IMPORTANT INFORMATION
Please read all warnings and instructions before use. Correct application is essential for proper product function and to reduce the risk of injury.

INTENDED USE
The DeRoyal® Esophageal Stethoscope with Temperature Sensor is to be used for routine monitoring of core body temperature, as well as heart and respiratory sounds in an anesthetized patient by inserting the stethoscope tube into the esophagus.

PRODUCT DESCRIPTION
The probe is sterile, individually packaged, and comes in different sizes and sensor types. The stethoscope has a male luer fitting for attachment to standard ear pieces.

CONTRAINDICATIONS
The use of an esophageal stethoscope may be contraindicated in patients with esophageal diverticulum or stenosis, in neonates or small infants undergoing neck surgery, in patients undergoing a tracheostomy or insertion of an internal jugular catheter, and in patients with conditions deemed unsafe for insertion of the stethoscope into the esophagus.

WARNINGS
Tracheal or bronchial insertion of stethoscope may cause airway obstruction and may be fatal if uncorrected. Correct placement may be verified with a laryngoscope.

ADVERSE REACTIONS
While adverse reactions are rare, the following have been associated with use of an esophageal stethoscope with temperature sensor during insertion or while the device was still in use: airway obstruction, aspiration pneumonitis, bronchial insertion, electrical burns and shock, epistaxis, esophageal abrasion, esophageal perforation, tracheal insertion, and trauma to pharynx.

CAUTIONS
• If incorrect temperature readings or excessive response time is noticed, discard probe and replace.
• Intubate patient with tracheal tube before inserting the esophageal stethoscope.
• Inform the surgeon that an esophageal stethoscope has been inserted.
• Lubricate the stethoscope before insertion and use accepted medical techniques in the insertion and removal of the stethoscope.
• Take care to insure that the cable and connector do not get wet and proper techniques are used during electrosurgical procedures to reduce radio frequency interference current and potential burn to the patient.
• An adequate electrosurgical dispersive ground electrode close to the active surgical site should be properly connected.
• Do not intertwine the cables, especially the monitor cables with the electrosurgical unit's cables.
• The operation of the patient temperature monitor may be temporarily affected during electrosurgical activations. Unusual temperature readings should be checked.
• If unusual or inconsistent temperature readings are noticed, check connections. If issue is unresolved, replace temperature probes.
• Inspect product for damage or contaminants prior to use. Do not use if damaged.

DIRECTIONS FOR USE
1. Remove the Esophageal Stethoscope with Temperature Sensor from its sterile package.
2. Lubricate the cuff with suitable water soluble lubricant.
3. Insert the stethoscope and guide it into the esophagus.
4. Listen for airway leaks when inserting. Invasion of the trachea may permit air to escape around the tracheal tube cuff. Do not seal the leak. Remove the esophageal stethoscope and reinsert. To verify proper placement, use a laryngoscope.
5. Adjust the stethoscope’s depth in the esophagus to maximize the heart and respiratory sounds.
6. Connect the temperature probe to the appropriate reusable temperature cable from DeRoyal. Connect the cable to the patient monitor. Secure the cable using the drape clip.
7. Follow the directions for use of the patient
8. Remove the probe prior to extubation of the tracheal tube following accepted medical technique.

9. Disconnect the probe (at the connector) and discard the probe. To disconnect, grasp both connectors firmly and pull. Do not pull cable or wire.

**STORAGE AND TRANSPORT CONDITIONS**

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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.