




INSTRUCTIONS FOR COMPLETING THE IMPLANT CARD BY A HEALTHCARE PROFESSIONAL


1. The health care professional takes the implant card, attached to the unit carton, which contained the implant implanted in the patient.
2. Self-adhesive identification labels are attached to each implant. The label should be removed from the package and pasted on the implant card in the place marked with a rectangle.
3. The healthcare professional shall complete the following fields in the implant card:
 - Patient's name,
 - Date of implantation,
 - Name and address of the health care facility
4. The implant card should be given to the patient together with the discharge from the hospital.
5. If more than one implant from LfC Ltd. is implanted during the same procedure, to one patient, a collective implant card can be printed from the website www.lfc.com.pl and individual implant identification labels can be pasted on one collective card, which will then be given to the patient.
6. Example of completed implant card


INTERNATIONAL IMPLANT CARD




 **Patient's name**
.....

 **Date of implantation**
.....

 **Name and address of**
.....
the health care facility
.....

 LfC Sp. z o.o.
ul. Kożuchowska 41
PL 65364 Zielona Góra

 www.lfc.com.pl/ifu




www.lfc.com.pl



PL ISaF Biodrowo-krzyżowa fuzja autogenna, zestaw L35/10+20 mm
GB ISaF Ilio-Sacral autogenous Fusion, set L35/10+20 mm
DE ISaF, Iliosakrale autogene Fusion, Set L35/10+20 mm
ES ISaF, Fusión autógena ileo-sacra, conjunto L35/10+20 mm
FR ISaF, Fusion coxo-sacrale autogene, ensemble L35/10+20 mm
IT ISaF Fusione autogena sacroiliaca, completo L35/10+20 mm

MD PL Stabilizator kręgosłupa **GB** Spinal stabiliser **DE** Wirbelsäulenstabilisator
ES Estabilizador espinal **FR** Stabilisateur spinal **IT** Stabilizzatore spinale
CZ Spinální stabilizátor


 LfC Sp. z o.o., ul. Kożuchowska 41
PL65364 Zielona Góra



QTY 1

REF 841DT-00351020

LOT 23L12

 19.08.2026

GS1

(01)05902363107905











(10)23L12

(17)8.2026


UDI



6.1 Example of completed collective implant card

<p>INTERNATIONAL IMPLANT CARD</p> <p>Patient's name</p> <p>Date of implantation</p>		<p>Name and address of the health care facility</p>	
<p>PL SpF Rodowniczy/złotawe łąga autogenne, zestaw L35f10-20 mm DE SpF Illo-Spina autogenne, Fusions, Spinal L35f10-20 mm DE SpF Illo-Spina autogenne, Fusions, Spinal L35f10-20 mm ES SpF Fusions autogenne, Fusions, conjunto L35f10-20 mm FR SpF Fusions auto-sacrale autogene, ensemble L35f10-20 mm IT SpF Fusions autogenne sacralizza, completo L35f10-20 mm</p> <p>MD PL Stabilizator kręgosłupa GB Spinal stabiliser DE Wirbelsäulenstabilisator ES Estabilizador espinal FR Stabilisateur spinal IT Stabilizzatore spinale CZ Spinalní stabilizátor</p> <p>LFC Sp. z o.o., ul. Kozuchowska 41 PL 65364 Zielona Góra</p> <p>OTYTI  UDI</p> <p>REF 841DT-00351020 GSI (01)05902363107905 LOT 23L12 (10)23L12 EXP 19.08.2026 (17)8.2026</p> 		<p>PL s-LIF Czop mięsisty/złoty/lętkowy H8 H6 L22 mm GB s-LIF Lumbar interbody cage H8 H6 L22 mm DE s-LIF Lumbar Interkorporeller Cage H8 H6 L22 mm ES s-LIF Espaldador intervertebral lumbar H8 H6 L22 mm FR s-LIF Cage intervertebrale lombaire H8 H6 L22 mm IT s-LIF Cage interbody lombare H8 H6 L22 mm</p> <p>MD PL Stabilizator kręgosłupa GB Spinal stabiliser DE Wirbelsäulenstabilisator ES Estabilizador espinal FR Stabilisateur spinal IT Stabilizzatore spinale CZ Spinalní stabilizátor</p> <p>LFC Sp. z o.o., ul. Kozuchowska 41 PL 65364 Zielona Góra</p> <p>OTYTI  UDI</p> <p>REF 895DT-00220806 GSI (01)05908215239985 LOT 21N10 (10)21N10 EXP 15.04.2027 (17)4.2027</p> 	
<p>LFC Sp. z o.o. ul. Kozuchowska 41 PL 65364 Zielona Góra</p> <p></p> <p>www.lfc.com.pl/itu</p> <p>   </p> <p></p> <p>www.lfc.com.pl</p>			

COMPATIBILITY WITH MRI

Implant material	Status in MR procedure			MR parameters
Titanium alloy Ti6Al4V	Conditional	X		MR Conditional 6 Check Appendix

The terminology was developed by ASTM International (American Society for Testing and Materials) and used by the US government agency FDA (Food and Drug Administration).

Conditional - the device may or may not be safe for a patient undergoing an MRI procedure or a person in an MRI environment, depending on the specific conditions that exist. The device poses no known risks in a specific MRI environment and specific conditions of use.

The Ti6Al4V titanium alloy implants used are conditionally MRI-safe devices. Nonferromagnetic material. Implants made of titanium and titanium alloys have MRI Conditional 6 status

For implants made of titanium or its alloys, there are no general contraindications to magnetic resonance imaging with the following parameters. This applies to passive (medical devices that perform their function without power), non-ferromagnetic implants.

The Ti6Al4V titanium alloy implants used are conditionally MRI-safe devices. Non-ferromagnetic material. Due to their non-ferromagnetic nature and poor electrical and thermal conductivity, implants made of titanium and titanium alloys have MR Conditional 6 status.

"MRI Conditional 6" - *The implant/device has been identified as MRI Conditional according to the terminology set forth in ASTM International: F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.*

*Non-clinical studies have shown that the implant/device is MRI Conditional. **A patient with this implant/device can be safely scanned immediately after implantation under the following conditions:***

- *static magnetic field of 3 Tesla or less;*
- *maximum spatial gradient magnetic field of 720 Gauss/cm (a higher value of spatial gradient magnetic field may be applicable if calculated correctly);*
- *maximum whole-body averaged specific absorption rate (SAR) of the MRI system of 2 W/kg for 15 minutes of scanning (per pulse sequence).*

MRI-related heating

In non-clinical testing, the implant/device produced a temperature rise of less than or equal to 6.0 degrees C using the MRI system's reported whole-body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes (per pulse sequence) of scanning on a 3 Tesla MRI system.

Artefact

MRI image quality may be degraded if the area of interest is in the exact same area or relatively close to the position of the implant/device. In some cases, the size of the artefact can be indicated relative to the size of the implant or device."

<https://www.mrisafety.com/index.html>

Safety precautions

Magnetic resonance imaging is a standard and widely used test. Magnetic resonance (MRI) is currently one of the most accurate methods of diagnostic imaging.















However, it should be remembered that in any case of installed implants, there is a potential risk of heating and migration in the MRI environment, as well as generating artifacts in the vicinity of the implant that interfere with diagnostics, even when their structural material does not have ferromagnetic (magnetic) properties.

Always inform the medical staff of the diagnostic laboratory of the presence of implants in the body and the extent of spinal stabilization before the test is performed, and follow the instructions of the medical staff and other medical advice.

Whether or not an MRI can be performed on a particular patient will be decided by the doctor/medical staff of the diagnostic laboratory on the basis of the medical records/implant information provided and the patient's current medical condition and related medical needs.

Due to the fact that there are different generations of MRI machines on the market, manufactured by different manufacturers, it is imperative to read the contraindications and warnings of the manufacturer of the MRI machine on which the test is planned to be performed.

Explanation of symbols:

	Patient's name
	Date of implantation
	Name and address of the health care facility that performed the implantation
	Name of the medical device
	Name and address of the manufacturer
	Patient information website
	UDI code
	Catalog number
	Lot code
	Production date
	Use before
	Number of devices in a package
	Read the instructions
	Conditional compatibility with MRI

Zielona Góra, 2024-01-05

Łukasz JĘDRYCH
zastępca Dyrektora
ds. jakości



Deputy Director of Quality Department