

MRI Safety Information

MR Conditional	
	A patient with one product of the type <i>aixstent CRE</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 CRE
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	MRICRE- 3 — 2026-07
Location of MRI safety information	www.leufen-medical.eu/cre
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 CRE</i> is expected to produce the following maximum temperature rise after 15 minutes of continuous scanning: REF 411-25-080 • 3 T: 2,3 ± 0,3 °C REF 411-25-100 • 1.5 T: 4,8 ± 0,6 °C • 3 T: 1,9 ± 0,3 °C
Patient Landmarking Criteria	No restrictions
Patient Position in Scanner	No restrictions

Parameter	Notes
MR Image Artifact	The presence of a product of the type <i>aixstent CRE</i> may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact. In vitro assessment on a comparable product (<i>aixstent OES</i>) 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)