


## MRI Safety Information

MR Conditional	
	A patient with one product of the type <i>aerstent TBJ</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	<b>aerstent TBJ</b>
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 <a href="http://www.leufen-medical.eu">www.leufen-medical.eu</a> <a href="mailto:contact@leufen-medical.eu">contact@leufen-medical.eu</a>
Document number and edition date	MRITBJ- 1 — 2021-02
Location of MRI safety information	<a href="http://www.leufen-medical.eu/tbj">www.leufen-medical.eu/tbj</a>
Static magnetic field strength	1,5 T / 3 T
Type of nuclei	Hydrogen
BO Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m
Maximum B0*ldB0/drl product	48 T <sup>2</sup> /m
RF Transmit Coil Type	Whole Body Coil (Integrated Transmit Coil)
RF Receive Coil Type	Whole Body Coil (Integrated Receive Coil)
RF Power Conditions	Normal Operating Mode
Maximum Whole-Body SAR	Whole body SAR ≤ 2 W/kg ATTENTION: Under the scan conditions defined above, the product <i>aerstent TBJ</i> is expected to produce the following maximum temperature rise after 15 minutes of continuous scanning: <ul style="list-style-type: none"> <li>• 1,5 T: 4,1 ± 0,5 °C</li> <li>• 3 T: 4,0 ± 0,5 °C</li> </ul> Tested REF: 533-20-050
Patient Landmarking Criteria	No restrictions
Patient Position in Scanner	No restrictions
MR Image Artifact	The presence of a product of the type <i>aerstent TBJ</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: <ul style="list-style-type: none"> <li>• On spin echo sequences a maximal artifact width of 25 mm (surrounding the device)</li> <li>• On the corresponding gradient echo sequences a maximal artifact width of 15 mm (surrounding the device)</li> </ul>