

Magnetic Resonance Imaging Conditions For S.M.A.R.T.™ Biliary Stent Systems

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The Magnetic Resonance Imaging (MRI) information below pertains to the S.M.A.R.T.™ and S.M.A.R.T. CONTROL™ Transhepatic Biliary Stent Systems (referred as "S.M.A.R.T. Biliary Stents" herein).



Patients with an implanted S.M.A.R.T. Biliary Stent may be safely scanned under the MRI conditions listed below. Parameters not listed have no associated scanning restrictions. Adherence to these guidelines is necessary to ensure patient safety.

Name/identification of device Cordis	S.M.A.R.T. Transhepatic Biliary Stent System and S.M.A.R.T.
	CONTROL Transhepatic Biliary Stent System
Nominal values of static magnetic field (t)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	30 T/m (4000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Whole body transmit coil, Head RF transmit-receive coil
RF receive coil type	Any receive only coil may be used
Maximum whole-body SAR (W/kg)	2.0 W/kg
Limits on scan duration	15 minutes of continuous RF (a sequence or back-to-back
	series/scan without breaks) followed by await time of 10 minutes
	if this limit is reached.
MR image artifact	The presence of this implant produces an image artifact of
	approximately 16 mm, when a gradient echo pulse sequence on a
	3.0 T MRI system is used.
Non-clinical testing has demonstrated S.M.A.	R.T. Biliary Stents are MRI Conditional in single and overlapped
configurations up to a maximum of 290 mm a	s defined in ASTM F2503-13.

ADDITIONAL INFORMATION

Under the scan conditions defined above, non-clinical testing and simulation results indicated the S.M.A.R.T. Biliary Stents are expected to produce a maximum temperature rise of 3.7 °C after 15 minutes of continuous scanning. MRI at 1.5T or 3T may be performed immediately postimplantation.

We appreciate your interest in S.M.A.R.T. Biliary Stents. If you require additional information, please feel free to contact Cordis Medical Information Center at CordisMedInfo@Cordis.com.

References

1. Cordis 2021 Data on File.

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