

## MRI Safety Information for Int'l prodisc

**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 15 minutes of scanning.

Under the scan conditions defined, the **prodisc L** implant is expected to produce a maximum temperature rise of 1.8 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.

**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 3,000 Gauss/cm (300-mT/cm)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 4-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 3.2 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.

**Prodisc C Nova** 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

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- Maximum spatial gradient magnetic field of 3,000 Gauss/cm (300-mT/cm)
  - Maximum MR system reported, whole body average specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning.

Under the scan conditions defined, the **prodisc C Nova** implant is expected to produce a maximum temperature rise of 4 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 Nova** implant device.