



DEROYAL® PRESSURE MONITORING LINES

	DO NOT REUSE
STERILE EO	STERILIZED WITH ETHYLENE OXIDE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

IMPORTANT INFORMATION

Please read all instructions and warnings before use. Correct application is essential for proper functioning of the product.

INTENDED USE

DeRoyal® Pressure Monitoring Lines are intended to be used as a conduit to transmit fluid back to a pressure-sensing device (transducer) to determine hemodynamic pressure during angiography and angioplasty.

CONTRAINDICATIONS

Not intended for high pressure injections.

WARNINGS

- All connections should be hand tightened, without over-tightening, to ensure their security and prevent damage to the device.
- Check all connections to ensure they are tight and secure to prevent air from entering the system.
- Examine the products carefully for entrapped air and fully de-bubble prior to injection.
- Connections should be made only with devices compliant with ISO 594-2 for luer connections.

CAUTIONS

- Product should not be used if sterile packaging is damaged or opened. If product is damaged, remove from the operative area to prevent unintended use, and return to the manufacturer.
- This device is for single use only. It is not intended for disinfection and subsequent re-use, which may result in device failure or create the risk of contamination.
- This device has not been evaluated for reprocessing or re-sterilization. Reprocessing or re-sterilization may damage the device, rendering it unusable or may lead to device failure, which could result in patient illness, injury or death.

STERIZATION INFORMATION

DeRoyal intends that non-sterile product for use in sterile environments be further processed by our customers, including further packaging and/or sterilization according to their own validated processes. These products are to be sterilized by ethylene oxide only, as other sterilization methods have not been validated by DeRoyal and may damage the product which could cause a device malfunction and/or injury to the patient.



STORAGE AND TRANSPORT CONDITIONS

DO NOT store product at extreme temperatures or in a moist/damp environment; doing so may damage the product which could cause a device malfunction and/or injury to the patient.

	KEEP DRY
	KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.

WARRANTY

DEROYAL® PRODUCTS ARE WARRANTED FOR NINETY (90) DAYS FROM THE DATE OF SHIPMENT FROM DEROYAL AS TO PRODUCT QUALITY AND WORKMANSHIP. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**



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