



## Magnetic Resonance Imaging (MRI) Compatibility

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Hollister Incorporated has tested the following products for safety in Magnetic Resonance Environment:

1. Premie One-Piece Ostomy Pouch (SKU 3777)
2. Newborn Pouch (SKU 3778)
3. New Image™ Drainable Irrigator Sleeve (SKU 1815x)
4. CenterPointLock™ Drainable Irrigator Sleeve (SKU 382x)

The results of the testing are as follows:

1. **Premie One-Piece Ostomy Pouch (SKU 3777) and Newborn Pouch (3778):** These products, with the soft wire closure attached, have been tested for safety in the Magnetic Resonance Environment. This product is labeled as “MR Conditional.” A patient with this device can be scanned safely with this device in an MR system under the following conditions:
  - a. Static magnetic field of 1.5-Tesla and 3-Tesla, only
  - b. Maximum spatial gradient magnetic field of 466-Gauss/cm (4.7-T/m)
  - c. Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e.: per pulse sequence) in the Normal Operating Mode
  - d. A 6 inch X 1 inch length of adhesive tape must be applied over the metallic strip to help stabilize this product when it is necessary for a patient to undergo an MRI examination at 1.5-Telsa or 3-Telsa
2. **New Image™ Drainable Irrigator Sleeve (1815x) and CenterPointLock™ Drainable Irrigator Sleeve (382x):** This product is “MR Unsafe” and should not be used in a Magnetic Resonance Environment.

We are currently in the process of updating our labeling associated with these products.

If you have any questions, please contact your Hollister Ostomy Care sales representative or our customer service team at 1.888.740.8999

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