

Summary of Safety and Clinical Performance

For

Millar Mikro-Cath™ Pressure Catheter

Reference Number: SSCP-Mikro-Cath

Version: 01

Summary of Safety and Clinical Performance (SSCP)

SIGNATURE PAGE

SSCP Author:

Name : Dr. Sravanthi Sreeram

Designation : Medical Writer

Company : MakroCare

Signature : Dr. sravanthi S

Date : 15 Sep 2023

SSCP Evaluator:

Name : Dr. Venkata Ramani Yarram

Designation : Medical Advisor

Company : MakroCare

Signature : Dr. Venkata Ramani Yarram Reddy

Date : 15 Sep 2023

SSCP Sponsor/Manufacturer Approval

Name : Jacqueline Jean-Baptiste

Designation : Sr. Director, RA/QA

Company : Millar LLC.

Signature : Jacqueline Jean-Baptiste

Date : 15 Sept. 2023

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ABBREVIATIONS

ABBREVIATION	MEANING
AR	Authorised Representative
CAPM	Continuous Airway Pressure Monitoring
CE	Conformity European
CS	Common Specification
CT	Computed Tomography
ECG	Electrocardiogram
EEG	Electroencephalogram
EOG	Electrooculogram
EU	European Union
EMG	Electromyogram
FSCA	Field Safety Corrective Action
LDF	Laser Doppler Flowmetry
IBP	Invasive Blood Pressure
IFU	Instructions for Use
ISO	International Organisation for Standardisation
MRI	Magnetic Resonance Imaging
NB	Notified Body
NIBP	Non-Invasive Blood Pressure
NIRS	Near-Infrared Spectroscopy
PCV	Pressure-Controlled Ventilation
PMCF	Post marketing Clinical Follow-up
PMS	Post Marketing Surveillance
PSG	Polysomnogram
SRN	Single Registration Number
SSCP	Summary of Safety and Clinical Performance
UDI-DI	Unique Device Identification-Device Identifier
VCV	Volume-Controlled Ventilation

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A. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR HEALTHCARE PROFESSIONALS

1. Identification of Device and Manufacturer, including the Basic UDI-DI and, if already issued, the SRNs

Table 1: Device Identification and General Information

Device Identification	Provide/identify Details of the Device
Device Trade Name(s)	• Millar Mikro-Cath™ Pressure Catheter • Millar® TC-510 Pressure Control Unit
Manufacturer's Details Name: Address:	Millar, LLC. 6001-A Gulf Freeway Houston, Texas 77023-5417 USA Phone: 832-667-7000 or 800-669-2343 (in the USA) Fax: 713-714-8497 Email: info@millar.com Website: www.millar.com
Manufacturer's single registration number (SRN)	US-MF-000027002
Basic UDI-DI	• Mikro-Cath – 00868924000205 • TC-510- 00868924000229
Medical Device Nomenclature Description/Text:	TC-510 – 46250 Mikro-Cath – 15071
Class of Device	• Millar Mikro-Cath™ pressure catheter classified as Class III device according to Rule 7, Annex VIII as per EU MDR 2017/745. • The Millar® TC-510 Pressure Control Unit is classified as Class I device according to Rule 1, Annex VIII as per EU MDR 2017/745.
Year of first certificate (CE) issued	• Millar Mikro-Cath™ pressure catheter had CE mark since 10 September 2010. • Millar® TC-510 Pressure Control Unit had CE mark since November 2000
Authorised Representative (AR) Details (If applicable) AR Name: SRN:	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands NL-AR-000000116
NB's Details NB's Name:	BSI

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Device Identification	Provide/identify Details of the Device
NB's single identification number:	2797

2. Intended Use of the Device and Indications, Contraindications and Target Populations

The IFU is developed in order to mitigate risks identified in the hazard analysis. For Millar Mikro-Cath™ Pressure Catheter to remain safe and effective as intended, the IFU should be adhered to by the intended users.

2.1. Intended Use/Indication

The Millar Mikro-Cath™ Pressure Catheter is a single-use catheter intended to be used for medical research and diagnostic purposes. The catheter is indicated to measure cardiovascular, intra-compartmental, and airway pressures in the human body. The typical cardiovascular application will be through the femoral artery with the use of an additional guiding catheter. Millar Mikro-Cath™ Pressure Catheter may be introduced into the targeted muscle compartment through an introducer. The Millar Mikro-Cath™ Pressure Catheter may be introduced into the respiratory system through an existing orifice.

2.2. Indications and Target Populations

The Millar Mikro-Cath™ Pressure Catheter is intended to be used by trained clinicians or research personnel.

2.3. Contraindications and/or Limitations

The device should not be used if:

- In the opinion of the physician, the risk of use clearly outweighs the benefits
- There is substantial risk of patient harm because of patient characteristics (e.g. accompanying therapy, disease state, or health status)
- There is a probability of tissue or organ damage
- There is vascular obstruction
- There is undiagnosed vasospasm
- Millar Mikro-Cath™ Pressure Catheter has passed expiration date
- Millar Mikro-Cath™ Pressure Catheter is not sealed in its original sterile package
- Avoid areas of cellulitis, infections or burns

3. Device Description

3.1. Description of the Device

The Millar Mikro-Cath™ Pressure Catheter is indicated to measure cardiovascular, intra compartmental, and airway pressures in the human body and is fitted with an ultra-miniature pressure sensor near the distal end with the sensor side-mounted at the catheter tip. There is a radiopaque marker located at catheter tip proximal to the sensor. The proximal end terminates in a

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connector. The pressure sensor produces an electrical output signal which varies in direct proportion to the magnitude of sensed pressure or sound. Extension cables are used for connection between the pressure connector and the pressure control unit. It provides high fidelity pressure readings. Millar Mikro-Cath™ Pressure Catheter has a straight tip size of 3.5F and body size of 2.3F and length of 120 cm and the catheter is made of BESNO 11 nylon material. It offers numerous advantages over traditional fluid-filled pressure catheters including lack of motion artifact, no catheter whip, and improved frequency response and position independence.

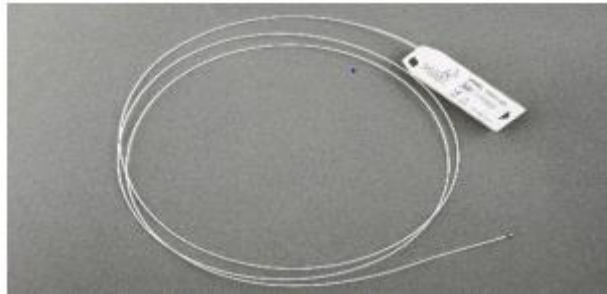


Figure 1: Millar Mikro-Cath™ Pressure Catheter

The Millar Mikro-Cath™ Pressure Catheter is used to assess physiological pressures in routine clinical settings such as CATH labs, sleep labs and orthopaedic research labs. These measurements include intra-compartmental pressure, airway pressure, valve gradient pressure and many other parameters helpful in determining the cardiovascular functions.

The cardiovascular pressure measurement that can be derived from the Millar Mikro-Cath™ Pressure Catheter signal includes left ventricular pressure, right ventricular pressure, left and right ventricular dP/dt, pulmonary artery pressure, and aortic syndrome.

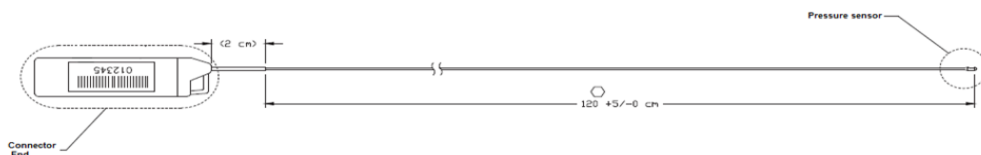


Figure 2: Millar Mikro-Cath™ Pressure Catheter Engineering Drawing/Block Diagram

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Table 2: Catheter Specifications of Millar Mikro-Cath™ Pressure Catheter

Millar Mikro-Cath™ Pressure Catheter	
Tip size	3.5F(1.2mm)
Body size	2.3F(0.8mm)
Length	120 cm
Tip characteristics	Straight

Table 3: Sensor Specifications of Millar Mikro-Cath™ Pressure Catheter

Type of Sensor	Diffused Semiconductor, piezoresistive
Pressure range	-30 to +300 mmHg (-4 to 40 kPa)
Over pressure	+4000 mmHg (+530kPa), -400 mmHg (-53kPa)
Rated excitation	5VDC
Excitation impedance	1000 ohms nominal
Signal (output) impedance	1000 ohms +/-5%
Sensitivity	5μV/V/mmHg, nominal (37.6μV/V/kPa)
Temperature error band at zero pressure	±1.0 mmHg (±0.13kPa), BSL, 25-15°C ±2.0 mmHg (±0.27kPa), BSL, 25-40°C
Sensitivity error band	<2.3% referenced to 25°C, BSL 25-15°C <3.5% referenced to 25°C, BSL 25-40°C
Accuracy (nonlinearity, hysteresis, sensitivity and repeatability combined)	±1 mmHg (0.13kPa) ±1% of reading from -30 to 50 mmHg (-4 to 6.7 kPa) ±3% of reading from 50 to 300 mmHg (6.7 to 40 kPa)
Zero drift	<3 mmHg (0.4 kPa) in 4 hours at 25°C
Frequency response	≥200 Hz
Bridge resistance	1000 ohms, nominal
Reference pressure	Atmospheric
Electrical leakage	<10 μA at 120 VAC
Zero offset	<±75 mmHg (± 10 kPa)
Shock	500G 3ms duration
Light sensitivity	<1mm Hg darkness to 3000fc 3400°K light source

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Table 4: Environmental Specifications of Millar Mikro-Cath™ Pressure Catheter

Operating	59°to 104°F(15°to 40°C),30% to 75% Relative Humidity (RH)
Transport and storage	-13°to 158°F(-25°to 70°C), 30% to 75% RH

3.2. A Reference to Previous Generation(s) or Variants if Such Exist, and A Description of the Differences

Two changes were made to the Millar Mikro-Cath™ Pressure Catheter. These modifications, including material and design changes, are intended to improve the design and use of the device. They did not result from a recall or a corrective action.

Table 5: Design Changes in the Millar Mikro-Cath™ Pressure Catheter

Description of the Changes	Cleared Device		New Device		Patient Contact
	Supplier	Material	Supplier	Material	
Change of epoxy resin adhesive on sensor	Armstrong Product Division (S. Easton, MA)	A-2/H-20 Epoxy resin adhesive	Loctite (Henkel)	M-121HP Epoxy	Direct
Addition of a radiopaque marker band in the catheter tip	N/A	N/A	Prince and Izant Co. Inc. (Cleveland, OH)	Pt90/Ir10 alloy per ASTM B684/B684M-16	None

3.3. Description of Accessories Which are Intended to be used in Combination with the Device

- The Millar® TC-510 Pressure Control Unit is used for monitoring diagnostic pressures and is intended for use with Millar Mikro-Cath™ Pressure Catheter that has the standard medical sensitivity of 5 µV/V/mmHg.
- 3.3.1 Device Accessories**

Millar Mikro-Cath™ Pressure Catheter consists of one accessory Control unit, Millar® TC-510 Pressure Control Unit.

Millar® TC-510 Pressure Control Unit

Intended Use/Indication

The Millar® TC-510 Pressure Control Unit is intended for use with Millar Mikro-Tip® pressure catheters that have the standard medical sensitivity of 5 µV/V mmHg. It is intended for use in monitoring diagnostic pressures, and when used in a clinical setting, must be used with CE monitors equipped with patient isolated circuitry.

Indications and target populations

The Millar® TC-510 Pressure Control Unit is intended for use by trained clinicians or research personnel.

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Contraindications and/or limitations

Results obtained by using non-Millar catheters have not been validated.

Device Description

The Millar® TC-510 Pressure Control Unit is a passive interface between the pressure sensor of any standardised sensitivity Mikro-Tip® catheter and strain gauge pressure monitors or recording systems which supply bridge excitation voltage and have balance and calibration controls for full-bridge strain gauge pressure transducers. The Millar® TC-510 Pressure Control Unit contains circuitry which facilitates monitor setup. In the standby (0) position the Millar® TC-510 Pressure Control Unit provides an electrical zero. In the 100 mmHg (13.3 kPa) position the Millar® TC-510 Pressure Control Unit provides a signal equal to 100 mmHg (13.3 kPa) at a sensitivity of 5 $\mu\text{V}/\text{V}/\text{mmHg}$. The transducer is operational in the transducer position and the transducer balance control allows balancing of the transducer. **Figure 3** below contains a schematic Millar® TC-510 Pressure Control Unit.

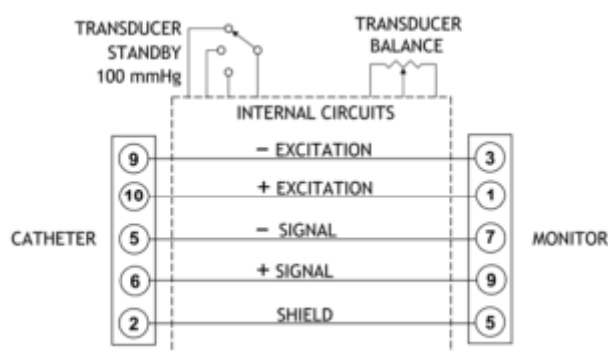


Figure 3: Millar® TC-510 Pressure Control Unit Schematic Diagram



Figure 4: Millar® TC-510 Pressure Control Unit

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Table 6: Millar® TC-510 Pressure Control Unit Specifications

Power source	Monitor must supply bridge excitation voltage
Excitation load resistance	325 Ω , nominal
Signal output load resistance	1000 Ω , nominal
Operating	50° to 104°F (10 to 40°C), 30 to 75 % RH
Transport and storage	-4° to 149°F (-20 to 65°C), 30 to 75% RH
Millar® TC-510 Pressure Control Unit Recording Systems	
Recording system input impedance	500 k Ω *
Bridge excitation voltage	4 to 5 Vdc
Bridge balance control	The recording system should have a bridge balance control which does not load the transducer bridge.

*If the recording system input impedance is less than 500k Ω , the output voltage of the transducer will be lowered proportionally due to loading (e.g., 10 k Ω input impedance reduces the output by 10%) thereby requiring a higher gain setting on the amplifier.

Table 7: Electromagnetic Compatibility of Millar® TC-510 Pressure Control Unit

Electromagnetic Emissions			
Emissions Test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The Millar® TC-510 Pressure Control Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The Millar® TC-510 Pressure Control Unit is suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.	
Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic Discharge IEC 61000-4-2	±8 kV Contact, ± 2kV,± 4kV,± 8kV,± 15kV Air	±8 kV Contact, ± 2kV,± 4kV,± 8kV,± 15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast	±1 kV for input/output	±1 kV for input/output	Mains power quality should

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Transient/Burst IEC 61000-4-4	Lines	Lines	be that of a typical commercial or hospital environment.
Magnetic Immunity IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	30 A/m, 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Radiated Immunity, Immunity to RF portable Transmitters IEC 61000-4-3	3 V/m, 80 MHz to 2.7 GHz Wireless frequencies 385MHz (27V/m); 450MHz (28V/m); 710,745,780MHz (9V/m); 810,870,930MHz (28V/m); 1720,1845,1970MHz (28V/m); 2450MHz (28V/m); 5240,5500,5785MHz (9V/m)	3 V/m, 80 MHz to 2.7 GHz Wireless frequencies 385MHz (27V/m); 450MHz (28V/m); 710,745,780MHz (9V/m); 810,870,930MHz (28V/m); 1720,1845,1970MHz (28V/m); 2450MHz (28V/m); 5240,5500,5785MHz (9V/m)	
Conducted Immunity IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz, 6 Vrms ISM Band	3 Vrms 150 kHz to 80 MHz, 6 Vrms ISM Band	

Table 8: Warnings and precautions for Millar® TC-510 Pressure Control Unit

Warnings	Precautions
- Use only with CE-approved monitoring equipment that has patient isolated input circuitry, type CF patient applied part per EN 60601-1. The monitoring equipment should be compliant to relevant harmonised standards - Ensure the balance knob is locked after adjustment - Recording system input impedance < 500k Ohm can affect output of unit - Do not use the Millar® TC-510 Pressure Control Unit during defibrillation. Disconnect all connections to the patient before defibrillation - This pressure control unit is not protected against defibrillation discharges. It must be used only with monitors labelled as having an isolated defibrillator-protected patient connection or shall be disconnected - Explosion hazard: Do not operate this unit in the presence of flammable anaesthetic mixtures with air or with oxygen or nitrous oxide - The Millar® TC-510 Pressure Control Unit is not to be used in wet environments. Discontinue use of the Millar® TC-510 Pressure Control Unit if it is suspected that liquid has entered the case. - Do not use Millar® TC-510 Pressure Control Unit in	- The Millar® TC-510 Pressure Control Unit should be used with Millar catheters and cables only - Do not use the Millar® TC-510 Pressure Control Unit and transducers with or near high-frequency surgical equipment

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Warnings	Precautions
MRI environment. The Millar® TC-510 Pressure Control Unit has not been tested for MRI compatibility - No modification of this equipment is allowed - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally - Use of accessories and cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Millar® TC-510 Pressure Control Unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result - The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	

3.4. Description of other Devices and Products Which are Intended to be used in Combination with the Device

No other devices and products which are intended to be used in combination with the device
 Millar Mikro-Cath™ Pressure Catheter.

4. Information on Residual Risks, Undesirable Effects, Warnings and Precautions

4.1. Residual Risks and Undesirable Effects

Overall residual risk remains acceptable and the risk/benefit analysis indicates the medical benefits of the device outweigh the residual risk. The overall residual risk is accepted and the product is suitable for commercial distribution from a safety point of view.

4.2. Warnings and Precautions

Table 9: Warnings and precautions for Millar Mikro-Cath™ Pressure Catheter

Warnings	Precautions
- Use only one time for a single patient - Use only with CE-approved monitoring equipment that has patient isolated input circuitry, type CF patient	Use of Millar Mikro-Cath™ Pressure Catheter should be restricted to specialists who are familiar with, and have been trained to perform, the catheterisation

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Warnings	Precautions
applied part per EN 60601-1. The monitoring equipment used should be compliant to relevant harmonised standards • Discard catheters after one procedure. Risk of infection may result if device is not discarded using proper regional disposal guidelines for procedures relating to biological hazards • Do not expose to organic solvents • This pressure transducer is not protected against defibrillation discharges. It must be used only with monitors labelled as having an isolated defibrillator-protected patient connection or shall be disconnected • Disconnect the transducer from the control unit prior to defibrillation or electro surgery • Explosion Hazard! Do not operate this catheter in the presence of flammable anaesthetic mixtures with air or with oxygen or nitrous oxide • Do not use Millar Mikro-Cath™ Pressure Catheter in MRI environment. The device has not been tested for MRI compatibility • Appropriate anticoagulation procedures must be observed to prevent thrombus formation, and the duration of each diagnostic procedure should be kept to a minimum • No modification of this equipment is allowed • Do not use the device in close proximity to high electrical noise-generating equipment, as this may cause interference with the signal • Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally • Use of accessories and cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation • Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result • The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-	procedures for which the device is intended • Exercise care to prevent perforating or traumatising the linings and associated tissue of the cardiovascular system • Avoid electrostatic discharge to the Millar Mikro-Cath™ Pressure Catheter sensor. Do not touch the sensor element while the catheter is disconnected from monitoring equipment • Insert and advance the Millar Mikro-Cath™ Pressure Catheter through an appropriately sized introducer or guiding catheter • When the Millar Mikro-Cath™ Pressure Catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding • Observe recommended storage and operating conditions listed in “Environmental Specifications” • Avoid impact to the Millar Mikro-Cath™ Pressure Catheter greater than the shock specified in “Sensor Specifications” • Reuse of this single use device is prohibited. Reuse may cause infection and/or impact performance • See package labelling information for expiration date allowing for safe use of device • Ensure any casting or bandaging is removed prior to performing intracompartmental pressure measurements • Completely inspect package prior to use. Do not use if the sterile packaging has been opened or damaged.

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Warnings	Precautions
frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	

4.3. Other Relevant Aspects of Safety, Including A Summary of any Field Safety Corrective Action (FSCA Including FSN) If Applicable

There were no FSCA initiated for Millar Mikro-Cath™ Pressure Catheter and Millar® TC-510 Pressure Control Unit from 01 January 2022 to 31 October 2022.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of Clinical Data Related to Equivalent Device, If Applicable

Equivalent device has not been claimed by manufacturer.

5.2. Summary of Clinical Data from Conducted Investigations of the Device Before the CE-Marking, If Applicable

No clinical investigations were conducted by manufacturer.

5.3. Summary of Clinical Data from Other Sources, If Applicable

The literature review identifies one published article related to the Millar Mikro-Cath™ Pressure Catheter from 01 January 2022 to 31 October 2022. The study enrolled 136 patients for heart catheterisation procedures, with 93% males and 29% females. Central aortic pressures were obtained using fluid-filled or solid-state pressure catheters. Pressure recordings were analysed using Mac-Lab and MATLAB.

Systolic, diastolic, and pulse aortic pressures were compared using a two-tailed paired t-test and Bland-Altman analysis. A linear-fit function reduced errors in systolic, diastolic, and pulse aortic pressures without affecting race. No major complications were reported in the literature. The study concluded that, the SphygmoCor data must be used with the linear-fit function to obtain aortic pressures that were comparable to the measurements obtained using pressure catheters for patients examined in this study.

A total of 1,320 units of Millar® Mikro-Cath™ Pressure Catheter were sold worldwide from 01 January 2022 to 31 October 2022. One complaint related to Mishandling was registered for Millar Mikro-Cath™ Pressure Catheter during the time period from 01 January 2022 to 31 October 2022. When considering the number of complaints in the context of sales, this equates to a complaint rate of 0.08%.

5.4. An Overall Summary of the Clinical Performance and Safety

A well-established longevity, well-known clinical safety and performance characteristics taking into account the generally acknowledged State of the Art, high satisfaction from customer surveys with no safety concerns and very low complaint rate in conjunction with preclinical evidence (performance validations and biocompatibility) demonstrates the safety and performance of Millar Mikro-Cath™ Pressure Catheter.

5.5. Ongoing or Planned Post-Market Clinical Follow-Up

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Millar Mikro-Cath™ Pressure Catheter is commercially available in the USA and Europe since 2010. The Millar Mikro-Cath™ Pressure Catheter was introduced into the marketplace in the US on 05 January 2010 and EU in September 2010.

Specific PMCF activities are not planned at this juncture based on well-established longevity, well-known clinical safety and performance characteristics taking into account the generally acknowledged State of the Art, high satisfaction from customer surveys with no complaints in conjunction with preclinical evidence (performance validations and biocompatibility) as evaluated in the clinical evaluation report.

However, general PMCF activities will be continued as per planned PMCF and are described below in **Table 12**.

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Table 10: Summary table of general/non-specific PMCF activities

S.No.	Description of activity	Aim/objective of the activity	Rationale and known limitations of the activity	Timelines of the activity
1	Scientific Literature review	To identify published clinical data relevant to the clinical safety and performance of the device.	Rationale – Periodic evaluation of safety and performance of the device throughout the life cycle of medical device. There are no limitations	One year as per risk classification of device.
2	Customer feedback	To identify design input requirements and required design changes.	Rationale – customer feedback is part of continuous proactive post market surveillance activities throughout the life cycle of medical device. Complaints highlight key areas where device need improvement. There are no limitations	An ongoing activity
3	Market feedback from similar designs, complaints and adverse events	To identify complaints and adverse events of similar devices	Rationale- complaints and adverse events of similar devices help to conduct proactive risk analysis of device under evaluation. There are no limitations	An ongoing activity

6. Possible Diagnostic or Therapeutic Alternatives

In benefit risk ratio collective evidence discussed and presented herein outlines that the use of Millar Mikro-Cath™ Pressure Catheter is crucial in emergency situations. The values provided by this device may help the healthcare provider to give accurate care to the patients. Therefore, the Millar Mikro-Cath™ Pressure Catheter, Millar® TC-510 Pressure Control Unit can be positioned within generally acknowledged State of the Art, relevant to the field of critical care management.

Alternative Methods

Alternative Methods for Measuring Cardiovascular Pressure

The alternative to Invasive Blood Pressure (IBP) monitoring is the Non-Invasive Blood Pressure (NIBP) system (oscillometric technique). However, NIBP measurement is not continuous and, during haemodynamic instability, severe hypotension, in conditions of increased arterial stiffness, and in obese patients, this technique is expected to be less accurate than the invasive one.

Fluid Filled systems: Intravascular pressures are typically measured with use of a fluid-filled catheter that is attached to a pressure transducer. The majority of pressure transducers used currently is disposable electrical strain gauges. There are a number of sources of error when pressures are measured with a fluid-filled catheter-transducer system. Distortion of the output signal occurs as a result of the frequency response characteristics and damping characteristics of the system. It shown an advantage of force or torque held constantly when compared with other techniques.

Ultrasound Techniques: Devices incorporating this technique use an ultrasound transmitter and receiver placed over the brachial artery under a sphygmomanometer cuff. As the cuff is deflated, the

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movement of the arterial wall at systolic pressure causes a Doppler phase shift in the reflected ultrasound, and diastolic pressure is recorded as the point at which diminution of arterial motion occurs. Doppler measurements of the velocity of flow at valve lesions can provide a potentially useful non-invasive means of assessing pressures in the cardiac chambers with no radiation.

Tonometry: The principle of this technique is that when an artery is partially compressed or splinted against a bone, the pulsations are proportional to the intra-arterial pressure. Although the technique has been developed for beat-to-beat monitoring of the wrist BP, it requires calibration in each patient and is not suitable for routine clinical use. As it is a non-contact in nature, which eliminates the risk of infection and corneal abrasions.

Alternative Methods for Measuring Compartmental Pressure

As an alternative to monitoring pressure, technologies from other areas of medicine have been investigated.

Near-Infrared Spectroscopy (NIRS): This is a non-invasive method of detecting variations in the level of muscle haemoglobin and myoglobin. It is applicable to compartment syndromes on the basis that light in this spectrum passes relatively easily through both skin and bone, but is differentially absorbed by haemoglobin and oxyhaemoglobin. It is a good method for detecting trends and changes in relative oxygenation, but of no value in the acute syndrome since changes in relative oxygenation may have already occurred. It gives the advantage of fast results in less than 1 minute.

Scintigraphy: This is used to evaluate regional perfusion, in particular, myocardial perfusion, and more recently, perfusion in peripheral vascular disease and popliteal entrapment. It is not known if this technique is applicable to ACS, but as it is not a continuous measure of changing perfusion, it is unlikely that it would be of value in acute trauma. The use of Scintigraphy in the diagnosis of chronic compartment syndrome has been found to be viable. There is no use of general anaesthesia.

Laser Doppler Flowmetry (LDF): LDF is a technique enabling the monitoring of skin microvascular blood flow that reflects responses in other vascular beds. It is a non-invasive, easy to use, and cost-effective technique to assess endothelial microvascular function. It offers the unique opportunity to test various pathways of vascular response. LDF is a commonly used, non-invasive technique for the assessment of peripheral micro-vascular function. The LDF technique is based on the emission of a beam of laser light carried by a fiber-optic probe. Tissue is illuminated with coherent laser light of 780 nm from a laser diode through a fiber-optic light guide. This velocimetry method is based on the “Doppler Effect” that describes the shift in the frequency of a sound or light wave when the wave source and/or the receiver is moving. The use of LDF as a method for assessing local perfusion in the diagnosis of chronic compartment syndrome has been found to be viable, however its utility in diagnosing ACS is yet to be evaluated. It is a highly sensitive and responsive to local blood perfusion and is also versatile and easy to use for continuous subject monitoring.

Alternative Methods for Measuring Airway Pressure

Continuous Airway Pressure Monitoring (CAPM) is a simple, non-invasive technique for displaying a patient’s real-time pressure waveforms on bedside monitoring systems. Because positive waveform deflections indicate positive pressure ventilation and negative deflections indicate spontaneous

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inspiratory effort, the technique provides clinicians with a method to visually observe the interactions between the patient's own spontaneous efforts and that of the ventilator. As a result, asynchrony and intolerance are quickly detected. Other uses of CAPM include ventilator mode identification, detection of auto-PEEP, improved accuracy in the measurement of haemodynamic waveforms, and assessment of "breakthrough" respiratory efforts when chemical muscle relaxants are used. In CAPM method better sleep quality, reduction or elimination of snoring, and less daytime sleepiness is shown compared to other treatment.

A laboratory test like Polysomnogram (PSG) is a complete, nocturnal, laboratory-based monitoring, which simultaneously records numerous variables during sleep. It includes sleep staging Electroencephalogram (EEG), Electrooculogram (EOG), submental Electromyogram (EMG), nasal or oral airflow, respiratory effort, oximetry, Electrocardiogram (ECG), anterior tibialis EMG, and position monitoring. Identification of the site(s) of obstruction is necessary for choosing the appropriate surgical intervention. Methods of localising the site of obstruction include endoscopy, pressure catheters, fluoroscopy, Computed Tomography (CT) scan, or Magnetic Resonance Imaging (MRI).

Esophageal manometry is an increasingly important tool in the management of complex, refractory respiratory failure, allowing the evaluation of the true amount of airway pressure used for lung inflation and the minimum level of PEEP required avoiding cyclic inflation and deflation. Manometry also has its disadvantages. In assessing the consequences of motility, the movement of intraluminal content is only by inference.

Volume-Controlled Ventilation (VCV) and Pressure-Controlled Ventilation (PCV):

VCV and PCV are not different ventilatory modes but are different control variables within a mode. VCV offers the safety of a pre-set tidal volume and minute ventilation but requires the clinician to appropriately set the inspiratory flow, flow waveform, and inspiratory time. During VCV, airway pressure increases in response to reduced compliance, increased resistance, or active exhalation and may increase the risk of ventilator-induced lung injury. PCV by design limits the maximum airway pressure delivered to the lung but may result in variable tidal and minute volume.

7. Suggested Profile and Training for Users

Use of Mikro-Cath is restricted to specialists who are familiar with, and have been trained to perform, the catheterization procedures for which the device is intended.

8. Reference to any Harmonised Standards and CS Applied.

The device complies with the following safety standards and requirements.

Table 11: Safety standards and requirements for device

Standard No.	Title
ISO 10993-1:2018	Biocompatibility test
ISO: 14971:2012	Risk management

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Standard No.	Title
ISO 11607-2:2019	Packaging test
ISO 11135-1:2007	Sterilisation
EN 60601-1	CE-approved monitoring equipment

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B. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) INTENDED FOR PATIENTS

Millar Mikro-Cath™ Pressure is not intended to be used by patients.