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Millar Worldwide Distribution

Millar, Inc. has a network of Authorized 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, TX.

CE

Millar™

Making the improbable possible.

Ultra-Miniature Electrophysiology Catheter For Small Animals

Instructions for Use

M.I. P/N: 004-2132 Rev. E

Notes

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**READ ALL INSTRUCTIONS,
WARNINGS AND PRECAUTIONS
PRIOR TO USE**

Device Description

The Mikro-Tip® catheter has a series of electrodes mounted along the distal segment of the catheter body. It terminates in an electrical connection at the proximal end.

The electrophysiology catheter is intended for ANIMAL USE ONLY

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: 850-5098, EPC-5A Electrode Interface Cable
All accessories are sold separately

Intended Use

Use of the Mikro-Tip electrophysiology catheter is indicated when multiple cardiac electrical signal monitoring is required.
This product is designed for use by professionals with appropriate education and training in life science and medical research applications.

Warnings

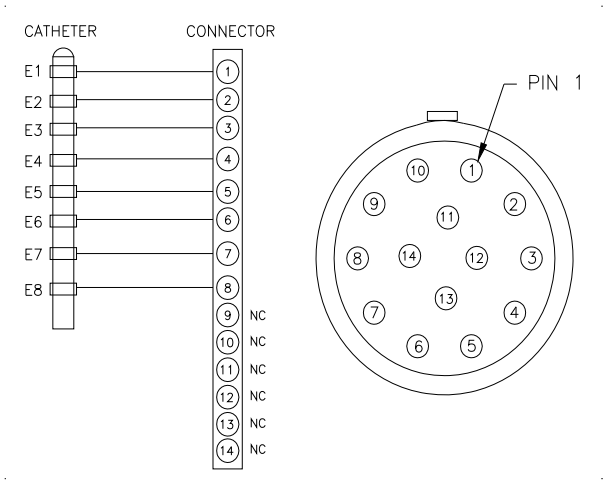
- The Mikro-Tip transducer catheters should be stored in a dark cool dry place.
- Compatibility with magnetic resonance imaging has not been determined.
- Consult Millar, Inc., before attempting sterilization by means other than ETO. Sterilization by autoclaving, ionizing (gamma) radiation, and exposure to formaldehyde vapor solutions are known to be incompatible with the Mikro-Tip transducers and cables and must not be used.

Millar Limited Warranty

Millar, 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 expressed of implied warranties of merchantability or fitness of purpose. Since handling, storage, cleaning, and sterilization of the product, as well as factors relating to 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 directly or indirectly arising from the use of this product.

Schematic



Electrodes

Precautions

- Use of the Mikro-Tip catheter should be restricted to specialists who are familiar with, and have been trained to perform, the catheterization procedures for which the device is intended.
- The Mikro-Tip catheter should be inspected for damage (cracking, kinks, etc.) prior to each use.
- The Mikro-Tip electrodes should be cleaned immediately after each use (see Cleaning After Use.)
- Refrain from touching the electrode area with sharp objects or making sharp bends in the catheter.

Maintaining Device Effectiveness

Storage

The catheter and cable should be stored in the sterilizing bag.

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 electrodes should be examined for any film of blood that has not been removed by cleaning. Such removal should consist of a thorough soaking in Alconox® detergent followed by a persistent wiping action along the electrodes with a moist tissue. The connector should undergo visual inspection for corrosion or bad contacts.

Initial Cleaning

Soak the catheter in a solution of Alconox (see manufacturer's directions) for at least 20 minutes.

Do not immerse the connector.

Gently wipe the catheter clean with a soft, wet gauze or tissue. Immediately rinse (do not allow to dry) the catheter with fresh, pyrogen-free distilled water; three separate rinses are recommended. Wipe the catheter dry.

Cleaning After Use

Mikro-Tip catheters should be promptly and thoroughly cleaned after each use. Do not use needles or other sharp objects to clean lumen openings as they may irreparably damage the catheter. When flushing catheters with a lumen, protect the connector(s) at the proximal end and the sensor(s) at the distal end.

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

1. Immediately after withdrawal of the catheter from the animal, submerge the catheter in cool water and flush the lumen (if any) until the effluent is clear. Do not immerse the electrical connectors. Gently wipe the catheter and electrodes clean with a soft, wet gauze or tissue.

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

2. Soak the catheter in a solution of Alconox detergent (see manufacturer's directions) for at least 20 minutes. Do not immerse the electrical connector. Millar recommends the use of Terg-A-Zyme® as an enzymatic cleaner to remove protein build up following the cleaning with Alconox. For transducers with a lumen, also flush the lumen with this solution.

3. Wipe the catheter clean with a soft, wet gauze or tissue. The surfaces of the catheter and electrodes must be thoroughly wiped to avoid a protein film buildup. Proceed to Step 4 without drying.

4. Rinse the catheter repeatedly with fresh, pyrogen-free or sterile water; three separate rinses are recommended. For transducers with a lumen, attach the catheter to a flusher and flush with cool water **per facility protocol**, then immerse the catheter lumen openings in sterile, pyrogen-free water and aspirate at least 50 mL through the lumen.

5. Dry the catheter lumen with a filtered air flush or carbon dioxide.

Recommended Method for Sterilization (Optional)

In most cases sterilization is not required and should only be used in the event of a possibility of infection between breeds of rodents due to microbial forms such as bacterial spores on the device. If an infection is possible, the use of a high level disinfectant is recommended since this process is less lethal and destroys most recognized pathogenic microorganisms. The use of Cidex OPA, Cidex Activated or Metricide disinfectant is recommended in lieu of ETO sterilization. If protocol mandates sterilization, the following cycle parameters are to be used.

Remove the 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. The catheter should be completely dry before sterilization as water on the units may react with ethylene oxide and reduce its effectiveness. Connector caps must be removed prior to sterilization.

The transducer should be completely dry before sterilization.

Sterilization Cycle Parameters

Preheat phase: Starting Temperature 110 ºF min. (43 ºC)
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 inHgA (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)

Specifications

Catheter Size	Per package labeling
Usable Length	Per package labeling
Pin-to-Electrode Resistance	≤ 15 Ohms
Electrodes	Gold
Electrode Spacing	1.0 mm