

MRI Safety Information

The STALIF and ACTILIF C FLX product lines have been evaluated for MRI safety. Products included in this family are:

- STALIF C
- STALIF C-TI
- STALIF C FLX
- STALIF M (MIDLINE II)
- STALIF M-Ti (MIDLINE II-Ti)
- STALIF M FLX
- STALIF L
- STALIF L FLX
- ACTILIF C FLX

Non-clinical testing has demonstrated a patient with a device in this product line can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,0000 Gauss/cm (20-T/m)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e. per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the STALIF and ACTILIF C FLX product family is expected to produce a maximum temperature rise of 2.0 degree C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by the STALIF and ACTILIF C FLX fusion devices extends approximately 10mm from the implants when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.