Innovative balloon-inflatable venous cannula for enhanced cardiopulmonary bypass in minimally invasive cardiac surgery

Faizus Sazzad[1,2], Ki Han Kim[1], Irwan Shah Bin Mohd Moideen[1], Abdulrahman El Gohary[1], John C Stevens[1], Theo Kofidis[1,2]

[1] Department of Surgery, National University of Singapore, Singapore
[2] Department of Cardiac, Thoracic and Vascular Surgery, NUHCS, Singapore

Corresponding author:
Faizus Sazzad
NUS, Singapore-117599
Email: surmfs@nus.edu.sg
Tel: +6586805292

ABSTRACT

Objectives: Minimally invasive cardiac surgery (MICS) struggles with effective caval isolation and cannulation for cardiopulmonary bypass (CPB). We aimed to develop a novel MICS venous cannula, eliminating external manipulations. The goal of this study is to thoroughly evaluate both the safety and the efficacy of a newly developed venous cannula.

Methods: The study presents the Aulus venous cannula for MICS, designed with internal balloons to block caval blood flow. Preclinical bench tests with a cardiac biosimulator and large animal studies per ISO10993-2016, evaluated performance and safety.

Results: The heparin-coated Aulus cannula had a post-sterilization comparable density of ~0.200 μg/cm². In ex-vivo tests, using porcine heart models, the cannula enabled full caval occlusion, with endoscopic views confirming precise positioning. The pressure drop remained below the hemolytic threshold of 100 mmHg, indicated lower values compared to BioMedicus. A non-GLP large animal study included eight ovine models, divided into short- and long-term follow-up groups. Clinical pathology values were consistent CPB procedures, and histopathology indicated favorable tolerance despite short-term vessel injuries and long-term stenosis with fibrosis.

Conclusion: The Aulus cannula showed effective anticoagulant activity, strong integrity, and good tolerance in vitro and in vivo, highlighting its clinical potential.

Keywords: open heart surgery; minimally invasive cardiac surgery; cardiopulmonary bypass; cannula; aulus;

INTRODUCTION

Minimally invasive cardiac surgery (MICS) is essential for reducing the trauma, recovery time, and complications typically associated with traditional open-heart surgery [1]. This approach allows for smaller incisions, which leads to less pain, shorter hospital stays, and faster recovery for patients. However, performing cardiac surgery through a minimally invasive right thoracotomy approach presents significant challenges, particularly in achieving effective caval isolation, which is crucial for procedures requiring cardiopulmonary bypass (CPB) [1–3]. In patients with dilated and hypertensive atria, these challenges are further compounded.

Effective caval isolation requires the superior vena cava (SVC) and inferior vena cava (IVC) to be occluded. This is typically achieved by dissecting around these major vessels, passing snares, and snaring off the inflow of blood to the heart. This process can be particularly traumatic and time-consuming. The dissection and manipulation required to isolate the SVC and IVC are inherently risky, often resulting in massive hemorrhage. The confined space of a MICS makes navigating and manipulating these vessels even more difficult. Cannulation for CPB in open-heart surgery poses inherent complexity and a significant risk of trauma, particularly in redo-surgical procedures, where scar tissue and adhesions complicate the process. The heightened risk of vessel injury and bleeding necessitates innovative solutions for safer and more efficient procedures [4,5]. Procedures involving the mitral or tricuspid valves, redo-surgeries, or correction of congenital defects typically require separate cannulation of the SVC and IVC, necessitating their dissection and encirclement with occlusive bands to halt venous return to the right atrium [6,7]. This process is not only time-consuming but also fraught with the risk of injuring the caval veins or adjacent structures, leading to severe bleeding and other complications [8–10].

Our proposed disposable medical devices facilitate CPB in both minimally invasive and conventional open cardiac surgeries, featuring innovative designs for quicker and less

injurious procedures. The cannula's integrated inflatable balloons can be externally inflated through slender lumens along the shaft, allowing internal occlusion of blood flow. This design eliminates complex manipulations around the SVC and IVC, significantly reducing the risk of vessel perforation and bleeding. In open cardiac surgery, where cannulation of the aorta and right heart is necessary, this approach provides a unique advantage, especially in minimally invasive surgeries with confined access or adhesions. This study aimed to evaluate the safety, effectiveness, and feasibility of a novel cannula in preclinical benchtop and large animal models. It assessed its reliability in surgical procedures, safety standards, and efficacy compared to existing venous cannulas. Key factors included its impact on hemodynamic stability, ease of use in minimally invasive surgeries, and potential to reduce complications.

METHODS:

Concept and device design:

Advancements in surgical techniques and devices, such as a novel MICS venous cannula, aim to reduce trauma and streamline the procedure. By enabling internal occlusion of blood flow, these devices mitigate risks associated with traditional methods, improving patient outcomes and broadening the use of minimally invasive approaches in cardiac surgery. By incorporating inflatable balloons, our cannula is designed to obstruct venous inflow from within the vessels, thus eliminating the need for external manipulations, dissections, and the application of snares around the SVC and IVC. Figure 1A summarises the device design, where the conventional cannulation technique was highlighted Figure 1B. The cannula is made of DEHP-free Polyvinyl Chloride, reinforced with stainless steel alloy SUS 302. It has an outer diameter of 7.7 mm (~23Fr), expanding to 9.5 mm (~28Fr) when deflated. The inner diameter ranges from 4.7 mm (~14Fr) to 9.5 mm (3/8"). The total length is 825 mm, with an effective length of 700 mm. It features four 2.0 mm fenestration holes near the SVC balloon and twelve 3.0 mm holes near the IVC balloon. The two thermoplastic elastomer (TPE) balloons (30 mm in length and diameter) occlude the SVC and IVC. The introducer shaft is

4.6 mm (~14Fr) in diameter and compatible with 0.035” or 0.038” guidewires. Heparin coating is applied throughout.

Operating mechanism of the novel cannula

The placement method used standard transfemoral access to enter the femoral vein sugically. The cannula was positioned with the SVC balloon aligned with the superior vena cava and the IVC balloon aligned with the inferior vena cava. Fluoroscopy and saline with contrast media were used for visual guidance. During preclinical testing, fluoroscopy and contrast material were used to evaluate balloon function, but these are unnecessary in clinical practice, where TEE will suffice for cannula placement. A bespak-valve was used for balloon inflation. Saline mixed with a contrast agent was injected using a syringe, with approximately 30cc of saline recommended to achieve a 30mm diameter and complete occlusion. Exceeding 90cc could cause balloon rupture. Figure 1 (C–F) provided a step-by-step guide for the cannula's operating mechanism.

Heparin coating

The cannula was heparin-coated to prevent blood thrombosis during CPB. An antithrombotic coating analysis was conducted at CD Bioparticles Pte Ltd, New York, USA, with two goals: optimizing the heparin density of the Aulus (Kardia Pte Ltd, Singapore) to match the PTT effect of the Bio-Medicus cannula (Medtronic Inc, MN, USA) and sterilizing the cannula for animal testing. A heparin gradient solution (0.64 mg/mL to 0.01 mg/mL) was prepared and incubated at room temperature. Additional reagents were added, and absorbance was measured at 650 nm. The PTT test followed ISO 10993.4-2017, using fresh anticoagulated whole blood to obtain platelet-poor plasma (PPP). Test samples, negative control (HDPE), and positive control (glass) were extracted in PPP (6 cm² surface area to 1 mL extract) at 37±1°C for 15 minutes and analyzed using an automatic coagulation analyzer.

Ex-vivo experiments

A freshly explanted porcine heart was connected to the Cardiac BioSimulator (CBS) system by the LifeTec Group (Eindhoven, NL) to simulate the right-heart circulation system. The inferior vena cava (IVC) was connected with a straight extension piping to facilitate the cannulation of the Aulus cannula. A camera port in the superior vena cava (SVC) allowed an endoscopic camera to record the movement of the Aulus (Kardia Pte Ltd, Singapore) as it was introduced from the vena cava into the right atrium.

In-vitro bench test

As blood flows through the cannula, the pressure drop should not exceed 100 mmHg to prevent hemolysis of red blood cells. A test chamber measures the pressure drop within the cannula, monitoring balloon functionality and detecting any leakage issues. The objective is to assess the pressure drop across the novel balloon cannula designed to block blood flow in the venae cavae during minimally invasive heart surgeries. Integrated into the heart-lung machine, this cannula aims to streamline operations and reduce trauma and risks. Testing was conducted in a customized chamber to evaluate balloon performance (Figure 2 A,B). A pressure drop test measured differences based on flow rates, ensuring optimal performance with minimal pressure drop. Both the new balloon cannula and a commercial cannula were compared using pressure sensors and a ViViTest data acquisition system (DAS) (Vivitro, Vancouver, Canada) for accurate pressure readings.

In-life procedures (Large animals)

The primary aim of the study was to evaluate the cannula's usability, focusing on ease of insertion, safety during balloon inflation/deflation, and heart-lung machine functionality, along with flow rate assessments under varied CPB conditions. In this non-GLP chronic study, eight animals were divided into two groups: a short-term group (four animals, monitored for 7 days with one control and three test articles) and a long-term group (four animals, observed for 90 days with one control and three test articles). Standard 23Fr EO-sterilized cannulas

were used in both test and control groups. Pre-operative cardiac CT scans evaluated cardiac anatomy.

Surgery involved thoracotomy at the 4th intercostal space, baseline echography, longitudinal pericardiotomy over the right atrium, and right iliac vessel exposure via mini-laparotomy. After heparin administration, the left carotid artery and right iliac vein were cannulated. The novel cannula facilitated SVC and IVC cannulation, with balloon positioning guided by echocardiography. Normothermic beating-heart CPB was initiated, followed by right atriotomy to inspect the tricuspid valve. Venous cannula balloons occluded the SVC and IVC for variable testing during CPB. Post-procedure, CPB separation, cardiac cavity air removal, and right atrium closure were completed, with final echography confirming outcomes. Anesthesia, intubation, and surgery adhered to the Testing Facility's SOPs.

Necropsy & Histopathology

After 7-day (Short-Term) and 90-day (Long-Term) follow-up periods, euthanasia was performed.Histological analysis, per ISO10993-2016 standards, evaluated injury, organ perfusion, and heparin effects. The heart, including the SVC, IVC, and iliac vein with surrounding tissues, were harvested, weighed, assessed, and photographed. Histological sections were taken from the right atrium, SVC, and IVC. Systemic organs (lungs, liver, spleen, kidneys, adrenal glands, lymph nodes, and brain) were fixed in 4% formalin for histopathology. Samples were processed, stained with Hematoxylin-Eosin & Saffron, and scanned for analysis.

Statistical analysis

Data analysis was performed using IBM SPSS 28.0 software (SPSS Inc., Chicago) for all variables of interest. Numerical variables were reported as means with standard deviation (SD), while categorical variables were presented as counts (N) with percentages.

Comparative outcomes were categorized based on the scale of assessment as defined by the study protocol.

RESULTS

Heparin coating studies

The cannula was coated with heparin, with a coating density of approximately 0.200 μg/cm² after sterilization. Heparin density assessment has been summarized in Table 1. There were no significant differences in density observed among the front end, middle, balloon, and tail end compared to the control BioMedicus cannula. Test results from the PPT time is shown in Figure 3. According to ISO 10993.4-2017, the Aulus sample demonstrates doubled PTT time compared to the uncoated sample, indicating effective anticoagulant activity.

Ex-vivo procedures

The CBS system effectively facilitated the positioning of the Aulus cannula in an ex-vivo porcine heart, with the respective SVC and IVC cannula being palpable and visible under endoscopic view during the procedure. The configuration of the CBS system is illustrated in Figure 4A, while the placement of the Aulus cannula is depicted in Figure 4B. A supplementary video clip (Supplementary video 1) demonstrates precise caval occlusion achieved by Aulus.

In-vitro bench test

Figure 4C depicts positive outcomes, as the intended diameter of 30mm was successfully achieved by injecting 20mL of liquid into both the SVC and IVC balloons. The new Thermoplastic Elastomer (TPE) balloon material can reach a maximum diameter of 41.25mm with 70mL of liquid injected, demonstrating increased tensile strength to withstand higher pressure. Additionally, there were no creases observed in the material after deflation. The findings (Figure 4D) indicated that the pressure drop was lower with the inflated balloon cannula than with the deflated one, within acceptable range. A notable rise in the pressure

drop was observed at high flow rates of 3 to 5L/min. The Aulus cannula, with a maximum inner diameter of 5.3mm, slightly increased the flow rate (3.0L/min to ≥3.6L/min), outperforming the BioMedicus cannula. However, the pressure drop of the Aulus cannula remained within the safe non-hemolytic range of <100 mmHg along its length.

Large animal study

In this non-GLP study, eight animals underwent surgery with CPB: six received the Test Article and two the Control Article. They were divided into two follow-up groups: four animals were monitored for 7±days (Short-Term: 3 Test, 1 Control), and four for 90±days (Long-Term: 3 Test, 1 Control). The device safety evaluation results are summarized in Table 2. Throughout the study, no significant changes in body weight or temperature were observed in any of the study animals during two distinct follow-up periods. Clinical pathology values remained within or near reference ranges, with minor fluctuations primarily linked to the surgery, normalizing post-CPB. CPB characteristics were consistent across both groups. CPB characteristics were uniform across both groups, with consistent variables such as Vacuum-Assisted Venous Drainage (VAVD), flow meter measurements, body temperature, and mixed venous oxygen saturation. Surgeons noted slight variations in cannula insertion and flow pattern between the Test and Control Articles, but these did not impact the CPB outcomes or physiological parameters significantly.

Histopathology analysis

In short term group: At Day 7 and Day 8, both groups showed vessel injuries in the iliac vein, including perforation and thrombosis. Thrombosis occurred in one vessel per group. Additionally, mild degenerative changes of the media were observed in one test group section. Mild, focal thrombosis was identified in one pulmonary vein per group. In Long term group: At Day 90 and Day 91, both test and control groups showed severe stenosis of the iliac vein with diffuse intimal hyperplasia and marked fibrosis of perivascular adipose tissue.

No thrombosis was found in the inferior vena cava sections. No significant microscopic changes were detected in the lungs. Microscopic findings corresponded with necropsy and trimming results, showing similar histological changes in both test and control groups. Overall, histological changes were as expected for short-term and long-term follow-up periods in healthy ovine veins, demonstrating good tolerance to the test article (Figure 5A-D).

DISCUSSION

To address challenges with effective caval isolation and cannulation for CPB, a novel MICS venous cannula (Aulus from Kardia Pte Ltd, Singapore) was developed, aiming to eliminate external manipulations. The cannula, featuring internal balloons to obstruct caval blood flow, underwent rigorous testing, including pressure drop tests, ex-vivo experiments, and animal studies assessing usability and safety. The extensive pre-clinical experiments summary suggest the Aulus cannula holds potential for clinical application in MICS.

Vascular access is vital for establishing CPB in both standard open-heart and minimally invasive cardiac surgery (MICS) procedures. Groin access is typically utilized for venous access in MICS, with only a few commercially available venous cannulas, including our control article Bio-Medicus (Medtronic Inc. MN, USA). However, there is currently no commercially available cannula capable of occluding the vena cava from inside using a balloon. Our novel design has been protected as intellectual property under Singapore Intellectual Property Office (SG IPO Ref#13738SG; application no 10202103212Q), with an international application published under the Patent Cooperation Treaty (PCT Ref#WO2022/211735A1). Although not yet commercially available, similar concept reports have been published, albeit differing from our design and concept [11, 12].

Despite the absence of our proposed cannula design on the market, all currently available commercial cannulas, including venous ones, are equipped with a heparin coating on their surfaces. This coating is indispensable due to its anticoagulant properties, which aid in insertion and prevent complications such as thrombosis. Therefore, it has become imperative for any new or innovative cannula to incorporate a heparin coating [13,14]. In line with this requirement, we have validated our heparin coating and found no significant differences in density between various sections of the cannula compared to the control cannula, and results showed comparable post-sterilization heparin density to controls. However, there were slightly higher densities observed, likely attributed to the control cannula being produced approximately a year ago, leading to a gradual decline in heparin activity over time.

PhysioHeart (LifeTec Group, Eindhoven, NL) serves as an isolated beating heart platform, offering valuable insights into the implantation, delivery, and efficacy of medical devices or therapies within realistic physiological cardiac dynamics. It provides comprehensive control over all cardiac parameters while enabling visual endoscopic inspection to assess device performance or procedural success [15–17]. The evaluation of Aulus using the PhysioHear-ex-vivo experimental setup showcased the precise placement, complete and efficient caval occlusion, validating the device's efficacy without causing harm to surrounding structures.

The balloon expansion test is a critical experiment to ensure the safety of the device. Aulus exhibited robust tensile strength, whereas some other cardiac devices encountered difficulties due to insufficient balloon function and has been withdrawn from the market [18]. In addition, the drainage cannula is the most important component in determining the flow through the CPB circuit. Understanding the relationship between shear stress, radius, and

length, as well as the pressure drop across the cannula, is crucial. A pressure drop of less than 100 mmHg is typically deemed non-hemolytic [19,20].

Subsequently a series of animal surgeries was conducted to assess the efficacy of our devices, following the device development strategy outlined in several other published articles [21–23]. The cannula's intercaval design avoids interference with the right atrial operative field. Positioned in the "Fontan tunnel" between the SVC and IVC, it stays outside the surgical area (Supplementary Video 1). Its design mirrors that of commercially available cannulae, offering equivalent functionality while ensuring unrestricted access to the tricuspid valve and atrial septum, making it ideal for routine CPB procedures. Additionally, a thorough histopathological analysis was conducted after explantation in these chronic experimental models. In vivo studies indicated consistent CPB characteristics and favorable tolerance, with histopathology revealing promising anticoagulant activity and structural integrity.

The Aulus cannula offers potential to enhance MICS by improving procedural efficiency and reducing risks. Its balloon occlusion mechanism ensures precise blood flow control in the SVC and IVC, reducing external manipulation and increasing surgical precision. Clinical adoption, however, requires validation through large-scale trials [24,25]. Future studies should assess long-term safety, efficacy, and cost-effectiveness across diverse populations, comparing its performance to existing techniques in various surgical contexts.

Limitations

Despite the novelty of the device, the current preclinical evaluation has encountered a few limitations. Firstly, the study may have been limited by the number of subjects or samples available for analysis, potentially impacting the generalizability of the findings. The study's

sample size reflects the logistical and financial constraints inherent in conducting animal studies. While formal power calculations were not feasible, the sample was adequate for preliminary safety and feasibility evaluations of the novel cannula. Future studies will include larger samples and comprehensive power analyses to ensure statistically robust results. Secondly, the duration of follow-up or observation period in our series might have been relatively short, limiting the ability to assess long-term outcomes. Lastly, while animal studies can provide valuable insights, they may not perfectly mimic human physiology or pathology, potentially affecting the translation of findings to clinical practice.

CONCLUSION

The evaluation of the novel venous cannula demonstrate its potential to enhance the safety and efficacy of minimally invasive cardiac surgeries. The Aulus cannula demonstrated effective anticoagulant activity, structural integrity, and good tolerance in both in vitro and in vivo studies, indicating its suitability for clinical application.

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Conflicts of Interest:

The author declares no conflict of interest, except for research funding. This research was funded by the Kickstart initiative (Ref# NUHSRO/2020/134/Kickstart/05)

Ethics statement:

The animal experiments were approved by IACUC, Reference number: #R20-0777. No human studies were conducted.

Data Availability Statement:

The data used in this investigation is available upon request. The study's corresponding author can be contacted if anyone is interested in requesting access to the data.

Author Contributions:

Study conceptualization, F.S., K.K., I.M., A.G., K.K., J.S., and T.K.; Methodology, F.S., and K.K.; Software, F.S., and K.K.; Validation, J.S., A.S., and F.S.; Formal analysis, K.K., and F.S.; Data curation, K.K., and F.S.; Writing—original draft preparation, F.S., K.K., I.M., A.G., K.K., J.S., and T.K.; Writing—review and editing, F.S., K.K., I.M., A.G., K.K., J.S., and T.K.; Visualization, K.K., A.G., and F.S.; Resources, T.K.; Supervision, F.S., and T.K.; Project administration, F.S.; Funding acquisition, T.K. All authors have read and agreed to the final version of the manuscript.

Abbreviations:

MICS - Minimally Invasive Cardiac Surgery
CPB - Cardiopulmonary Bypass
SVC - Superior Vena Cava
IVC - Inferior Vena Cava
TEE - Transesophageal Echocardiography
TPE - Thermoplastic Elastomer
PTT - Partial Thromboplastin Time
PPP - Platelet-Poor Plasma
GLP - Good Laboratory Practice
IACUC - Institutional Animal Care and Use Committee
VAVD - Vacuum-Assisted Venous Drainage
ViViTest DAS - ViViTest Data Acquisition System

Figure legends:

Figure – 1: Device design and concept A) Novel Aulus venous cannula features inflatable balloons; B) Conventional venous cannulation technique; C) Guidewire-assisted insertion via the femoral vein; D) Positioned in the SVC/IVC with balloon inflation; E) Use of the Aulus cannula for MICS; F) Use of the Aulus cannula for open heart surgery.

Figure – 2: In-vitro bench tests A) A schematic diagram and test setup were used to assess pressure drop in the Aulus cannula; B) ViViTest system was used to acquire data.

Figure – 3: Heparin coating studies showing the PTT time in the study groups. Here: Blank control is platelet-poor plasma (PPP); Negative control is a high-density polyethylene (HDPE); Positive control is glass; uncoated customer sample is the test article, Medtronic tube is the control article and coated customer tube is the heparin coated text article.

Figure – 4: Ex-vivo and ballon expansion tests A) Ex-vivo set up and experiments; B) The cannula tested in a explanted porcine heart; C) Balloon expansion test showing the inflatable balloons; D) Pressure drop test showing the material reaches a maximum diameter of 41.25mm with 70mL liquid.

Figure – 5: H&E-stained samples showing A) SVC with locally extensive, minimal to mild thrombosis, B) IVC with multifocal, minimal intimal hyperplasia, C) Iliac vein with multifocal to diffuse degenerative changes of the media, D) RA with minimal to mild endocardial hyperplasia with no thrombosis.

Central Image: Aulus in position for a MICS procedure with a right atrial incision via right thoracotomy

Table 1: Heparin density assessment of Aulus before and after sterilization compared to BioMedicus

Test*		Heparin Density (μg/cm²)#			Result
Section Position	**Sample Size (n)**	**Aulus (Before Sterilization)** mean ± SD	**Aulus (After Sterilization)** mean ± SD	**BioMedicus (Sterilized)** mean ± SD	**P-value**
Distal Cannula (The front end)	≥ 3	0.206 ± 0.014	0.214 ± 0.019	0.194 ± 0.014	0.216
Middle part of the cannula	≥ 3	0.198 ± 0.014	0.193 ± 0.007	0.166 ± 0.008	0.012
The Balloon	≥ 3	0.196 ± 0.022	0.188 ± 0.014	N/A	N/A
Proximal Cannula (The tail end)	≥ 3	0.218 ± 0.019	0.203 ± 0.011	0.266 ± 0.012	0.003

**1 cm test sections were prepared. #Colometry with toluidine blue was used*

Table 2: Summary of functional evaluation of test and control articles

Test / Endpoint	Groups	Short-Term (D-7)				Long-Term (D-90)			
	Articles	Test			Control	Test			Control
	Assessment timepoint / Assessment Methods	#11425	#11453	#21366	#21420	#11140	#21416	#21251	#21080
Cannula Insertion	Following entry vessel exposure / Surgical, and TEE	Fair	Fair	Fair	Smooth	Fair	Fair	Fair	Smooth
Cannula flow pattern and operation at different suction points, and flow intensities	Start of CPB / CPB monitor, Perfusionist, and Surgical positioning	Good	Good	Good	Very Good	Good	Good	Good	Very Good
Occlusion of SVC / IVC	Full bypass, opening of the right atrium / TEE and direct vision	Very Good	Very Good	Very Good	NA	Very Good	Very Good	Very Good	NA
Air in venous line* / venous drainage	During CPB / Venous line								
VAVD	CPB / VAVD <50mmHg	0	0	-10	0	0	-15	-20	0
Flowmeter: CI 2.4	After Initiation of CPB	2.6	2.5	2.9	2.7	2.3	2.8	2.2	2.6
	During IVC inflation	-	-	-	-	2.2	-	2.8	-
	During SVC inflation	-	-	-	-	2.4	-	2.9	2.8
	After both caval isolation	-	-	-	2.5	2.5	-	2.9	3.0
	Minimum 30min on full CPB	-	2.9	3.2	2.8	2.5	3.0	2.9	3.0
	Before weaning	2.8	2.8	3.5	3.5	2.5	3.4	2.9	3.2
Body Temperature: 35-36.5^{0}C	After initiation of CPB	34.7	37.5	37	35.6	35.7	35.3	34.2	35.4
	During surgery	38.6	37.5	37	37.8	37.7	36.7	36.3	36.0
	Before weaning	38.5	37.5	37	38.2	38.0	38.3	37.6	38.7
Mixed Venous Oxygen Saturation	During CPB / MVO_2 monitor >65%	59	66	61	71	55	57	76	65
Deflation of balloons and back on partial flow	Before the end of CPB / CPB monitor, Perfusionist, and TEE	Very Good	Very Good	Very Good	NA	Very Good	Very Good	Very Good	NA
End of CPB / Canula	End of CPB / Surgical	Very Good	Very Good	Very Good	Very Good	Very Good	Very Good	Very Good	Very Good

CPB= Cardiopulmonary bypass, TEE= Transoesophageal Echocardiography, VAVD= Vacuum Assisted Venous Drainage

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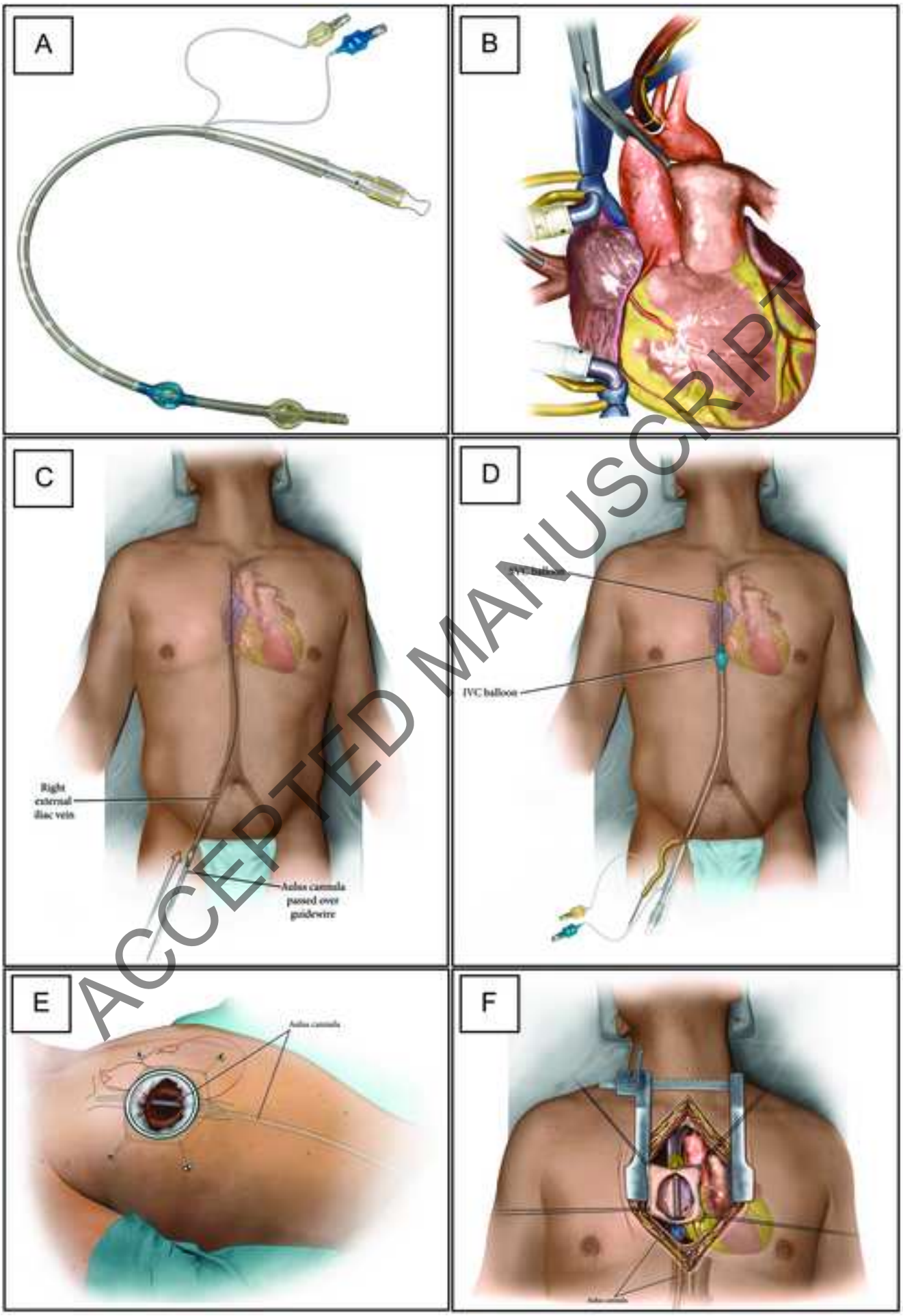
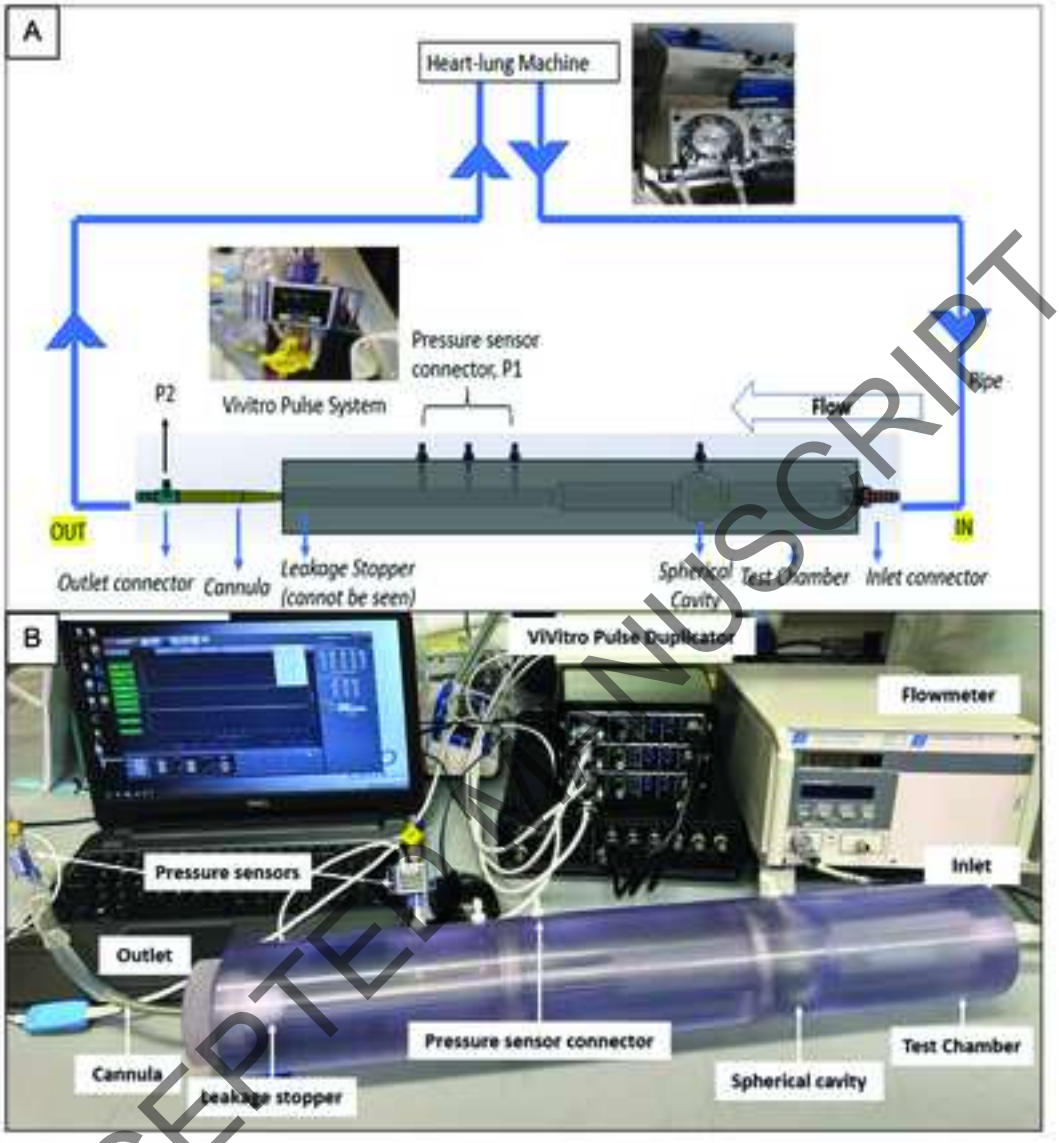
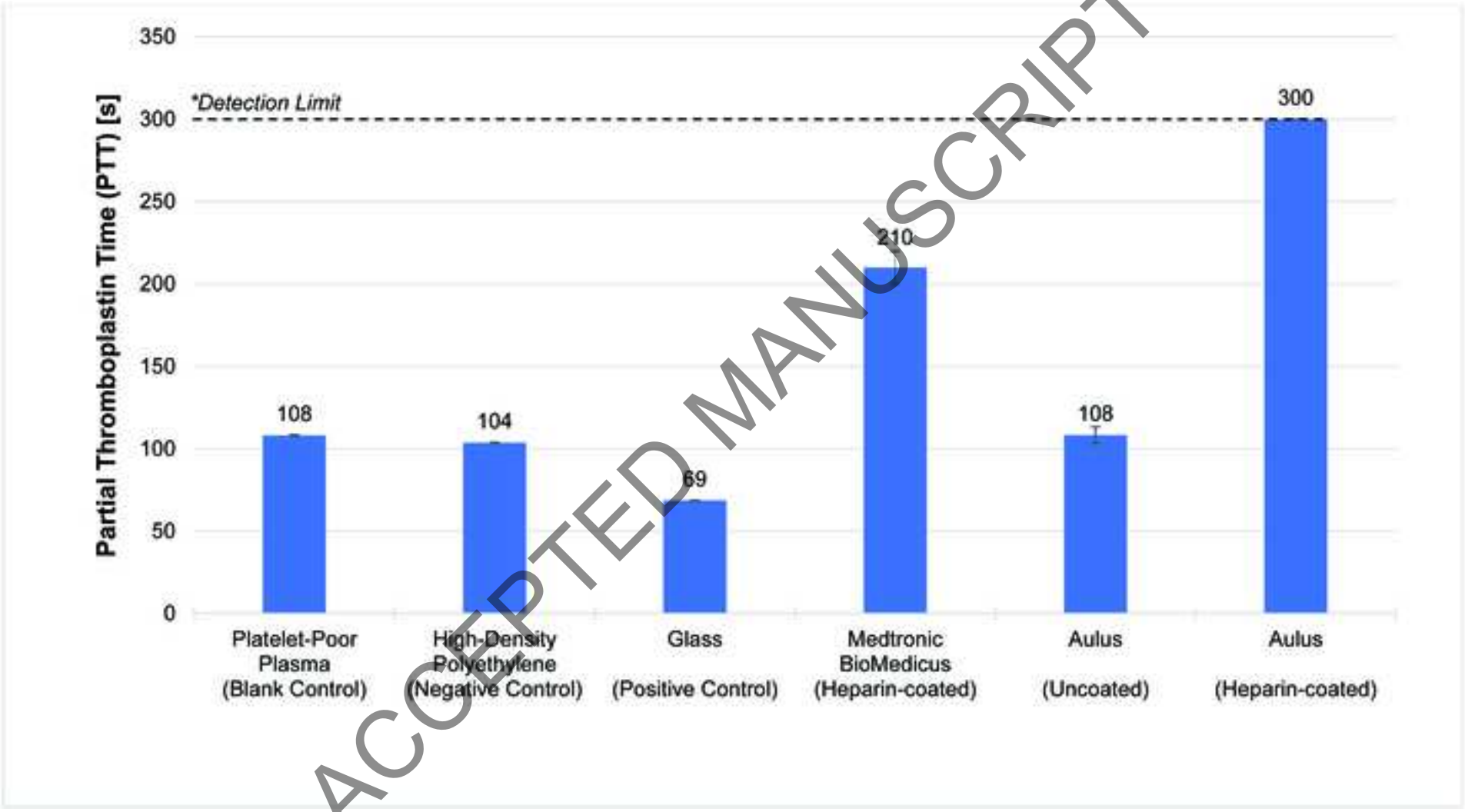
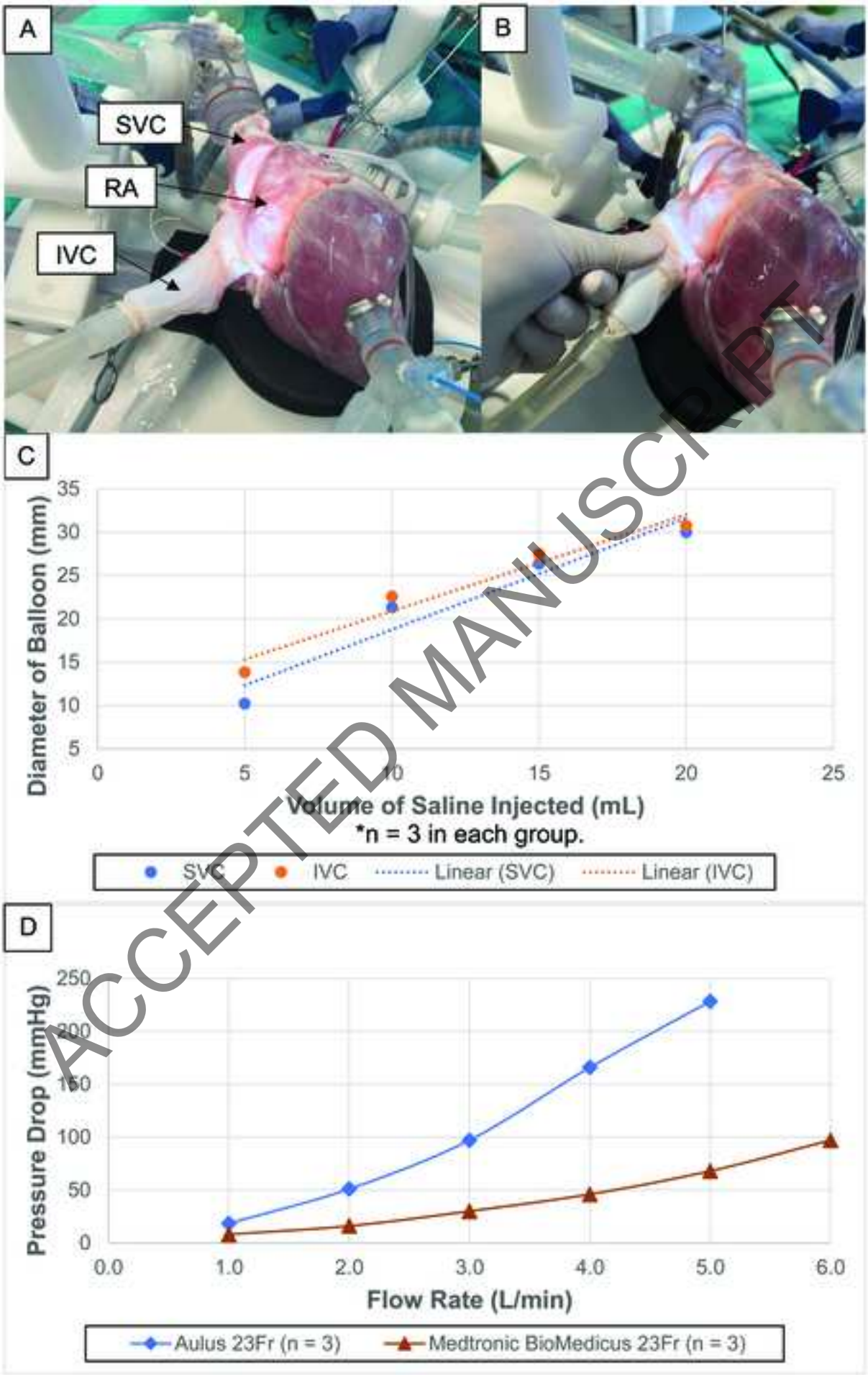
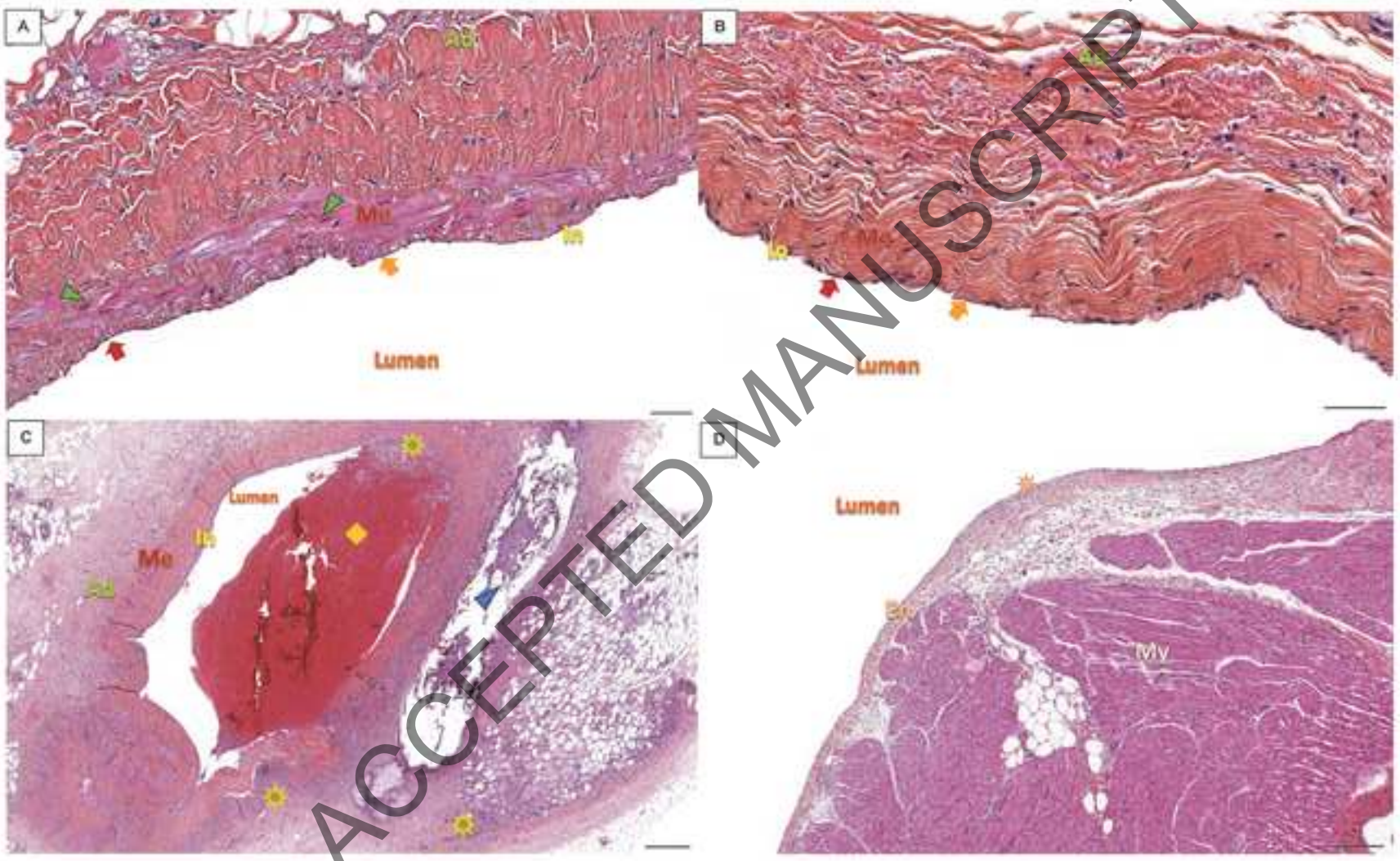






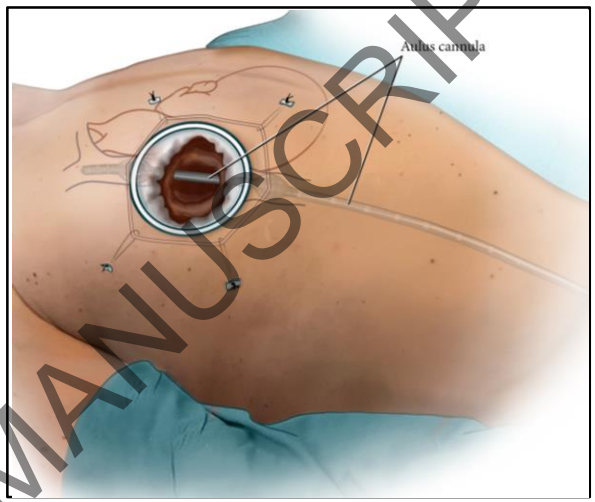




Innovative balloon-inflatable venous cannula for enhanced cpb in mics

Summary

Aulus, a heparin-coated venous cannula for MICS with dual balloons, was tested in a large animal study against the Medtronic BioMedicus cannula. It demonstrated precise placement, full vena cava occlusion, consistent CPB performance, and satisfactory short—and long-term safety. The pressure drop was lower than the control but within acceptable limits.



Legend: CPB= Cardiopulmonary bypass; MICS= Minimally invasive cardiac surgery