

prodisc[®] C MRI Safety Information

The **prodisc C** 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, at Normal Operating Mode or First Level Controlled Mode
- 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 the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning.

Under the scan conditions defined, the **prodisc C** 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** implant device. The artifact may extend approximately 3.5cm from the implant.

prodisc[®] L MRI Safety Information

The **prodisc L** 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, at Normal Operating Mode or First Level Controlled Mode
- 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 the normal operating mode and 4-W/kg for the First Level Controlled Mode for 15 minutes of scanning.

Under the scan conditions defined, the **prodisc L** 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 L** implant device.

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