QuickClip Pro™ Device
Single Use Repositionable Clip
HX-202LR, HX-202UR
Patient Implant Card

Patient Name: ________________________________

Date Placed: ________________________________

Location Placed: ________________________________

Number of Clips Placed: ________________________________

This patient has received temporary mechanical endoscopic clipping device and can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in a deployed GI hemoclip dislodging from tissue or heating of tissue at the GI hemoclip location. A GI hemoclip dislodgement may result in rebleeding requiring additional intervention or surgery, serious injury, or death.

MRI Safety Information
-Non-clinical testing has demonstrated that single and multiple configuration of instruments are MR conditional. It can be scanned safely under the following conditions:
  - Static magnetic field of 3 Tesla or less, with:
    - Spatial gradient field of 1800 Gauss/cm and less
  - Maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg at 1.5 Tesla and 3 Tesla, for 15 minutes of continuous MR scanning.
- In non-clinical testing the instrument, multiple configuration produced a temperature rise of less than 1.5 °C (with a background temperature increase of 1.2 °C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 64 MHz (1.5 Tesla equivalent) Medical Implant Test System, Zurich Medtech AG (Software: MITS-DUALBAND 1.2.5.2).
- In non-clinical testing the instrument, multiple configuration produced a temperature rise of less than 3.0 °C (with a background temperature increase of 2.3 °C) at a maximum whole body averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 3 Tesla Magnetom Trio, Siemens (Software: Numaris/4, syngo MR A30) MR Scanner.
- No other RF heating testing was performed other than the 1.5 Tesla and 3 Tesla as listed above.

Manufactured By
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan. Fax: (042)646-2429, Telephone: (042)642-2111

Distributed By
OLYMPUS AMERICA INC., U.S.A., Telephone: (484)896-5000
OLYMPUS CANADA INC., Canada, Telephone: (800)387-0437
OLYMPUS LATIN AMERICA, INC., U.S.A., Telephone: (305)266-2332

QuickClip Pro™ Device
Single Use Repositionable Clip
HX-202LR, HX-202UR
Patient Implant Card

Patient Name: ________________________________

Date Placed: ________________________________

Location Placed: ________________________________

Number of Clips Placed: ________________________________

This patient has received temporary mechanical endoscopic clipping device and can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in a deployed GI hemoclip dislodging from tissue or heating of tissue at the GI hemoclip location. A GI hemoclip dislodgement may result in rebleeding requiring additional intervention or surgery, serious injury, or death.

MRI Safety Information
-Non-clinical testing has demonstrated that single and multiple configuration of instruments are MR conditional. It can be scanned safely under the following conditions:
  - Static magnetic field of 3 Tesla or less, with:
    - Spatial gradient field of 1800 Gauss/cm and less
  - Maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg at 1.5 Tesla and 3 Tesla, for 15 minutes of continuous MR scanning.
- In non-clinical testing the instrument, multiple configuration produced a temperature rise of less than 1.5 °C (with a background temperature increase of 1.2 °C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 64 MHz (1.5 Tesla equivalent) Medical Implant Test System, Zurich Medtech AG (Software: MITS-DUALBAND 1.2.5.2).
- In non-clinical testing the instrument, multiple configuration produced a temperature rise of less than 3.0 °C (with a background temperature increase of 2.3 °C) at a maximum whole body averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 3 Tesla Magnetom Trio, Siemens (Software: Numaris/4, syngo MR A30) MR Scanner.
- No other RF heating testing was performed other than the 1.5 Tesla and 3 Tesla as listed above.

Manufactured By
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan. Fax: (042)646-2429, Telephone: (042)642-2111

Distributed By
OLYMPUS AMERICA INC., U.S.A., Telephone: (484)896-5000
OLYMPUS CANADA INC., Canada, Telephone: (800)387-0437
OLYMPUS LATIN AMERICA, INC., U.S.A., Telephone: (305)266-2332