MRI Safety Information

MR Conditional

MR

A patient with one product of the type *aixstent PPS* may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Notes
Product name	aixstent PPS
Manufacturer	bess pro gmbh Gustav-Krone-Str. 7 D—14167 Berlin Germany
Distributor	Leufen Medical GmbH Gustav-Krone-Str. 7 D—14167 Berlin Germany Tel.: +49 30 816 90 93 00 Fax: +49 30 816 90 93 93 <u>www.leufen-medical.eu</u> <u>contact@leufen-medical.eu</u>
Document number and edition date	MRIPPS-1-2023-08
Location of MRI safety information	www.leufen-medical.eu/pps
Static Magnetic Field Strength (B ₀)	1.5 T
Type of nuclei	Hydrogen
Static Magnetic Field (B ₀) Orientation	Horizontal
Magnet Type	Cylindrical-bore
Maximum Spatial Field Gradient	64.99 T/m (6499 G/cm)
RF Polarization	Circularly polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF coil, extremities and head local RF transmit coil
RF Receive Coil Type	Any receive RF coil can be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Whole Body Averaged SAR	Whole Body Averaged SAR ≤ 2 W/kg
Scan Duration and Wait Time	Maximum 1 h of continuous scanning without a cooling period
MR Image Artefact	 The presence of an <i>aixstent PPS</i> within the MR image field of view may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In vitro assessment on a comparable product (<i>aixstent OES</i>) at 1.5 T showed: An artifact that extends approximately 25 from the device edge or spin echo images An artifact that extends approximately 15 from the device edge or gradient echo images

