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

DESCRIPTION
The DeRoyal® Laprador® Specimen Retrieval System consists of a handle, a cylindrical tube, a string, and a ripstop nylon bag. The system deploys and retracts the ripstop nylon bag, which encloses tissue specimens for retrieval during laparoscopic surgical procedures. The device is designed for introduction and use through appropriately sized trocars.

INTENDED USE
The DeRoyal® Laprador® Specimen Retrieval System is a sterile device intended to be used for collection and extraction of tissue, organs, and calculi during laparoscopic surgical procedures.

CONTRAINDICATIONS
The DeRoyal® Laprador® Specimen Retrieval System is contraindicated for use when, in the judgement of the licensed clinician, use of such a device would not be in the best interest of the patient.

WARNINGS
• This device contains components with a metal alloy having high nickel content. Therefore, do not use this device if patient is allergic to nickel.
• Read and understand all warnings, cautions, and directions completely and carefully before use. Failure to do so may result in serious injury.
• Do not reuse, reprocess, or re-sterilize this device. This device is for single use only. Reuse, reprocessing, or re-sterilization may damage the device, and may result in injury, infection, or death.
• Do not use if the individual package is opened or if the package or the device is damaged.
• Carefully inspect the device for damage or defects prior to use.
• Before application, ensure device does not contain foreign particulate or debris.
• The device is not for use with morcellators.
• If contents are too large to be extracted, enlarge the port site for safe removal. Failure to do so risks damage to components of the device.
• Visualization of the device while in vivo should be maintained at all times to mitigate the chance of organ and/or tissue damage.
• Make sure bag is properly closed prior to removal.
• Device should not come into close contact with sharp objects such as scissors and/or electrosurgical equipment.
• Do not extract bag and/or its contents through trocar cannula and/or introducer shaft.
• This device contains metal components. Proper knowledge of electrosurgical techniques is required to avoid shock and burn hazards to the patient and operator.
• Do not sever cinch string cord.
• Do not pull on tail alone to retrieve tissue bag.

CAUTIONS
• Prior to use ensure device is compatible with other endoscopic instruments and accessories.

DIRECTIONS FOR USE
1. Using sterile technique, grasp introducer shaft or introducer handle and pull back with the deployment handle until bag is fully retracted into the distal portion of the introducer shaft. If there is strong tension during retraction, gently manipulate the bag into the introducer shaft. **NOTE:** Short rotations or “wiggling” of the deployment handle may aid in retraction. Also, ensure loop stays on hook during retraction.

2. Insert the introducer shaft through a compatible trocar. Ensure the rotating hook is facing up to indicate the bag.
is properly positioned for retrieval.

3. Deploy bag by pushing deployment handle with thumb or palm for full deployment. Maintain visualization of device at all times.

4. Place specimen into bag.

5. Once the specimen is completely in the bag, turn the rotating hook 180° to release the bag assembly from deployment handle.

6. Remove the deployment shaft utilizing the deployment handle.

7. Cinch the bag by pulling back on the cinch string loop. Make sure tension is not placed on the bag tail.

8. Remove the introducer shaft using the introducer handle.

9. After trocar is removed, retrieve bag and its contents through the port site using the cinch string, taking care not to perforate or burst bag. If the bag does not move easily through the port site, enlarge the incision site to accommodate safe removal. Do not pull on tail alone to retrieve tissue bag.

10. Dispose and discard all used products according to hospital protocol.

STORAGE AND TRANSPORT CONDITIONS

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<th>Condition</th>
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<tr>
<td>KEEP DRY</td>
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<td>KEEP AWAY FROM SUNLIGHT</td>
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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.