



Improving Care. Improving Business.®

VESSEL LOOPS X-RAY DETECTABLE

	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

Please read all contraindications, warnings, cautions, and instructions before use. Correct application is essential for proper product function and to reduce risk of injury.

INTENDED USE STATEMENT

The DeRoyal® Vessel Loops are intended for use by a licensed practitioner for various procedures for temporary vessel occlusion, as well as identification or retraction of vessels, nerves, tendons, ureters, or other structures.

PRODUCT DESCRIPTION

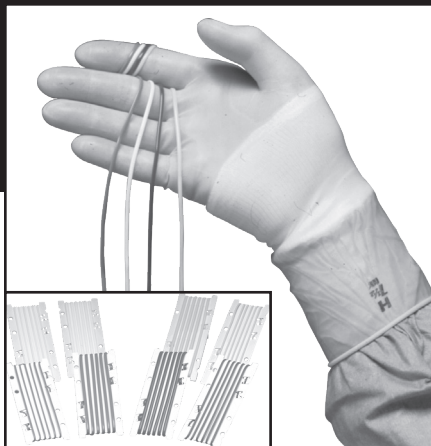
Vessel Loops are high quality medical grade silicone strands which are used during surgical procedures. The strands include radiopaque material that ensures x-ray detectability through the entire device. Vessel loops are strong, durable, and non-porous to slide smoothly over the vessels.

CONTRAINDICATIONS

- Device is **NOT** intended for implantation.

! WARNINGS

- DO NOT** reuse, reprocess, or re-sterilize. This device is for single use only. Reuse, reprocessing, or re-sterilization may damage the device, and may result in user or patient injury, patient infection, or patient death.
- Product should **NOT** be used if sterile packaging is damaged or opened. If damage is found, remove the product from the operative area to prevent unintended use.
- DO NOT** use an expired device.
- Failure to remove Vessel Loops from the patient may result in a foreign body reaction.
- Count all devices before and after the procedure prior to surgical closure. In the event a device cannot be located, an x-ray can be used to locate the devices. The size and position of the device or devices may impact its visibility.
- Vessel loops may be difficult to detect with x-ray in certain situations such as when the device is behind bony structures or in morbidly obese individuals. It is recommended that at least three views, using the optimal parameters for the imaging (x-ray) equipment, at a variety of angles for anterior and posterior, or the appropriate plane, be taken and examined for a missing device.
- DO NOT** cut vessel loop because it could create a count discrepancy or affect visualization.



CAUTIONS

- DO NOT** use damaged product.

DIRECTIONS

For one time use in occluding, retracting, and identifying arteries, veins, tendons, and nerves in surgical procedures:

- After removing the vessel loops from its sterile package, the clinician may:
 - RETRACT** – wrap loop around structure. Clamp loop to drape or hang outside wound.
 - OCCLUDE** – wrap loop around vessel.
 - IDENTIFY** – wrap loop around structure.
- After completion of procedure, remove loop(s), and dispose of vessel loop(s) in accordance with facility protocol.

STERILIZATION INFORMATION

NOTE: VESSEL LOOPS ARE AVAILABLE STERILE AND NON-STERILE.

DeRoyal® intends that non-sterile products for use in sterile environments be further processed by our customers, including further packaging and/or sterilization. These products are to be sterilized by ethylene oxide, utilizing the following parameters: Temperature: 120°F – 135°F (48.9°C – 57.2°C), Ethylene Oxide Gas Concentration: 625 – 800 mg/l, Exposure Time: 4 hrs minimum (Preconditioning: Temperature 100°F – 120°F (37.8°C – 48.9°C), Humidity 55 – 75%, Time 18 hrs. minimum), (Aeration: Temperature 100°F – 135°F (37.8°C – 42.2°C), Time 18 hrs. minimum). 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.

The device has not been evaluated for re-processing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure which could result in patient illness, injury or death.



Improving Care. Improving Business.®

STORAGE AND TRANSPORT CONDITIONS

Do not store at extreme temperatures or in 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.**



Improving Care. Improving Business.®



Manufactured by:
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849 USA
888.938.7828 or (001) 865.938.7828
www.deroyal.com

Part#0-1530 Revised 8/2022

©2022 DeRoyal Industries, Inc.

All Rights Reserved. DeRoyal, the DeRoyal logo, and Improving Care. Improving Business. are trademarks or registered trademarks of DeRoyal Industries, Inc.