

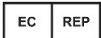
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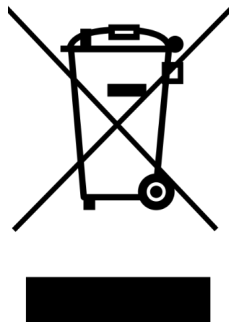
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Making the
improbable possible.

PEC Series Cables

Models PEC-4D/10D

Instructions for Use

Millar Limited Warranty

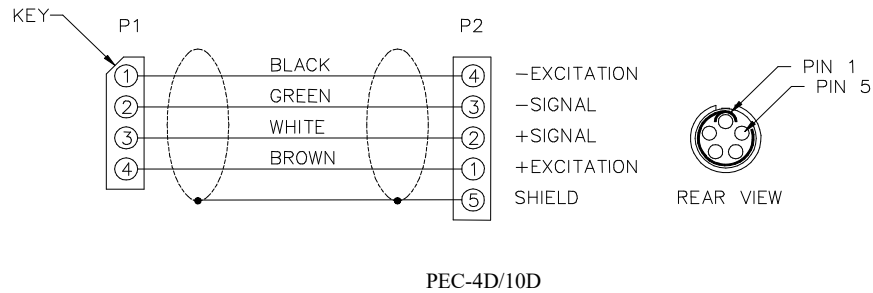
Millar, LLC warrants all of its cables to be free from defects in workmanship and materials at the time of shipment to the original purchaser.

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.

Specifications subject to change without notice.

Schematic



Definition of Symbols

	Consult instructions for use or consult electronic instructions for use
	Attention, consult accompanying documents
	Date of Manufacture
REF	Catalog Number
SN	Serial Number
LOT	Batch Code
	Authorized representative in the European Community
	Authorized representative in the United Kingdom
	EU Declaration of Conformity
	Medical Device
	Waste Electrical and Electronic Equipment

Device Description

The PEC series of cables are designed as an interface between the Millar Mikro-Tip™ catheters and the model PCU-2000 or MPS-2000 pressure control unit with patient isolation. The suffix "D" references catheters with a flat low-profile connector.

Cleaning

Wipe the cable and connectors clean with a soft wet gauze or tissue. If extremely dirty, the cable may be soaked in a solution of Alconox® or other mild detergent.

CAUTION: Do not immerse the electrical connector.

Recommended Method of Sterilization for Extension Cables

CAUTION: DO NOT sterilize by autoclaving, radiation (gamma or e-beam), plasma, peroxide or formaldehyde vapor solutions.

Cables must be completely cleaned and dried before sterilization. Aeration may be performed at room temperature or in a heated aeration (max. 145 °F, 63 °C) cabinet. Cables should be placed in a breathable polyethylene pouch (e.g., 3M™ Steri-Lok™).

The ETO sterilization parameters included below provide effective sterilization. Due to the variety of ETO sterilization equipment, final sterilization parameters should be selected and approved by each facility's processing department.

Ethylene Oxide Sterilization Cycle Parameters

Preheat phase:	Starting Temperature 110 °F (43°C) minimum. Duration 30 minutes
Initial Vacuum:	6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
Rate:	1.0 ± 0.5 inHgA/min. (3.4 ± 1.7 kPa/min)
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/min)
Conditioning	
Humidification:	1.5 ± 0.5 inHgA (5.1 ± 1.7 kPa)
Steam Conditioning:	10 minutes.
Humidity Dwell:	30 ± 5 minutes. at 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
Temperature:	110-130 °F (43-54 °C)
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 minutes.
Gas Wash A:	4 cycles (minimum)
Release:	30.0 ± 0.5 inHgA. (101.6 ± 1.7 kPa)
Rate:	1.4 ± 0.5 inHgA/min. (4.7 ± 1.7 kPa/min)
Vacuum	6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
Rate:	1.0 ± 0.5 inHgA/min. (3.4 ± 1.7 kPa/min)
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/min)
Aeration (Hot Cell)	
Duration:	At least 8 hours
Temperature:	110 ± 10 °F (43 ± 6 °C)

CAUTION: Cables should not be used earlier than 5 days after sterilization.

Routine Inspection

Conductive liquid entering the cable connectors can cause erratic operation and possible corrosion of wires within the connectors. The connector pins should be routinely inspected for corrosion.