

1. General Information

- **Equipment:** Double Balloon Enteroscope (DBE) System.
 - **Clinical Purpose:** High-resolution visualization and therapeutic intervention (biopsy, stenting, hemostasis) of the small bowel using a push-pull technique to pleat the intestine over an overtube.
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2. Physical Characteristics

- **Total Working Length:** Minimum 2,000 mm.
 - **Total Length:** Approximately 2,300 mm to 2,350 mm.
 - **Distal End Diameter:** ≤ 9 mm.
 - **Flexible Portion Diameter:** ≤ 9 mm.
 - **Working Channel Diameter:** ≥ 3 mm
 - **Weight:** Ergonomically balanced control handle, < 1 kg.
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3. Imaging and Optical System

- **Viewing Direction:** Forward-viewing (0°).
 - **Field of View (FOV):** 140° or greater.
 - **Observation Range:** 3 mm to 100 mm (depth of field).
 - **Image Quality:** High-Definition (HD) CCD or CMOS sensor.
 - **Frame Rate:** 60 fps for smooth, real-time motion.
 - **Illumination:** Dual or triple LED/Xenon fiber optic light guide.
 - **Color Imaging:** Yes; includes Narrow Band Imaging (NBI) or equivalent digital chromoendoscopy.
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4. Angulation & Maneuverability

The scope must provide 4-way tip deflection for navigating complex small bowel loops:

- **Up:** $\geq 180^\circ$
 - **Down:** $\geq 180^\circ$
 - **Left / Right:** $\geq 160^\circ$
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5. Performance Characteristics

- **Scope Insertion:** Utilizes a dedicated overtube with an integrated balloon.
 - **Suction and Therapeutic Capability:** High-flow suction capability; compatible with argon plasma coagulation (APC), snares, and injection needles.
 - **Balloon Pleating Mechanism:** Pressure-controlled pump system with safety alarms to monitor balloon inflation/deflation within the overtube and on the scope tip.
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6. Data Interface and Software

- **Video Output:** DVI, HDMI, or SDI for high-resolution monitor display.
 - **Recording & Storage:** Integrated Workstation for still image and video capture (MPEG-4/DICOM).
 - **Software Features:** Patient database management and annotation tools for lesion marking.
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7. Safety, Sterility & Compliance

- **Biocompatibility Standards:** ISO 10993 compliant for all patient-contact materials.
- **Sterilization Method:** Compatible with Ethylene Oxide (EtO) or high-level disinfection (HLD) via glutaraldehyde/peracetic acid.
- **Contraindications:** Intestinal perforation, severe shock, or acute myocardial infarction.
- **EMC Compatibility:** IEC 60601-1-2 compliant.