

MRI Safety Information

*Non-clinical testing has demonstrated that Sewoon Medical's Bonastents, which include **Esophageal, Esophageal Anti-reflux valve, Biliary, Biliary Covered, Pyloric/Duodenal, Pyloric/Duodenal Covered, Colo-Rectal, Colo-Rectal Covered, Tracheal/Bronchial**, can be scanned safely under the following conditions:*

- *Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).*
- *Maximum spatial field gradient of 5,590 G/cm (55.90 T/m).*
- *Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg.*

Under the scan conditions defined above, Sewoon Medical's Bonastents are expected to produce a maximum temperature rise of less than 6.0°C after 15 minutes of continuous scanning.

Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

In non-clinical testing, the image artifact caused by Sewoon Medical's Bonastents extends approximately 1.6 cm from the device when imaged with a spin-echo pulse sequence in a 3 T MRI system.

[MR Conditional]

