



ASPECTS OF MRI COMPATIBILITY

Prefix² System is designed as MRI conditional up to 1.5 Tesla. The MRI components have been tested according to ASTM Standards F2052, F2182, F2213 and F2119.

Prefix² System can only be guaranteed for MRI when using Orthofix XCaliber Bone Screws and the following rods to build a frame.

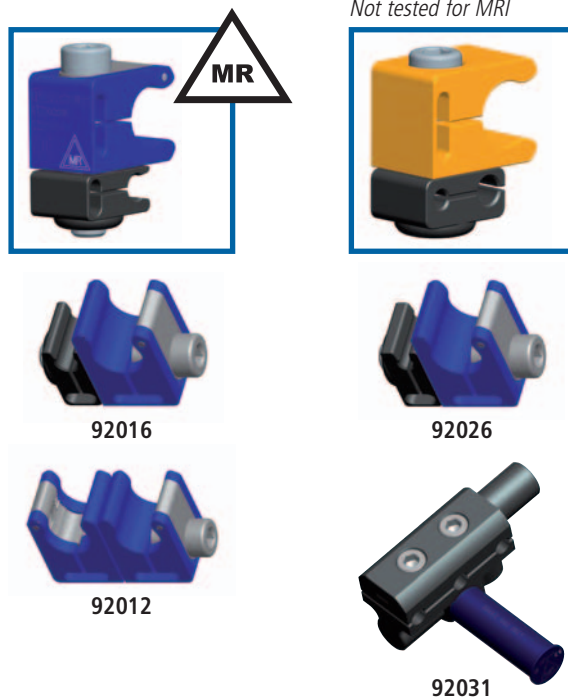
Rods

Code	Description
92125	Rod 125 mm long
92175	Rod 175 mm long
92275	Rod 275 mm long
92350	Rod 350 mm long

XCaliber Screws

Thread Length (mm)	Total Length	
	150 mm	260 mm
30	911530	912630
40	911540	912640
50	911550	912650
60	911560	912660
70	911570	912670
80	911580	912680
90	911590	912690

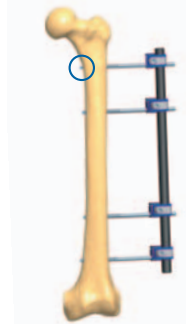
All Prefix² **Clamps** are blue and MRI conditional. They are marked with "MR".



It has been shown by specific MRI tests that the Prefix² System may be used for patients undergoing MRI procedures using up to 1.5 Tesla MR systems if certain specific conditions are followed.

Four commonly used frames have been tested for MRI use at 1.5 Tesla. The results are as follows:

Blue Screw Clip Clamp in Single Bar Configuration



- A maximum temperature increase of 6.0 °C has been measured at the tip of the most external screw (Maximum Whole Body averaged SAR of 2W/kg for 3.5 minutes of scanning)

Code	Description
1x92350	Rod 350 mm long
4x911560	Self-Drilling XCaliber Screw, L. 150 mm, thread length 60 mm
4x92016	Blue Screw Clip Clamp

Blue Multi Screw Clamp



No MRI Conditional Configuration

- A maximum temperature increase of 4.0 °C has been measured at the tip of the indicated screws (Maximum Whole Body averaged SAR of 2W/kg for 6 minutes of scanning)

Code	Description
2x92350	Rod 350 mm long
4x911560	Self-Drilling XCaliber Screw, L. 150 mm, thread length 60 mm
4x92012	Blue Rod Clip Clamp
2x92031	Blue Multi Screw Clamp



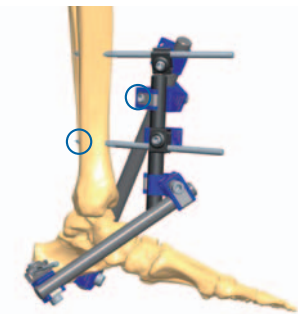
Z Configuration



- A maximum temperature increase of 7.0 °C has been measured at the tip of the most external screw (Maximum Whole Body averaged SAR of 2W/kg for 6 minutes of scanning)
- Nearby the tip of the screw a temperature increase of 3.5 °C was measured

Code	Description
2x92125	Rod 125 mm long
1x92275	Rod 275 mm long
2x911560	Self-Drilling XCaliber Screw, L. 150 mm, thread length 60 mm
2x911540	Self-Drilling XCaliber Screw, L. 150 mm, thread length 40 mm
4x92016	Blue Screw Clip Clamp
2x92012	Blue Rod Clip Clamp

Ankle Configurations



- A maximum temperature increase of 2.1 °C has been measured at the tip of the indicated screw (Maximum Whole Body averaged SAR of 2W/kg for 6 minutes of scanning)
- At the indicated clamp a temperature increase of 12.2 °C (with reference to room temperature) has been measured

Code	Description
1x92125	Rod 125 mm long
1x92175	Rod 175 mm long
1x92275	Rod 275 mm long
2x911540	Self-Drilling XCaliber Screw, L. 150 mm, thread length 40 mm
1x92080	Transfixing Pin, thread length 80 mm, thread Ø 5 mm, shaft Ø 4 mm
2x92016	Blue Screw Clip Clamp
2x92012	Blue Rod Clip Clamp
2x92026	Blue Transfixing Pin Clamp

MRI machine: PHILIPS Achieva 1.5T A series
 Device Position: isocenter of MRI scanner
 Magnetic Field Strength: 1.5 Tesla
 Spatial gradient field: 9.37mT/m

Please note that temperature changes reported apply to the designated MRI system and characteristics used. If a different MRI system is used, temperature changes may vary. Contact is advised with the supplier of the MRI system and Orthofix.

These tests have been performed in areas where the greatest temperature increase is expected with commonly used frames: at the tip and surrounding the tip of the most external screw. Literature review^{1,2,3} demonstrates that these temperature increases do not damage tissues. Due to the versatility of the system, an unlimited number of frames can be built which makes it impossible to test every construct.

There are factors that can influence these results (e.g. the number of screws used). Therefore, it is recommended that each frame be evaluated by a radiologist or MR scientist before the MRI procedure is undertaken to ensure patient safety. Since different frame configurations and frame sizes might lead to higher temperature increases, Orthofix recommends that the SAR settings are minimised as much as possible.

None of the components should move or migrate in the 1.5 Tesla MRI environments. Non-clinical testing has not been performed to rule out the possibility of component movement or migration at static magnetic field strengths higher than 1.5 Tesla or maximum spatial gradients higher than 9.37mT/m.

MR image quality may be compromised if the area of interest is in the same vicinity or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. For aspects of MRI compatibility please refer also to PQ PFX.

References

- 1) Summary, conclusions and recommendations: adverse temperature levels in the human body. Goldstein L.S., Dewhirst M.W., Repacholi M., Kheifets L. Int. J. Hyperthermia Vol 19 N. 2003 pag 373-384.
- 2) Assessment of bone viability after heat trauma Eriksson R.A., Albrektsson T., Magnusson B. Scand J Plast Reconst Surg 18:261-68 1984.
- 3) Temperature threshold levels for heat-induced bone tissue injury: A vital-microscopic study in the rabbit Eriksson A.R., Albrektsson T. J Prosthet Dent. 1983 Jul;50(1):101-7.

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