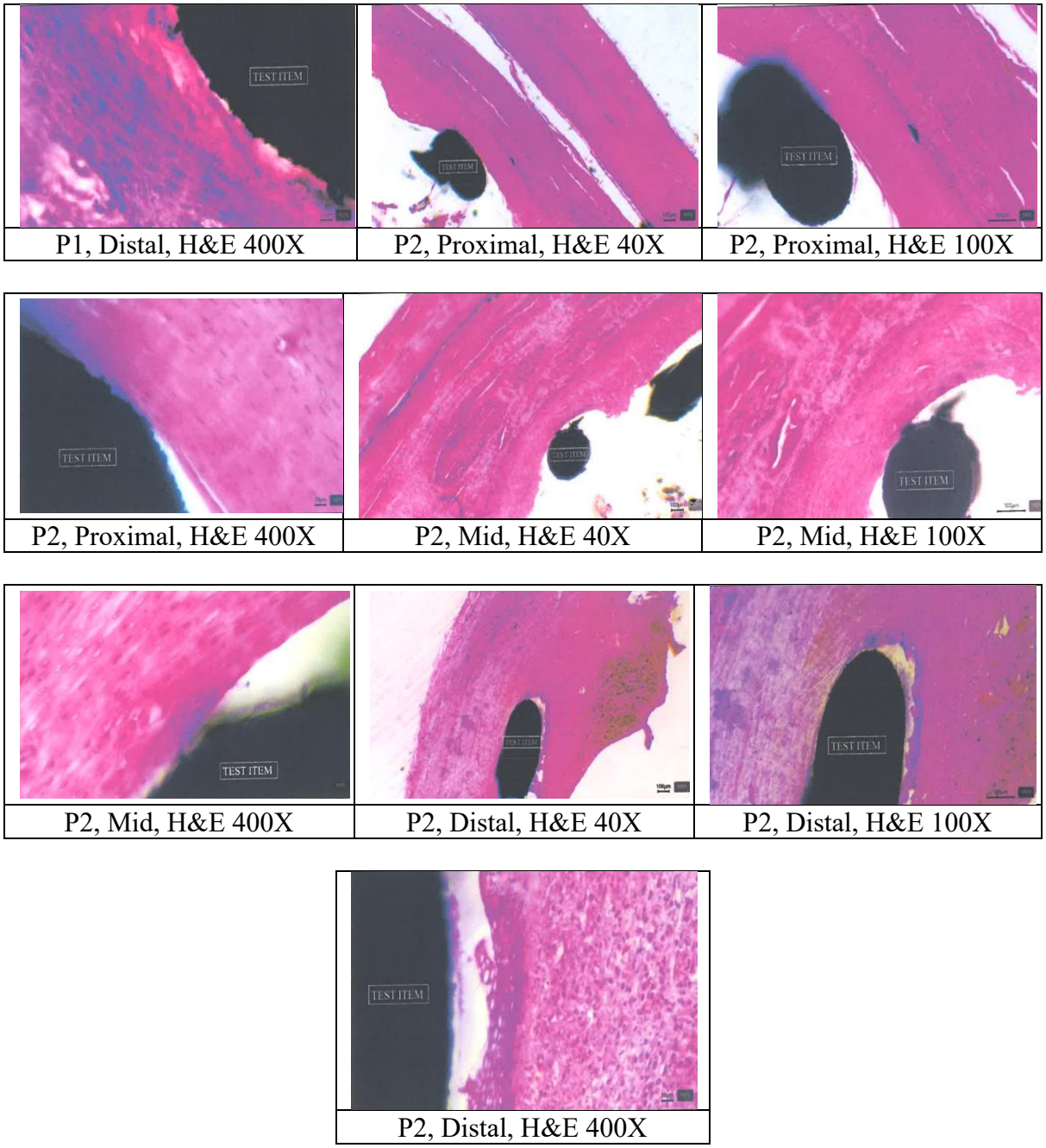
Animal P1

		
P1, Proximal, H&E label image 40X	P1, Proximal, H&E 40X	P1, Proximal, H&E 100X

		
P1, Proximal, H&E 400X	P1, Mid, H&E 40X	P1, Mid, H&E 100X

		
P1, Mid, H&E 400X	P1, Distal, H&E 40X	P1, Distal, H&E 100X

International Journal of Advanced Research in Science, Engineering and Technology
Vol. 12, Issue 11, November 2025
ISSN: 2350-0328
IJARSET IMPACT FACTOR 7.150



P1, Distal, H&E 400X | P2, Proximal, H&E 40X | P2, Proximal, H&E 100X

P2, Proximal, H&E 400X | P2, Mid, H&E 40X | P2, Mid, H&E 100X

P2, Mid, H&E 400X | P2, Distal, H&E 40X | P2, Distal, H&E 100X

P2, Distal, H&E 400X

Figure 8: Histopathology Images of EsoRevive™ Esophageal Stent System

International Journal of Advanced Research in Science, Engineering and Technology
ISSN: 2350-0328
Vol. 12, Issue 11, November 2025

DISCUSSION

This research's goal was to clarify the role of the EsoRevive™ Esophageal Stent System in keeping the esophagus open, dealing with the symptoms caused by the narrowing of the esophagus, and monitoring any complications that might arise, for up to 95 days post-implantation in an animal model. Two males, whose initial weights were 50.1 kg and 54.2 kg, respectively, were included in the study.

On day 0, the animals underwent implantation of two esophageal stents (20 mm × 120 mm) in the esophagus (one stent per animal) with the combination of fluoroscopic and endoscopic guidance. During the entire study period, which included acclimatization and termination, all animals were continuously monitored for morbidity, mortality, and clinical signs. There were no clinical signs observed that could be classified as abnormal in any of the two animals which could imply that the procedure and stent implantation did not result in any severe adverse effects. From the very beginning until the end of the study, the health of both animals was excellent, they were very playful and interactive, and no changes in behavior, posture, locomotion, or skin were observed that could be considered normal.

Blood and biochemical parameters were assessed on day 0 and at the conclusion of the study (at P1 on day 30, P2 on day 95). All the parameters were within the range of normal values and no abnormalities were reported. The esophageal stent was assessed in regard to its performance and it showed that it had been correctly deployed and its position was stable throughout the study period, which was very important for the device's effectiveness. There was a little migration of the stent observed up to 30th day, which guaranteed the stent's functionality within the esophageal lumen. However, by day 95, some caudal migration was detected, though this did not result in device failure.

In animal P2, vegetative growth within the esophageal lumen, along with mucosal irregularity and ulceration, was observed; this unexpected finding warrants further investigation. Total scores of inflammatory cells and tissue response at the Esophageal Stent System implantation sites were recorded as 18 and 9 for P1 (day 30) and P2 (day 95), respectively. It could be concluded that the process of inflammatory cell infiltration and tissue reaction was not very significant in general and the parameters mentioned above were lower in P2 on day 95 as compared to P1 on day 30. It’s important to note that stents only provide temporary solution for esophageal strictures caused by tumors, fistulas and other main causes. The stent keeps the esophagus open and alleviates the problem but does not treat it. Also, being a non-degradable device, the stent has to be either manually removed or left inside permanently which in some cases can lead to raising safety issues in the long term.

CONCLUSION

The in-life outcomes of the esophageal stent in the porcine model (N=2) demonstrated effective short-term performance with stable positioning maintained until day 30. However, by day 95, vegetative growth within the esophageal lumen over the endothelialized stented segment resulted in partial obstruction, accompanied by mucosal irregularity and ulceration under the controlled conditions of this study. Histopathological analysis revealed a decrease in inflammatory response over time, indicating a favorable tissue reaction to the stent.

The results of this research indicate that the Esophageal Stent System, which was tested in controlled preclinical conditions, has the potential to keep the esophagus open with the least possible safety issues that can be addressed. However, the drawback of the research was that only two animals were used in the experiment, thus the results could only be applied to the animal population and no further. Therefore, the research team is conducting a follow-up study in which a bigger group of animals will be used in order to obtain stronger and more trustworthy data before clinical trials are started.

Future considerations entail the conduction of clinical trials in patients with malignant strictures or fistulas to evaluate the long-term efficacy, safety, and quality of life improvements. The creation of biodegradable or drug-eluting stents with the addition of anti-tumor or anti-inflammatory agents is a move that would not only reduce the incidence of stent retrieval but also help to increase the effectiveness of the treatment. In addition, the introduction of anti-reflux features, enhanced anchoring designs, and adjustable stent sizes could result in better adaptation to different anatomies. It is possible that clinical evaluation for benign situations, pediatrics, or the treatment of combined airway-esophageal fistulas could be considered but only if the flexibility and safety profiles of the stents allow it. Lastly, the production of custom-made stents based on individual anatomical imaging data could be a significant improvement in terms of both patient comfort and stent effectiveness.

International Journal of Advanced Research in Science, Engineering and Technology

Vol. 12, Issue 11, November 2025

ISSN: 2350-0328

IMPACT FACTOR 7.150

REFERENCES

1. Dua KS, Vleggaar FP, Santharam R, Banerjee R. Removable self-expanding metal esophageal stents. Gastrointest Endosc Clin N Am. 2011;21(3):435-450.
2. Repici A, Vleggaar FP, Hassan C, et al. Efficacy and safety of partially covered self-expanding metal stents in malignant dysphagia: a prospective study. Gastrointest Endosc. 2010;72(5):927-934.
3. Wang X, Zhao Y, Liu C, et al. Management of stent misplacement in esophageal stricture treatment: role of proximal suture. Surg Endosc. 2022; 36(3):1568-1575.
4. Verschuur EM, Kuipers EJ, Siersema PD. Esophageal stents for malignant strictures close to the upper esophageal sphincter. Gastrointest Endosc. 2007;66(6):1082-1090.
5. Vanbiervliet G, Filippi J, Karimdjee BS, et al. Bench test and clinical evaluation of a new generation of self-expandable metallic stents with anti-migration design. Surg Endosc. 2013;27(4):1410-1417.
6. Swindle MM, Smith AC, Laber-Laird K, Dungan L. Swine as models in biomedical research and toxicology testing. Vet Pathol. 1994; 31(3):303-313.
7. Schomisch SJ, Yu H, Marks JM, et al. Precision and reproducibility of porcine models of benign esophageal strictures. Gastrointest Endosc. 2010; 71(5):858-864.
8. Miyazaki T, Kato H, Ishida H, et al. Biodegradable stents in the treatment of benign esophageal strictures: an experimental study in a porcine model. World J Surg. 2009;33(6):1234-1240.
9. Hirdes MM, Siersema PD, Vleggaar FP. Stent placement for esophageal strictures: predictors of complications. World J Gastroenterol. 2013; 19 (18):2844-2852.
10. Zhang Y, Chen M, Liao Z, et al. Animal models and biomarker validation for esophageal stenting: advances and challenges. J Transl Med. 2021; 19 (1):112.
11. Biological Evaluation of Medical Devices - Part 2: Animal welfare requirements, ISO 10993-2:2022(E).
12. CPCSEA Guidelines for Laboratory Animal Facility, Indian Journal of Pharmacology. 2003; 35: 257-274.
13. Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources. Commission on Life Sciences. National Research Council. National Academy Press. Washington, D.C. 1996.