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HIGH PRESSURE INJECTION LINES

	DO NOT REUSE
	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

The DeRoyal® High Pressure Injection Lines are indicated for use during coronary angiography procedures as a connecting line for the injection of radiopaque dye or saline.

DESCRIPTION

High Pressure Injection Lines are intended to be used by a licensed medical professional in conjunction with a power injector to administer contrast to the body for use in angiographic or angioplasty procedures. The non-braided high pressure lines will withstand one injection of hydrodynamic pressure at 1000 PSI (~69 Bar) using the following settings:

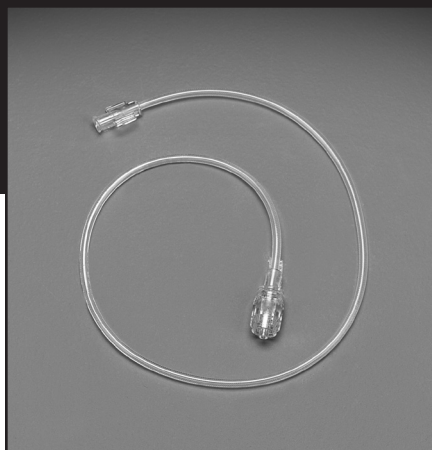
- Limiting pressure: up to 1200 PSI (~83 Bar)
- Injector volume: up to 20 ml
- Flow rate: up to 20 ml per second
- Linear rise: 0 seconds

WARNINGS

- All connections should be hand tightened, without over-tightening, to ensure their security and prevent damage to the device.
- Check all bonding and connections for damage. If damaged, discard and replace with a new 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 debubble prior to injection.
- Contents supplied non-sterile should be sterilized prior to use. Sterilization should be by ethylene oxide according to the manufacturer's validated sterilization parameters.
- Connections should be made only with devices compliant with ISO 594-2 or 80369-7 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.

STERILIZATION INFORMATION

NON-STERILE PRODUCT: DeRoyal intends that non-sterile products 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 or injury to the patient.

DIRECTIONS FOR USE

1. Check that the package is well sealed and without any damage.
2. Open using sterile technique.
3. Check the pressure line and flush it with normal saline before use.
4. Connect the luer connector with other devices, and eliminate air in the tube before connection.
5. Once procedure is complete, dispose of device according to hospital protocol.

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



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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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Manufacturer:
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849 USA
888.938.7828 or 865.938.7828
www.deroyal.com

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