

Książyno, 28.12.2022

Statement

Company "MEDGAL" sp. z o.o. with its registered office at 16-001 Książyno, Niewodnicka 26A Street declares that our implants are manufactured from the following materials:

1. Of implantable steel:
- in accordance with ISO 5832-1

Content of alloying components in % - max values										
Cr	Ni	Mo	Cu	C	Si	Mn	P	S	N	Fe
19	15	3	0,5	0.03	1	2	0,025	0.01	0.1	Rest

2. Of implantable steel:
- according to ISO 5832-9

Content of alloying components in % - max values											
Cr	Ni	Mo	Cu	C	Si	Mn	P	S	N	Nb	Fe
22	11	3	0.25	0.08	0.75	4.25	0,025	0.01	0,5	0,8	Rest

3. Cobalt alloy (CoCrMo):
- in accordance with ISO 5832-12

Content of alloying components in % - max values									
Cr	Mo	Fe	Mn	Si	C	Ni	N	Co	
30	7	0,75	1	1	0,14	1	0,25	Rest	

4. Titanium alloy:
- according to ISO 5832-3

Content of alloying components in % - max values							
Al.	V	Fe	O	C	N	H	Ti
6,75	4,5	0,3	0,2	0,08	0,05	0,015	Rest

5. High molecular weight polyethylene UHMWPE according to ASTM F2695
6. Aluminium-zirconia ceramics according to ISO 6474
7. In addition, selected products can be covered with a layer:

- carbon-silicon (Si-DLC)
- hydroxyapatite according to ISO 13779.

The above-mentioned materials belong to non-ferromagnetic materials, therefore it should not be assumed that in a 1.5 tesla magnetic resonance environment, the products will move or deform.

The implanted implant may cause interference (artifacts) caused by the created interference waves in the MR image, thus creating the possibility of incorrect interpretation of the test result. The patient with such an implant is obliged to report this fact to the MR Diagnostic Laboratory and provide full medical documentation of the treatment process.

The decision to conduct an MRI examination is made only by specialist doctors based on the patient's medical records.

However, the products have not been tested for safety and compatibility in the environment of 1.5 and 3.0 tesla magnetic resonance.

Sincerely,

MEDGAL Sp. z o.o.
Management Board Representative
for Development
Marcin Skrodzki
Marcin Skrodzki

PEŁNOMOCNIK
ds. Zarządzania Jakością
inż. Szymon Grygoruk
.....



Dated on: 24/06/2023

LETTER FOR MRI COMPATIBILITY OF TI-6AL-4V AND SS 316L AND SS 316LVM

We, Auxein Medical Private Limited is declaring that our orthopaedic implants are manufactured using non ferromagnetic forms of materials. We are using Titanium Alloy Ti-6Al-4V ELI as per ISO 5832-3/ASTM F 136 and Austenitic Stainless Steel 316L and SS 316 LVM as per ISO 5832-1/ASTM F138.

Patients that have the implants made from nonmagnetic or "weakly" magnetic materials listed above are not at risk for injury during MR procedures. For the devices that have been implanted to date, there has been no report of an injury to a patient associated with the MR environment. Patients with non-ferromagnetic versions of these implants may undergo MR procedures immediately after they are placed.

It would be acceptable for patients with these particular metallic surgical implants to undergo MRI at 3-Tesla or less for a max. duration of 15 minutes.

Note:

The aforementioned parameters are the maximum limits to the MRI scanning, and is mentioned to avoid any potential harm to the patients.

For Auxein Medical Pvt. Ltd.

Authorised Signatory

Mr. Mohit Kumar

Management Representative and PRRC

Auxein Medical Private Limited, Sonapat, Haryana, India

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*** Scientific Rationale behind Claiming MRI Compatibility:**

FOR TI-6AL-4V ELI

Auxein Medical Pvt. Ltd. is manufacturing the implants using Titanium material for fixation of various bone including Cranial, etc. For the risk mitigation relating to MR Safety, we have conducted an analytical approach which is explained below.

The common ferromagnetic materials are the transition metals iron, nickel, cobalt and their alloys, and alloys of rare-earth metals^[1]. There is no presence of Cobalt in Ti-6Al-4V and though there is presence of iron ($\leq 0.40\%$) in Ti-6Al-4V which is very less in amount as compared to Titanium, Aluminium and Vanadium, so it does not create additional risk in regards to MR Safety.

To support the above paragraph, we have done some literature based study. From the conclusion, the following points are observed:

- Paramagnetic substances (Titanium) are weakly magnetized by an external magnetic field and lose their magnetism when the external magnetic field is removed. The risk of implant-based complications is meagre, and MRI can be safely used in patients with implants.
- Studies have shown that implants firmly fixed to the bone are not affected by MRI-induced displacement. RF heating is theoretically possible because the eddy currents in implants are parallel to the static magnetic field of the scanner. However, all cohort studies have revealed that this temperature change is negligible, indicating that concerns about tissue damage from RF heating are unfounded^[2].

Conclusion- Based on the aforementioned state of art scientific information it can be concluded that Ti-6Al-4V ELI orthopaedic implants are safe for MRI scan at 3-Tesla or less for a max. duration of 15 minutes.

FOR STAINLESS STEEL (SS 316L and SS 316LVM)

Stainless steel due to its characteristics does not disturb the imaging process or interfere with it and can be used inside an MRI machine without any problem^[3].

Auxein Medical Pvt. Ltd. is using Austenitic stainless steel 316L and 316LVM for manufacturing the bone plates and Screws. Implanted and medical devices from austenitic stainless steel meet the MRI safety and compatibility in the up to 1.5 Tesla systems^[4]. A similar kind of result has been published by WillisHRD in 2009, claiming Austenitic stainless steel is MRI compatible in general^[5].

A study published by Zou et al. concludes that the average deflection angle of titanium alloy and stainless steel implants were 4.3° and 7.7° , respectively, (less than 45°) which indicated that the magnetically induced force was less than the weight of the object. Also, in the study it was revealed that plates and screws used in orthopaedic surgery do not pose an additional hazard or risk to patients undergoing MR imaging at 1.5 Tesla or less^[6].

For Auxein Medical Pvt. Ltd.

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Conclusion- Based on the aforementioned state of art scientific information it can be concluded that austenitic grade stainless steel (316 L and 316 LVM) orthopaedic implants are safe for MRI scan at 3-Tesla or less for a max. duration of 15 minutes.

References:

1. <https://en.wikipedia.org/wiki/Ferromagnetism>
2. Kim et al. "Are titanium implants actually safe for magnetic resonance imaging examinations?" Arch Plast Surg. 2019 Jan; 46(1): 96-97. Published online 2019 Jan 15. doi: [10.5999/aps.2018.01466](https://doi.org/10.5999/aps.2018.01466)
3. <https://blog.thepipingmart.com/metals/is-stainless-steel-mri-compatible-an-overview/>
4. Suprihanto et al, "Magnetic Properties of Austenitic Stainless Steel 316l and 316lvm after High Temperature Gas Nitriding Treatment". July 2017 ROTASI 19(2):72, DOI:[10.14710/rotasi.19.2.72-75](https://doi.org/10.14710/rotasi.19.2.72-75)
5. Willishrh "Magnetic Resonance Imaging Hazards And Safety Guidelines" Aug, 2009, Strategic Outcomes Practice, Technical Advisory Bulletin. www.willis.com
6. Zou et al, "Evaluation of MR issues for the latest standard brands of orthopedic metal implants: Plates and screws" European Journal of Radiology Volume 84, Issue 3, March 2015, Pages 450-457, Doi: <https://doi.org/10.1016/j.ejrad.2014.12.001>

For Auxein Medical Pvt. Ltd.

A handwritten signature in black ink, consisting of several overlapping loops and strokes.

Authorised Signatory

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Datum: 13.07.2023

Unser Kürzel:

Ihre Referenz

Kundennummer:

Geschäftszeichen:

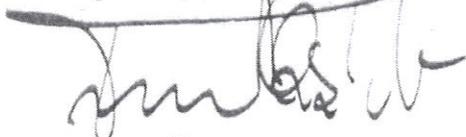
Ihr Kürzel:

Confirmation of MRI safety

We hereby confirm that the implants, listed in DSA.08.60080, have been tested for MRI safety and are "MR conditional".

Furthermore we evaluate that all implants, manufactured from pure titanium and titanium alloy, under the same conditions as described in DSA.08.60080 are "MR conditional".

Königsee Implantate GmbH



Frank Orschler
CEO

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Technical data sheet

MR safety

Product groups:

Proximal
humerus plates

Distal
femoral plates

KI-CVA
plates

Dens axis
screw fitting

- Proximal humerus plates
4.795.xx, 4.799.xx, 5.795.xx, 5.797.xx, 5.799.xx, 5.790.8x, 5.07913.8x
- Distal femoral plates
4.9482.xx, 4.9492.xx, 5.9482.xx, 5.9492.xx
- KI-CVA plates
5.555.xxxx
- Dens axis screw fitting
3.123.xxx

Standards/Tests:

ASTM F2182-11a
Heating

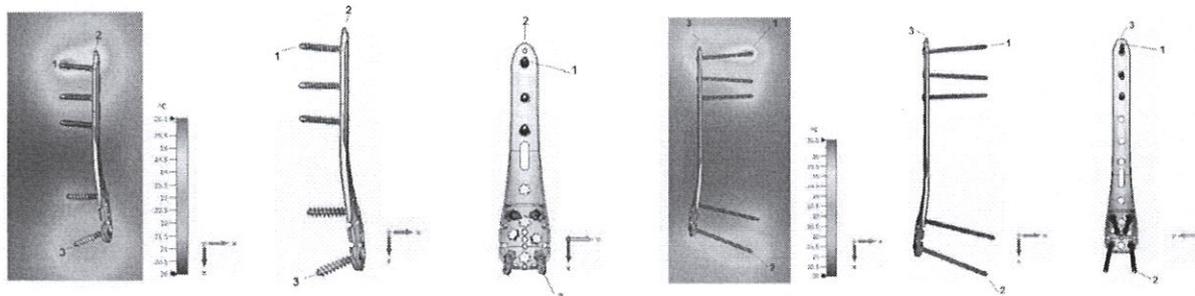
ASTM F2119-07
Artifact

ASTM F2213-17
Torque

ASTM F2052-15
Displacement force

Graphic illustration of the implant heating:

(Examples, extract from report TR0647-202)



 **Königsee
Implantate**

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In addition, the instructions for use contain general information about how to handle DSA.08.41100EN implants and DSA.08.41200EN instruments. Both documents are available in various languages at www.koenigsee-implantate.de/ifu.

DaTi | DSA.08.60080EN | Edition 02 | 2020-05

Technical data sheet

MR safety

Non-clinical tests have shown that the implants are conditionally MR-safe. A patient with these implants can be safely scanned in an MR system if the following conditions are met:

- Static magnetic field of 1.5 and 3 Tesla
- maximum spatial field gradient of 2,000 G / cm (20 T / m)
- maximum power product of 36,000,000 G² / cm (36 T² / m)
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W / kg (normal operating mode)

Under the scan conditions defined above, the implants have a maximum temperature increase of less than

- 6.8 °C (2 W / kg, 1.5 Tesla) HF-related temperature increase with a background temperature increase of ≈ 1.2 °C (2 W / kg, 1.5 Tesla)
- 5.0 °C (2 W / kg, 3 Tesla) HF-related temperature increase with a background temperature increase of ≈ 1.3 °C (2 W / kg, 3 Tesla)

expected after 15 minutes of continuous scanning.

In non-clinical tests, the MR image artifact caused by the implant extends approx. 31.2 mm for titanium and approx. 96.8 mm for stainless steel using a gradient echo sequence and a 3 Tesla MR system.



MR conditional