MRI Safety Information

Parameter	Notes
Product name	**aixstent BDP**
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	MRIBDP- 2 — 2023-01
Location of MRI safety information	www.leufen-medical.eu/bdp
Static magnetic field strength	3 T
Type of nuclei	Hydrogen
BO Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m
Maximum B0*ldB0/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	Whole Body Coil (Integrated Receive Coil)
RF Power Conditions	Normal Operating Mode
Maximum Whole-Body SAR (specific absorption rate)	Whole body SAR ≤ 2 W/kg ATTENTION: Under the scan conditions defined above, the product *aixstent BDP* is expected to produce the following maximum temperature rise after 15 minutes of continuous scanning: **Tested REF: 301-10-080**: **1,5 T:** 6,9 ± 0,8 °C / **3 T:** 4,1 ± 0,5 °C **Tested REF: 302-10-080**: **1,5 T:** 7,8 ± 1,9°C / **3 T:** 6,1 ± 1,1 °C **Tested REF: 303-10-080:** **1,5 T:** 6,4 ± 1,6°C / **3 T:** 5,9 ± 1,1 °C
Patient Landmarking Criteria	No restrictions
Patient Position in Scanner	No restrictions
Patient Conditions	Patients implanted with one stent of the type *aixstent BDP* 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 *aixstent BDP* 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 (*aixstent OES*) at 1.5T showed:

Parameter	Notes
	• 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)