MATHYS
European Orthopaedics

Mathys Implants in the Magnetic Resonance (MR) Environment

Guideline

Mathys Hip Implants

Mathys Hip Implants in the Magnetic Resonance (MR) Environment

MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MRI Safety Information: Non-clinical testing has demonstrated that hip implants are MR Conditional. A patient with such a device can be safely scanned during a MR session with the following conditions listed below. The effects of MRI procedures using MRI systems and conditions outside of the normal operating mode and outside of levels stated below have not been determined.

- Static magnetic field strength 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m)
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) for 15 minutes of scanning:
  a) Devices built in combination without ceramic: SAR ≤ 2 W/kg. Under the defined scan conditions, Hip implants are expected to cause a maximum temperature rise of less than 7.4 °C after 15 minutes of continuous scanning.
  b) Devices built in combination with ceramic: SAR ≤ 1 W/kg. Under the defined scan conditions (SAR ≤ 1 W/kg), Hip implants are expected to cause a maximum temperature rise of less than 7.1 °C after 15 minutes of continuous scanning.
  Note: Ceramic may cause higher RF-induced heating of tissue around the devices due to interaction effects.

  Note: The defined SAR is mandatory if the nearest part of the implant is closer than 30 cm from the isocenter of the scanner.
  If the implant is completely at a distance of more than 30 cm from the isocenter of the MRI device, the RF-induced heating of tissue around the devices will be reduced, and MRI within the normal operating mode is allowed for all implants.
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant.

Caution:
Combination with other devices has not been evaluated for safety and compatibility in the MR environment. It has not been tested for RF heating in the MR environment. The safety of combination with other devices in the MR environment is unknown. Scanning of a patient with such a device combination may result in patient injury. Therefore a combination of devices has to be declared as MR unsafe.

Note: If cerclages are used, the devices have to be at a distance of more than 30 cm from the isocenter of the MRI device.

In non-clinical testing, the image artifact caused by the device extends approximately 95 mm from the hip implants when imaged with a gradient echo sequence and a 3.0 T MRI system. In non-clinical testing, the magnetically induced displacement force was tested. The maximum deflection angle was measured to be less than 66 ° in the 3.0 T setting. In non-clinical testing, the magnetically induced displacement torque was tested. No torque was measured.

Mathys balanSys REV Implants

Mathys balanSys REV Implants in the Magnetic Resonance (MR) Environment

MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MRI Safety Information: Non-clinical testing has demonstrated that balanSys REV implants are MR Conditional. A patient with such a device can be safely scanned during a MR session with the following conditions listed below. The effects of MRI procedures using MRI systems and conditions outside of the normal operating mode and outside of levels stated below have not been determined.

- Static magnetic field strength 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m)
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning.

  Note: The defined SAR is mandatory if the nearest part of the implant is closer than 30 cm from the isocenter of the scanner.
  If the implant is completely at a distance of more than 30 cm from the isocenter of the MRI device, the RF-induced heating of tissue around the devices will be reduced, and MRI within the normal operating mode is allowed for all implants.
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant.

Caution:
Combination with other devices has not been evaluated for safety and compatibility in the MR environment. It has not been tested for RF heating in the MR environment. The safety of combination with other devices in the MR environment is unknown. Scanning of a patient with such a device combination may result in patient injury. Therefore a combination of devices has to be declared as MR unsafe.

Under the defined scan conditions, a balanSys REV implant is expected to cause a maximum temperature rise of less than 5.1 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 65 mm from the balanSys REV implants when imaged with a gradient echo sequence and a 3.0 T MRI system. In non-clinical testing, the magnetically induced displacement force was tested. The maximum deflection angle was measured to be less than 45° in the 3.0 T setting. In non-clinical testing, the magnetically induced displacement torque was tested. No torque was measured.

Mathys balanSys Bi/UNI Implants

Mathys balanSys Bi/UNI Implants in the Magnetic Resonance (MR) Environment

MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MRI Safety Information: Non-clinical testing has demonstrated that balanSys Bi/UNI implants are MR Conditional. A patient with such a device can be safely scanned during a MR session with the following conditions listed below. The effects of MRI procedures using MRI systems and conditions outside of the normal operating mode and outside of levels stated below have not been determined.

- Static magnetic field strength 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m)
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

  Note: The defined SAR is mandatory if the nearest part of the implant is closer than 30 cm from the isocenter of the scanner.
  If the implant is completely at a distance of more than 30 cm from the isocenter of the MRI device, the RF-induced heating of tissue around the devices will be reduced, and MRI within the normal operating mode is allowed for all implants.
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant.

Caution:
Combination with other devices has not been evaluated for safety and compatibility in the MR environment. It has not been tested for RF heating, migration, or image artifact in the MR environment. The safety of combination with other devices in the MR environment is unknown. Scanning of a patient with such a device combination may result in patient injury. Therefore a combination of devices has to be declared as MR unsafe.

Under the defined scan conditions, a balanSys Bi/UNI implant is expected to cause a maximum temperature rise of less than 6.1 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 65 mm from the knee implants when imaged with a gradient echo sequence and a 3.0 T MRI system. In non-clinical testing, the magnetically induced displacement force was tested. The maximum deflection angle was measured to be less than 45 ° in the 3.0 T setting. In non-clinical testing, the magnetically induced displacement torque was tested. No torque was measured.

Mathys Shoulder Implants

Mathys Shoulder Implants in the Magnetic Resonance (MR) Environment

MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MRI Safety Information: Non-clinical testing has demonstrated that Shoulder implants are MR Conditional. A patient with such a device can be safely scanned during a MR session with the following conditions listed below. The effects of MRI procedures using MRI systems and conditions outside of the normal operating mode and outside of levels stated below have not been determined.

- Static magnetic field strength 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m)
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

  Note: The defined SAR is mandatory if the nearest part of the implant is closer than 30 cm from the isocenter of the scanner.
  If the implant is completely at a distance of more than 30 cm from the isocenter of the MRI device, the RF-induced heating of tissue around the devices will be reduced, and MRI within the normal operating mode is allowed for all implants.
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant.

Caution:
Combination with other devices has not been evaluated for safety and compatibility in the MR environment. It has not been tested for RF heating in the MR environment. The safety of combination with other devices in the MR environment is unknown. Scanning of a patient with such a device combination may result in patient injury. Therefore a combination of devices has to be declared as MR unsafe.

Note: If cerclages are used, the devices have to be at a distance of more than 30 cm from the isocenter of the MRI device.

Under the defined scan conditions, a Shoulder implant is expected to cause a maximum temperature rise of less than 6,8 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 45 mm from the Shoulder implants when imaged with a gradient echo sequence and a 3.0 T MRI system. In non-clinical testing, the magnetically induced displacement force was tested. The maximum deflection angle was measured to be less than 42 ° in the 3.0 T setting. In non-clinical testing, the magnetically induced displacement torque was tested. No torque was measured.

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