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Millar Worldwide Distribution

Millar, Inc. has a network of Authorized International Distributors in most countries around the world. For information on the Millar distributor in your country, please contact the Millar Customer Service Department at our headquarters in Houston, Texas.

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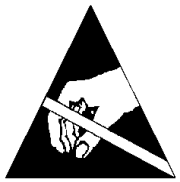

OBSERVE PRECAUTIONS
FOR HANDLING
ELECTROSTATIC
SENSITIVE DEVICES

M.I. P/N: 004-2134 Rev. C

Millar™

Making the
improbable possible.

Mikro-Tip® Special Pressure-Volume Combination Catheter Transducer

Animal Use Only

Instructions for Use

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Millar Limited Warranty

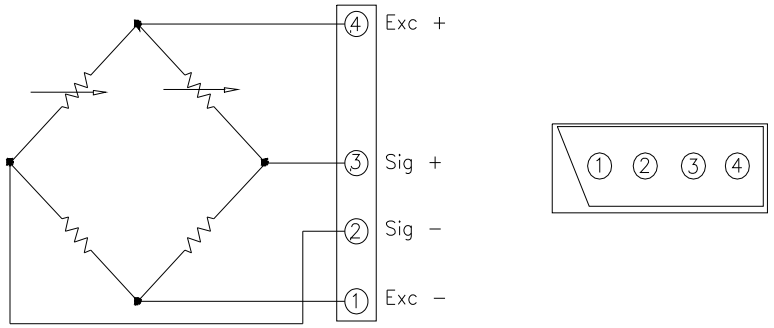
Millar, Inc. (Millar) warrants that at the time of sale to the original purchaser, the device was free from defects in both materials and workmanship. For a period of 60 days or five uses (whichever occurs first) from the date of original shipment to the original purchaser, Millar will, at no charge and at its option, either repair or replace any Mikro-Tip transducer found to have been shipped with defects in either materials or workmanship. Our warranty does not cover damage to the product from alterations, misuse, abuse, negligence, or accident.

Millar hereby excludes all warranties not herein stated, whether express or implied by operation of law or course of dealing or trade usage or otherwise, including but not limited to any implied warranties of fitness or merchantability.

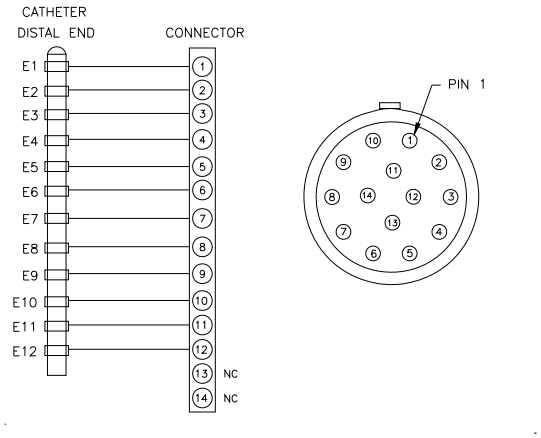
Since handling, storage, cleaning and sterilization of the product, as well as factors relating to patient diagnosis, treatment, catheterization procedures, and other matters beyond Millar's control, directly affect the product and the results obtained from its use, Millar shall not be liable for any incidental or consequential loss, damage, or expense arising directly or indirectly from the use of this product.

The user shall determine suitability for use of these medical devices for any surgical or clinical procedure. Therefore, the user accepts these devices subject to all the terms hereof.

Schematics



Pressure Connector



Electrode Connector

READ ALL INSTRUCTIONS, WARNINGS, AND PRECAUTIONS PRIOR TO USE

Device Description

The Mikro-Tip special apical approach transducer combines one or two Mikro-Tip pressure transducers and a series of electrodes mounted along the distal segment of the catheter body. The distal end of this catheter may have a rounded tip, a pigtail, or a U-shaped curve. The proximal end of the catheter terminates with one connector for the electrodes and one connector for each pressure sensor.

Definition of Symbols

	Attention, consult accompanying documents
	Date of Manufacture
REF	Catalog Number
SN	Serial Number
LOT	Batch Code
	Electrostatic Sensitive Device
CE	EU Declaration of Conformity

Recommended Accessories

M.I. P/N: 851-5918, Model TC-510 Control Unit
M.I. P/N: 852-1018, Model TCB-500 Control Unit
M.I. P/N: 880-0046, Model TCB-600 Control Unit
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
M.I. P/N: 850-5090, PEC-10D Extension Cable to PCU-2000
Monitor Input Cables as appropriate for monitor.
Electrode Catheter Cable, as appropriate.

All accessories sold separately.

Intended Use

The use of Mikro-Tip® catheter pressure transducers is indicated when physiological pressures, sounds, and other biopotentials are to be measured in the cardiovascular system. This device is intended exclusively for animal use only. Use of the apical approach pressure-volume (P-V) Mikro-Tip transducer is indicated when combined pressure and volume monitoring is required when the catheter is introduced into the heart through the apical approach.
This product is designed for use by professionals with appropriate education and training in life science and medical research applications.

Warnings

Mikro-Tip transducer catheters should be stored in a dark, cool, dry place.

The recommended duration of each diagnostic procedure should be under four (4) hours.

Compatibility with magnetic resonance imaging has not been determined.

Precautions

Mikro-Tip transducers are precise, delicate instruments which must be handled with care to insure continued accuracy and long service life. To avoid damage to the transducer, the following precautions must be observed.

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

Inspect the Mikro-Tip catheter for damage (cracking, kinks, etc.) before each use.

Clean the Mikro-Tip catheter immediately after each use (see Cleaning After Use).

Use a sheath introducer to insert the Mikro-Tip transducer.

Do not use sharp objects in the sensor/electrode area or make sharp bends in the catheter.

Be careful to avoid perforating or traumatizing the linings and associated tissue of the cardiovascular system.

Disconnect the Mikro-Tip transducer before defibrillation or electrosurgery.

The pressure sensor element is sensitive to electrostatic discharge. Do not touch the sensor element while the catheter is not connected to monitoring equipment.

Storage

The transducer and cable, with a plastic cover bag over the pressure sensor(s) and electrodes, should be stored in the white plastic shipping tray.

Routine Inspection

The Mikro-Tip catheter should be thoroughly inspected after each use to determine its condition. Carefully examine the catheter for cuts, kinks, or creases. The active surface of the sensor should be examined for any film that has not been removed by cleaning. Any film build-up may cause short-term baseline drift of the pressure signal and should be removed (such removal should consist of a thorough soaking in an enzymatic cleaner followed by a persistent and gentle wiping action along the sensor with a moist tissue). The connector(s) should undergo visual inspection for corrosion or bad contacts.

Specifications

Type of Sensor:	Diffused semiconductor
Type of Catheter:	3F & 5F: Nylon 6F & 7F: Polyurethane
Length:	125 ± 5cm or per special request
Catheter Size:	3F to 7F
Pin to Electrode Resistance:	3F: ≤ 30 ohms 5F – 7F: ≤ 12 ohms
Electrodes:	Platinum (Pt)

NOTE: Specifications are subject to change without notice.

Sterilization Cycle Parameters

Preheat phase: Starting Temperature 110 ºF (43 ºC) min.
Duration 30 minutes

Initial Vacuum: 6.0 inHgA (20.3 kPa)
Rate: 3 minutes

Nitrogen Flush: 2 cycles

Nitrogen Addition to :	28.0 ± 0.5 inHgA (94.8 ± 1.7 kPa)
Rate:	1.4 ± 0.5 inHgA/min. (4.7 ± 1.7 kPa/min.)
Evacuation:	6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
Rate:	1.0 ± 0.5 inHgA/min. (3.4 ± 1.7 kPa)

Conditioning

Humidification:	1.5 ± 0.5 inHg (5.1 ± 1.7 kPa)
Steam Conditioning:	10 min. + 5 min. - 2 min.
Humidity Dwell:	30 ± 5 min.
	7.5 ± 0.5 inHgA (25.4 ± 1.7 kPa)
Relative Humidity:	15-70%
Ethylene Oxide Concentration:	500 ± 50 mg/L
Dwell Pressure:	16.5 ± 1.0 inHgA (55.8 ± 3.4 kPa)
Dwell Time:	2 hours - 1.0 + 30 min.
Temperature:	110-130 ºF (43-54 ºC)
Relative Humidity:	30-70%
	(35-44% nominal)

After Vacuum

Vacuum:	6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
Rate:	1.0 ± 0.5 inHgA/min. (3.4 ± 1.7 kPa)
Vacuum Hold:	10 min.
Gas Wash A:	3 cycles (minimum)
Release:	28.0 inHgA/min. (94.8 ± 1.7 kPa)
Rate:	1.4 ± 0.5 inHgA/min. (4.7 ± 1.7 kPa)
Vacuum:	6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
Rate:	1.0 ± 0.5 inHgA/min. (3.4 ± 1.7 kPa)
Release (Filtered Air):	28.0 ±0.5 inHgA (94.8 ± 1.7 kPa)
Rate:	2.0 ± 0.5 inHgA/min. (6.6 ± 1.7 kPa)

Aeration

Duration:	At least 8 hours
Temperature:	110 ± 10 ºF (43 ºC)

Consult Millar, Inc., before attempting sterilization by any other means. Sterilization by autoclaving, ionizing (gamma) radiation, and exposure to formaldehyde vapor solutions are known to be **incompatible** with the Mikro-Tip transducers and cables and must not be used.

Millar, Inc. does not recommend manual calibration with this catheter.

Handling Precautions for Mikro-Tip Transducers

	DO	DO NOT
Pressure Sensor	Clean immediately after use.	Clean with stiff-bristled brush or high pressure water jet.
	Protect with plastic cover bag when not in use.	Tap sensor against a rigid surface.
	Disconnect during electrical defibrillation or electrocautery.	Apply excessive force to the sensor surface
	Use only o-ring type sealing introducers.	Use cusp-type self-sealing introducers.*
		Expose to excessive pressure.
Catheter & Pigtail	Clean immediately after use with a soft wet gauze or tissue.	Cut, crease, knot, fold, kink, or crush with forceps or clamps of any kind.
Connector & Cables	Protect connectors from fluid.	Immerse connectors in liquid.
Cleaning	Keep catheter, lumen and sensor wet until cleaning.	Expose to alcohol, cresols, phenols, acetones, peroxide, mercury compounds, chlorine, hypochlorites, xylenes, trichloroethylene, Freon, or Silicone.
	Clean thoroughly with Terg-A-Zyme immediately after use.	Use ultrasonic cleaner.
		Use Sporox™ or Cidex® PA solutions
		Immerse electrical connector(s).
Sterilizing	Dry catheter before sterilizing.	Autoclave or use radiation.
	Place in plastic shipping tray with lid.	

* Such introducers may be used in conjunction with a thin-walled introducer sleeve over the sensor to protect the sensor during insertion and withdrawal.

Maintaining Device Effectiveness

Operating Instructions

To minimize drift, presoak the pressure sensor in sterile water or sterile saline for 30 minutes prior to use.

Connect the Millar pressure control unit to the monitor.

Turn the Millar pressure control unit function switch to STANDBY 0.

Adjust the monitor to a zero baseline.

Turn the Millar pressure control unit function switch to 100 mmHg (13.3 kPa) and adjust monitor sensitivity.

Connect the extension cable to the Millar pressure control unit.

Connect the catheter to the extension cable.

Turn the Millar pressure control unit function switch to TRANSDUCER and, with the pressure sensor just below the surface of the sterile water or saline and shielded from ambient light, adjust the TRANSDUCER BALANCE control to the same zero baseline as in Step 4. After obtaining desired zero baseline, activate the catheter balance locking mechanism by moving it to the LOCK position.

The catheter is now ready for use.

Monitor calibration can be checked without removal of the catheter from the animal by turning the control unit selector switch to STANDBY 0. Calibration can be obtained by turning the selector switch to the 100 mmHg (13.3 kPa) position on the control unit.

The “zero” output produced by placing the control unit function switch in the STANDBY 0 position is an electrical zero, not an atmospheric zero.

Cleaning

Cleaning After Use

The Mikro-Tip catheter must be promptly and thoroughly cleaned after each use.

The supplied water-resistant caps should be placed over the connector(s) prior to cleaning and should remain in place during cleaning. The caps must be removed prior to sterilization.

Immediately after withdrawal of the catheter from the animal, submerge the catheter in either distilled water or saline. **Do not immerse the electrical connector(s)**. Gently wipe the catheter, sensor, and electrodes clean with a soft, wet gauze or tissue.

The slightest delay in rinsing greatly increases the probability of clot formation.

Soak the catheter in a solution of Terg-A-Zyme (see manufacturer’s directions) for at least 20 minutes. **Do not immerse the electrical connector(s)**.

Wipe the catheter clean with a soft, wet gauze or tissue. The surfaces of the catheter, electrodes and pressure sensor must be thoroughly wiped to avoid a protein film buildup.

Rinse the catheter repeatedly with fresh, pyrogen-free or sterile water; three separate rinses are recommended.

Gently dry the catheter by brushing it with a clean dry gauze or soft tissue.

Store the catheter with the plastic cover bag over the pressure sensor(s) and electrodes, and in its original packaging in a cool, dry place until the next usage.

Sterilization Procedure (optional)

Do not autoclave this catheter.

The catheter should be completely dry before sterilization. Remove the connector caps prior to sterilization. The caps should be saved and reused each time the catheter is cleaned.

Millar recommends the use of Ethylene Oxide gas for sterilization. Sterilization cycle parameters are shown below. The ethylene oxide sterilizer should be thoroughly cleaned before each sterilization cycle. Transducers should be completely dry before sterilization as water on the units may react with ethylene oxide and reduce its effectiveness. Aeration may be performed at room temperature or in a heated aeration (max. 145 ºF, 63 ºC) cabinet. Transducers may be gas sterilized in the white plastic shipping tray. The plastic cover bag should **not** be used during sterilization. The tray, with lid, should be placed in a breathable polyethylene bag (e.g., 3M™ Steri-Lok™).