

**OLYMPUS MH-246R BALLOON SHEATH**

K961048

**Device Name:** Olympus MH-246R Balloon Sheath**Common/Usual Name:** Balloon Sheath**Classification Name:** Endoscope and Accessories

**Predicate Devices:** Olympus  
 GF-UM2/EU-M2 K872027  
 GF-UM-3/EU-M3 K882061  
 EUS-20 System K926514

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**Summary Preparation Date:** February 23, 1996**Statement of Intended Use**

The balloon sheath MH-246R is designed to be used with the Olympus Ultrasonic Probe UM-2R/3R for intraluminal ultrasonic imaging of the gastrointestinal tract wall and surrounding organs.

**Device Description**

The MH-246R Balloon Catheter consists of two sections - insertion section and connector section. The insertion section is constructed of a balloon with the light shielding cover, insertion tube, and adapter. The connector section consists of a connector body, probe lock ring, sheath lock ring, and irrigation port.

The insertion section is connected to the connector body through a sheath locking ring, while the ultrasonic probe is inserted into the balloon sheath through a probe locking ring. The water filled syringe is connected to the irrigation port via an extension tube and three-way stopcock. The insertion section with the balloon will be provided sterile and intended for single use only. The connector section can be reused after proper cleaning and sterilization as outlined in the instruction manual.

## **General Safety**

When compared to the predicate devices, Olympus MH-246R Balloon Sheath does not incorporate any significant change in intended use, method of operation, material, or design that could affect the safety or effectiveness.