

Książyno, 2024-09-06

Statement

MEDGAL sp. z o.o. with its registered office in 16-001 Książyno, 26A Niewodnicka Street, declares that the implants manufactured by us are made of the following materials:

1. Made of implant steel:
- according to ISO 5832-1

Alloying content 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. Made of implant steel:
- according to ISO 5832-9

Alloying content 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. Made of cobalt alloy (CoCrMo):
- according to ISO 5832-12

Alloying content 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. Made of titanium alloy:
- according to ISO 5832-3

Alloying content 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

- according to ASTM F3001-14 (products made by 3D printing)

Alloying content in % - max values										
Al	V	Fe	O	C	N	H	Y	Other elements (individually)	Other elements (sum of all)	Ti
6,5	4,5	0,25	0,1	0,08	0,03	0,0125	0,005	0,1	0,4	rest

5. Made of UHMWPE high molecular weight polyethylene, according to ASTM F2695
6. Made of aluminum-zirconia ceramics in accordance with ISO 6474
7. In addition, selected products can be covered with a layer of:
- carbon-silicon (Si-DLC),
 - hydroxyapatite according to ISO 13779.

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

The implant may cause interference (artefacts) caused by the interference waves generated in the MR image, thus creating the possibility of misinterpretation of the examination result. A patient with such an implant is obliged to report this fact to the MRI Diagnostic Laboratory and provide full medical documentation of the treatment process.

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

However, the devices have not been tested for safety and compatibility in the 1.5 and 3.0 tesla MRI environment.

Best Regards,

MEDGAL Sp. z o.o.
Pełnomocnik Zarządu ds. Systemu Jakości
- Kierownik Działu Certyfikacji

Tomasz Łapiński