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OBSERVE PRECAUTIONS
FOR HANDLING
ELECTROSTATIC
SENSITIVE DEVICES

M.I. P/N: 004-2174 Rev. D

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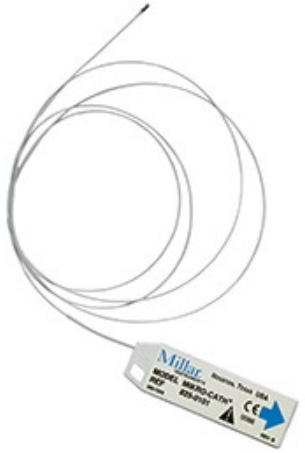

Mikro-Cath® Cardiovascular Catheter

Instructions for Use

Model: Mikro-Cath

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Table of Contents

Catheter Specifications

Mikro-Cath	
Tip Size	3.5F
Body Size	2.3F
Length	120 cm
Tip Characteristics	Straight

Environmental Specifications

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

Sensor Specifications

Type of Sensor	Diffused Semiconductor, piezoresistive
Pressure Range	-50 to + 300 mmHg (-6.7 to 40 kPa)
Overpressure	+4000 mmHg (+530 kPa), -760 mmHg (100 kPa)
Rated Excitation*	2.5-7.5 V_{DC}
Excitation Impedance	1000 ohms nominal
Signal (output) Impedance	1000 ohms +/- 1%
Sensitivity	5 µV/V/mmHg, nominal (37.6 µV/V/kPa)
Temperature Error Band at Zero Pressure	±1.0 mmHg (±0.13 kPa), BSL, 25-15 ºC ±2.0 mmHg (±0.27 kPa), BSL, 25-40 ºC
Sensitivity Error Band	< 2.3% referenced to 25 ºC , BSL 25-15 ºC < 3.5 % referenced to 25 ºC , BSL 25-40 ºC
Accuracy (nonlinearity,hysteresis, sensitivity and repeatability combined)	± 1 mmHg (0.13 kPa) ±1% of reading from -50 to 50 mmHg (-6.7 to 6.7 kPa) ±3% of reading from 50 to 300 mmHg (6.7 to 40 kPa)
Zero Drift	< 6 mmHg (0.8 kPa) in 4 hours at 25 ºC
Frequency Response	Flat to ≥10 kHz
Bridge Resistance	1000 ohms, nominal
Reference Pressure	Atmospheric
Electrical Leakage	< 10 µA at 120 V_{AC}
Zero Offset	<±50 mmHg (± 6.7 kPa)
Shock	500 G 3ms duration
Light Sensitivity	< 1mmHg darkness to 3000fc 3400ºK light source

* Performance specifications are for 5 V_{DC}. Transient voltages up to 20 V will not damage the transducer.

Millar Limited Warranty

Millar Instruments, Inc. warrants all products of its manufacture to be free of defects in workmanship and material at the time of shipment.

This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied warranties of merchantability or fitness of purpose. Since handling, storage, initial cleaning, and sterilization of the product, as well as factors relating to patient diagnosis, treatment, catheterization procedures, and other matters beyond the control of Millar Instruments, Inc. directly effect the product and the results obtained from its use, Millar Instruments, Inc., shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the misuse of the product.

Special Flushing Instructions

To prevent thrombus formation:

1. Use these catheters only for short term pressure measurements.
2. If a guide catheter is used, forcibly aspirate, then flush the guide catheter with heparinized saline every two minutes, or more frequently.
3. Consider use of systemic heparinization (see Bibliography references 1. and 2.).
4. Prefill the guide catheter lumen(s) with saline before introducing the guide catheter

   OR

   Follow guide catheter IFU to insure that proper flushing and heparinization procedures are followed per the guide catheter manufacturer's recommendation.
5. The guide catheter lumen(s) should always be filled with either flushing solution or saline while the Mikro-Cath catheter is in the vascular system (3).

Operating Instructions

When Using a Millar Pressure Control Unit (see Control Unit's IFU)

Note: Millar Mikro-Cath is a sterile single use catheter. It does not require a 30-minute presoak prior to balancing.

1. Connect the Millar pressure control unit to the monitor.
2. Turn the pressure control unit function switch to STANDBY 0 and adjust the monitor to zero baseline.
3. Turn the pressure control unit function switch to 100 mmHg and adjust the monitor sensitivity.
4. Connect the extension cable to the pressure control unit.
5. Connect Mikro-Cath to the extension cable.
6. Turn the pressure control unit function switch to TRANSDUCER. Shield the sensor from light. Adjust the TRANSDUCER BALANCE CONTROL to zero baseline. LOCK Mikro-Cath balance.
7. The Mikro-Cath system is now ready for use.

Monitor ZERO-REFERENCE can be verified by turning the Millar pressure control unit selector switch to STANDBY 0 to reproduce the original zero baseline. Monitor zero baseline adjustment can be performed at this time if required. Monitor GAIN can then be verified by turning the selector switch to the 100 mmHg (13.3 kPa) position on the control unit. Monitor GAIN adjustments can be made at this time if required.

CAUTION: The "**zero**" output produced by placing the control unit function switch in the STANDBY 0 position is an electrical zero, not an atmospheric zero!

Bibliography

Wallace, S., Medellin, H., deJonsh, D., Gianturco, C. "System Heparinization for Angiography." Amer J 116: 201-209, Roentgen, 1972.

Judkins, M., Gander, M. "Prevention of Complications of Coronary Arteriography" (editorial). Circulation 49: 599-602, 1974.

Judkins, M. "Percutaneous Transfemoral Selective Coronary Arteriography." Radio Clin N Amer 6: 467-492, 1968

Recommended Accessories

M.I. P/N: 851-5918, Model TC-510 Control Unit, No patient isolation
M.I. P/N: 880-XXXX, Model TCB-500 Control Unit, No patient isolation
M.I. P/N: 880-0129, Model PCU-2000 Control Unit with Patient Isolation
M.I. P/N: 850-1308, Model TEC-10D Extension Cable to TC-510 or TCB-500
M.I. P/N: 850-5103, Model PEC-4D Extension Cable to PCU-2000
M.I. P/N: 850-5090, Model PEC-10D Extension Cable to PCU-2000
Monitor Input Cables as appropriate for monitor.
All accessories sold separately.

Definition of Symbols


Attention, consult accompanying documents


Date of Manufacture

REF
Catalog Number

SN
Serial Number

Batch Code


Use By Date


Electrostatic Sensitive Device


EU Declaration of Conformity


Single Use Only


Keep in Cool Place


Keep Dry

Do Not Re-Sterilize


Don't Use When Packing Damaged


Manufacturer Symbol

Device Description

The Millar Mikro-Cath Cardiovascular Catheter is fitted with an ultra-miniature pressure sensor near the distal end. The sensor is side mounted at the catheter tip. The proximal end terminates in a 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 available for connection between the pressure connector and the pressure control unit. Cables may be sterilized.

Intended Use / Indications

The Mikro-Cath is a single-use cardiovascular catheter intended to be used for medical research and diagnostic purposes. The catheter is used to measure hemodynamic cardiac pressures in the human body to allow physicians to better understand cardiac health. The catheter would be used as a minimally invasive device under short term limited body contact <24 hours. The typical application will be through the femoral artery with the use of an additional guiding catheter.

Contraindications

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
- Mikro-Cath has passed expiration date.
- Mikro-Cath is not sealed in its original sterile package

Complications

Possible complications include, but are not limited to, the following:

- Air embolism
- Hematoma at the puncture site
- Infection
- Cardiac perforation
- Thrombus formation
- Vasospasm
- Myocardial infarction
- Serious arrhythmia
- Vascular injury
- Protamine reaction
- Congestive heart failure
- Death

Warnings

- Use only one time for a single patient.
- 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 used should be compliant to relevant harmonized standards.
- Patient isolated input is not required if used with Millar PCU-2000.

- Discard catheters after one procedure. Risk of infection may result if device is not discarded using proper 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 labeled as having an isolated defibrillator-protected patient connection, or shall be disconnected.
- Disconnect the transducer from the Millar Control Unit prior to defibrillation or electrosurgery.
- EXPLOSION HAZARD! Do not operate this catheter in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- Do not use Mikro-Cath in MRI environment. The Mikro-Cath 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 Mikro-Cath in close proximity to high electrical noise-generating equipment, as this may cause interference with the signal.

Precautions

- Use of Mikro-Cath should be restricted to specialists who are familiar with, and have been trained to perform, the catheterization procedures for which the device is intended.
- Exercise care to prevent perforating or traumatizing the linings and associated tissue of the cardiovascular system.
- Avoid electrostatic discharge to the Mikro-Cath sensor. Do not touch the sensor element while the catheter is disconnected from monitoring equipment.
- Insert and advance the Mikro-Cath through an appropriately sized introducer or guiding catheter.
- When the Mikro-Cath 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 Mikro-Cath greater than the shock specified in “Sensor Specifications."
- Reuse of this single use device (Mikro-Cath) is prohibited. Reuse may cause infection and/or impact performance.
- See package labeling information for expiration date allowing for safe use of Mikro-Cath.

Adverse Events

None known