IMPORTANT
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® Nasopharyngeal/Nasal Temperature Probe is to be used for routine monitoring of core body temperature.

PRODUCT DESCRIPTION
The probe can be placed into the nasal, nasopharynx or esophageal cavities. It is sterile, individually packaged, and comes in different sensor types. It has a low-friction surface finish to improve ease of insertion. The temperature sensor, beneath the cuff at the distal tip, is highly accurate and designed to be compatible with the temperature monitor using the appropriate DeRoyal® reusable interface cable.

CONTRAINDICATIONS
The use of this device in the nasopharynx cavity may be contraindicated in patients with esophageal diverticulum or stenosis, in neonates or small infants undergoing neck surgery and in patients undergoing a tracheotomy or insertion of an internal jugular catheter. Nasopharyngeal insertion is not recommended for patients who are taking anticoagulants or when manipulation of mucosa is undesirable. Do not use rectally.

WARNINGS
• Tracheal or bronchial insertion of the probe may cause airway obstruction and may be fatal if uncorrected. Correct placement may be verified with a laryngoscope. While adverse reactions are rare, the following have been reported to be associated with the use of temperature probes during insertion or while the device was in use:
  • airway obstruction
  • aspiration pneumonitis
  • bronchial insertion
  • electrical burns
  • epistaxis
  • esophageal abrasion
  • esophageal perforation
  • tracheal insertion
• trauma to pharynx
• Not tested for use in MR environments. Use in an MR environment may cause burn to patient or other serious injury.
• May cause epistaxis (nosebleed). In the pregnant patient, children with large adenoids, and patients with clotting disorders, the incidence of epistaxis is high.
• The nasal mucosal temperature can vary based on exact location (i.e., anterior versus posterior mucosa) and respiratory cycle (i.e., inspiration versus expiration). The exact location and timing of the respiratory cycle should be noted and taken into consideration when using a nasopharyngeal or nasal temperature probe.
• Inspect packaging for any damage and product for any damage, contaminate or missing parts prior to use.

PRECAUTIONS
• If the probe is to be used in the esophagus on an anesthetized patient, intubate the patient with the endotracheal tube before inserting the probe.
• Lubricate the probe with a medical grade water-soluble lubricant before insertion and use accepted medical techniques during insertion and removal of the probe.
• Take care to ensure that the cable and connector do not get wet and that proper techniques are used during electrosurgical procedures to reduce radio frequency interference current and potential burns 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 probe has inaccurate, unstable, or no temperature readings, discard and replace.

DIRECTIONS FOR USE

1. Remove the Nasal, and/ or Nasopharyngeal Temperature Probe from its sterile package.
2. Lubricate the probe tip with a suitable water soluble lubricant.
3. Insert the probe and guide it into the nostrils, nasopharynx cavity or esophagus.
4. Connect the temperature probe to the appropriate reusable temperature cable from DeRoyal. Connect the cable to the patient monitor. Secure the cable using drape clip.
5. Follow the directions for use of the patient temperature monitor instrument.
6. If used in the esophagus, remove the probe prior to extubation of the tracheal tube following accepted medical technique.
7. Disconnect the probe (at the connector) and discard the probe. To disconnect, grasp both connectors firmly and pull. DO NOT pull on cable or wire.
8. This probe is NOT reusable.
9. Discard according to facility protocol.

STORAGE AND TRANSPORT CONDITIONS

| KEEP DRY |
| KEEP AWAY FROM SUNLIGHT |

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.