

		P			PETER LAZIC MICROSURGICAL
		IMPLAN [*] PASSPOR			INNOVATIONS
olding					
Falzung	<u> </u>	PATIENT DATA			
		Patient's name			
		Date of birth			
		Street			
		Place			
olding					
Falzung	<u> </u>	This person received a medical implant This may interfere with metal detection devices			
		IMPLANTATION DATA			
		Date of implantation Surgeon's name			
		Clinic			
olding		Implant label or decsrip	otion	Material Titanium	O Phynox
-alzung	<u> </u>	Label (REF/SN)	UDI		
		Label (REF/SN)	UDI		
		Label (REF/SN)	UDI		
		Label (REF/SN)	UDI		
		Other languages are availa	ble at www.lazic.d	e/downloads	

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MRI SAFETY INFORMATION for Titanium Clips

Non-clinical testing demonstrated that Peter Lazic GmbH Titanium Aneurysm Clips are MR Conditional. A patient with this aneurysm clip can be scanned safely in an MR system under the following conditions:

- · Static magnetic field of 1.5-Tesla or 3-Tesla, only
- · Maximum spatial gradient magnetic field of 6,000-Gauss/cm (60-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, an aneurysm clip from the Titanium Clip Family is expected to produce a maximum temperature rise of 1.7°C or less after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by an aneurysm clip from the Titanium Clip Family extends approximately 10 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.



MRI SAFETY INFORMATION for Phynox Clips

Non-clinical testing demonstrated that Peter Lazic GmbH Phynox Aneurysm Clips are MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- · Static magnetic field of 1.5-Tesla or 3-Tesla, only
- · Maximum spatial gradient magnetic field of 700-Gauss/cm (7-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, an aneurysm clip from the Phynox Product Family is expected to produce a maximum temperature rise of 1.4°C or less after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by an aneurysm clip from the Phynox Product Family extends approximately 20 mm or less from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

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