

MRI Safety Information

Prodisc C SK Total Disc Replacement Implant has been evaluated for MRI safety.

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 900 Gauss/cm (90 mT/m)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning.

Under the scan conditions defined, the **prodisc C SK** implant is expected to produce a maximum temperature rise of 2 degree C after 15 minutes of MR scanning.

In non-clinical testing, the image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the **prodisc C SK** implant device.

Prodisc C Vivo Total Disc Replacement Implant has been evaluated for MRI safety.

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 900 Gauss/cm (90 mT/m)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning.

Under the scan conditions defined, the **prodisc C Vivo** implant is expected to produce a maximum temperature rise of 2 degree C after 15 minutes of MR scanning.

In non-clinical testing, the image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the **prodisc C Vivo** implant device.

