



MRI information for Health Care Providers GyneFix®/GYN-CS®/ReLARC®

GyneFix®/GYN-CS®/ReLARC® with MRI

Non-clinical testing has demonstrated that "GyneFix®/GYN-CS®/ReLARC®" is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field of 1.5 Tesla and 3 Tesla, with:

- Maximum spatial field gradient of 12,900 G/cm (129 T/m)
- Maximum force product of 229,000,000 G2/cm (229 T2/m)
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

The test object GyneFix® 330/GyneFix® 10/GYN-CS® 10/ReLARC® 10 has been exposed within a 64 MHz RF-laboratory system (equivalent 1.5 Tesla) and within a 128 MHz RF-laboratory system (equivalent 3 Tesla).

Results of temperature increases are shown below:

Test configuration and test run	Exposure to 1.5 T	Exposure to 3 T
Maximum temperature rise at the test object (°C)	2.8	5.0
Local SAR in relation with the temperature probe showing max. temperature rise at the test object (W/kg)	10.8	19.1
Maximum temperature difference between the temperature rise of the test object and phantom background temperature on the control test run (°C)	0.5	1.0
Maximum temperature increase per local SAR (from control test) °C/W/kg	0.3	0.3
Hole body averaged SAR, measured calorimetrically (W/kg)	2.8	3.5
Local SAR of reference probe P4 measured calorimetrically (W/kg)	10.18-10.55	16.61-16.8
Scanning duration of sequence (min)	15	15

(Ref: Test Report MR: comp GmbH TR1174-304)

Results of measurement of magnetically induced torque are shown below:

Upper bound of the magnetically induced torque	Worst case torque due to gravity	ASTM F2213-17 (2017) requirement for MR safety (torque): magnetically induced torque < worst-case torque
0.01 mNm	≈ 0.2 mNm	Fulfilled

(Ref: Test Report MR: comp GmbH TR1174-302)

Results of measurement of magnetically induced displacement force are shown below:

Force due to gravity	Deflection angle	At technically accessible spatial gradient ∇B	At magnetic field strength B	Magnetically induced displacement force
4.45 mN	1.0°	≈ 4.51 T/m	≈ 1.78 T	0.08 mN ± 0.03 mN

(Ref: Test Report MR: comp GmbH TR1174-301)

The values of the detected deflection angles in the tests are below 45°, which results in a magnetically induced displacement force F_{m mean} for the test object which is less than the force on the test object due to gravity.

Results of evaluation of MR Image Artifacts from passive implants are shown below:

Worst-case artifacts of	Spin Echo	Gradient Echo
Test object length	7.5 mm ± 2.0 mm	9.3 mm ± 2.5 mm
Test object diameter	10.6 mm ± 2.8 mm	14.2 mm ± 3.7 mm

(Ref: Test Report MR: comp GmbH TR 1174-305)