

MRI Safety Information

MR Conditional			
	A patient with one product of the type <i>aixstent OES</i> 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 OES		
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 www.leufen-medical.eu contact@leufen-medical.eu		
Document number and edition date	MRIOES- 3 — 2026-07		
Location of MRI safety information	www.leufen-medical.eu/oes		
Static magnetic field strength	1.5 T / 3 T		
Type of nuclei	Hydrogen		
Static Magnetic Field (B ₀) Orientation	Horizontal		
Maximum Spatial Field Gradient	1.5 T: 30 T/m (3000 G/cm) 3 T: 19 T/m (1900 G/cm)		
Maximum B0*IdB0/drl product	48 T ² /m		
RF Transmit Coil Type	Whole Body or extremities transmit RF coils (trunk and head local transmit coils are excluded)		
RF Receive Coil Type	Any receive RF coil can be used.		
MR System (RF) Operating Modes or Constraints	Normal Operating Mode		
Maximum Whole-Body SAR	Whole body SAR ≤ 2 W/kg ATTENTION: Under the scan conditions defined above, the product <i>aixstent OES</i> is expected to produce the following maximum temperature rise after 15 minutes of continuous scanning:		
	REF	1.5 T	3 T
	102-20-100		7.3 ± 0.8 °C
	102-20-140	7.6 ± 0.8 °C	
	102-24-100		6.5 ± 1.2 °C
	102-24-140	6.0 ± 0.7 °C	
	103-20-080		5.6 ± 0.6 °C
	103-20-100		7.6 ± 0.8 °C
	103-20-120	12.8 ± 1.5 °C	2.6 ± 0.4 °C
	103-20-140	9.8 ± 1.0 °C	2.9 ± 0.6 °C

Patient Landmarking Criteria	Stent length = 10 cm (REF 10X-2X-100): Landmarks within the following anatomical area are excluded: From the neck down (larynx level), including the complete cervical spine down to lumbar spine 5 (transition to the sacrum). Stent length > 10 cm: No restrictions
Patient Position in Scanner	No restrictions
Patient Conditions	Patients implanted with one stent of the type <i>aixstent OES</i> only. Patients with uncompromised thermoregulation (all persons without impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).
MR Image Artifact	The presence of a product of the type <i>aixstent OES</i> may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact. In vitro assessment at 1.5T showed: • On spin echo sequences a maximal artifact width of 25 mm (surrounding the device) • On the corresponding gradient echo sequences a maximal artifact width of 15 mm (surrounding the device)