

MRI Information

Galaxy Fixation System is designed as MR conditional at 1.5 and 3 Tesla. The MR conditional components have been tested according to ASTM Standards F2052, F2182, F2213 and F2119.

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

Rods Diam. 12mm 



Code	Description
932100	Rod 100mm long
932150	Rod 150mm long
932200	Rod 200mm long
932250	Rod 250mm long
932300	Rod 300mm long
932350	Rod 350mm long
932400	Rod 400mm long

Rods Diam. 9mm 



Code	Description
939100	Rod 100mm long
939150	Rod 150mm long
939200	Rod 200mm long
939250	Rod 250mm long
939300	Rod 300mm long


Rods Diam. 6mm 



Code	Description
936060	Rod 60mm long
936080	Rod 80mm long
936100	Rod 100mm long
936120	Rod 120mm long
936140	Rod 140mm long
936160	Rod 160mm long
936180	Rod 180mm long
936200	Rod 200mm long

Note: All components of Galaxy Fixation System frames must be identified as MR Conditional prior to being placed in or near an MR Environment.





The Threaded Wires (93100), the Wire Locking Clamps (93620), and the L-Rod (936010) and Semi-Circular Rods (939010, 939020, 939030) are not MR Conditional. Any construct/frame that is using Threaded Wires, the Wire Locking Clamps, the L-Rod and Semi-Circular Rods must therefore be considered as MR Unsafe.

All the following Galaxy Fixation components are MR conditional. They are marked with "".

Clamps

<p>Large (93010) </p> 	<p>Medium (93110) </p> 
<p>Large-Medium Transition Clamp (99-93030) (Sterile) </p> 	<p>Small Multiscrew Clamp-Short (93330) </p> 
<p>Small Multiscrew Clamp-Long (93320) </p> 	<p>Small (93310) </p> 
<p>Multiscrew (93020) </p> 	<p>Medium Multiscrew Clamp (99-93120) (Sterile) </p> 

Modules

<p>Elbow Hinge (93410) </p> 	<p>Wrist Module (93350) </p> 
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Results of MR tests

It has been shown by specific MR tests that the Galaxy Fixator System may be used for patients undergoing MRI procedures using 1.5 and 3 Tesla systems if certain specific conditions are followed. Galaxy System Fixator Components are labeled MR CONDITIONAL according to ASTM F2503.

Non-clinical testing, done according to ASTM F2052-06, F2213-06, F2182-11, F2119-07, demonstrated that the configurations reported below (Fig.1-10) are MR Conditional.

However, based on the versatility of the Galaxy Fixation System, Orthofix has decided to follow the most stringent MR guidelines as indicated by the US Food and Drug Administration (FDA) and recommends performing all MR investigations with the entire frame outside of the MR scanner bore.

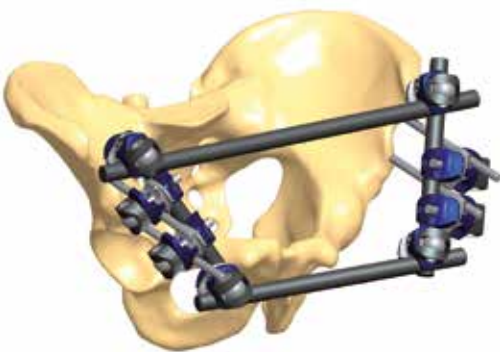
Orthofix has performed MR tests in the following conditions:

- MR SYSTEMS:

- 1.5-Tesla/64-MHz: Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner
- 3-Tesla/128-MHz: Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI Active-shielded, horizontal field scanner

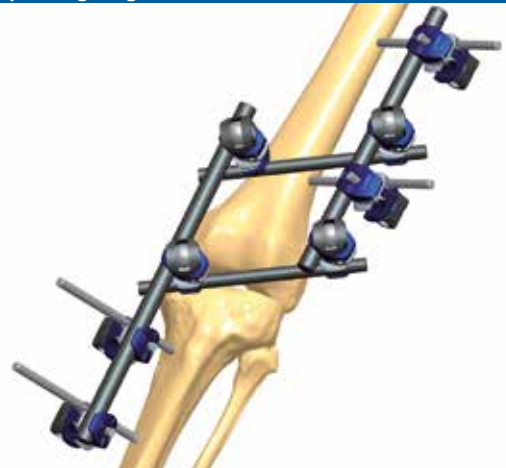
Tested Configurations

Pelvis - Fig 1



Code	Description
8x93010	Large Clamp
4x912640	XCaliber Bone Screws
2x932350	Rod d 12mm L 350mm
2x932300	Rod d 12mm L 300mm

Knee Spanning - Fig 2



Code	Description
8x93010	Large Clamp
4x912640	XCaliber Bone Screws
2x932200	Rod d 12mm L 200mm
2x932300	Rod d 12mm L 300mm

Ankle Transfix - Fig 3



Code	Description
6x93010	Large Clamp
2x911540	XCaliber Bone Screws
1x932300	Rod d 12mm L 300mm
2x932200	Rod d 12mm L 200mm
1x93080	Transfix Pin 80mm - Shaft d 6mm/Thread d 7mm

Ankle Transfix - GALAXY LINE EXTENSION - Fig 4



Code	Description
4x93010	Large Clamp
2x99-93030	Large-Medium Transition Clamp (Sterile)
1x932350	Rod d 12mm L 350mm
1x932250	Rod d 12mm L 250mm
1x932200	Rod d 12mm L 200mm
1x92080	Transfix Pin 80mm, d 4mm
2x911540	XCaliber Screw 150/40 6-5.6mm

Multi-Screw Clamp Tibia - Fig 5



Code	Description
2x93020	Multi-Screw Clamp
6x912640	XCaliber Bone Screws
1x932300	Rod d 12mm L 300mm

"Z" with Medium Clamp - Fig 6



Code	Description
6x93110	Medium Clamp
4x912640	XCaliber Bone Screws
3x939150	Rod d 9mm L 150mm

Elbow - Fig 7



Code	Description
1x93020	Multi Screw Clamp
2x93110	Medium Clamp
4x912640	XCaliber Bone Screws
1x93410	Elbow Hinge
2x10136	Bone Screws
1x932200	Rod d 12mm L 200mm
1x93010	Large Clamp
1x939150	Rod d 9mm L 150mm

Wrist - Fig 8



Code	Description
6x93310	Small Clamp
4x35156	Bone Screw d 4mm
3x936120	Rod d 6mm L 120mm

Wrist - Fig 9



Code	Description
1x93350	Wrist Module
2x93330	Small Multiscrew Clamp-Short
4x35100	Bone Screws (Shaft Ø 4mm - Thread Ø 3.3-3.0mm)
or 4xM321	Self-drilling Bone Screws Shaft (Ø 3mm - Thread Ø 3.0-2.5mm)

Wrist - Fig 10



Code	Description
1x93350	Wrist Module
2x93320	Small Multiscrew Clamp-Long
4x35100	Bone Screws (Shaft Ø 4mm - Thread Ø 3.3-3.0mm)
or 4xM321	Self-drilling Bone Screws Shaft (Ø 3mm - Thread Ø 3.0-2.5mm)

HEATING INFORMATION

Comprehensive electromagnetic computer modeling and experimental testing was performed on the following systems:

1.5-Tesla/64-MHz: Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner

3-Tesla/128-MHz: Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI, Active-shielded, horizontal field scanner

to determine the worst heating in ten configurations of Orthofix Galaxy Fixation System. From these studies, it is concluded that once the entire external fixation frame is visible outside the MRI bore, the maximum heating is less than 1 degree Celsius. In non-clinical testing the worst scenarios produced the following temperature rises during MRI under the conditions reported above:

	1.5 Tesla System	3.0 Tesla System
Configurations fig.1-10		
Minutes of scanning	15	15
Calorimetry measured values, whole body averaged SAR (W/kg)	2.2 W/Kg	2.5 W/Kg
Highest temperature Change (°C)	1°C	1°C

Please note that temperature changes reported apply to the designed MR systems and characteristics used. If a different MR system is used, temperature changes may vary but are expected to be low enough for safe scanning as long as all Galaxy System Fixator Components are placed **outside** the MR bore.

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.

DISPLACEMENT INFORMATION

The system will not present an additional risk or hazard to a patient in the 1.5 and 3-Tesla MR environment with regard to translational attraction or migration and torque.

ARTIFACT INFORMATION

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.

For complete information on MR indications, please refer to PQ GAL.

MR PATIENT SAFETY

MRI in patients with Galaxy Fixation System can only be performed under these parameters. It is not allowed to scan the Galaxy Fixation System directly. Using other parameters, MRI could result in serious injury to the patient. When the Galaxy Fixation System is used in conjunction with other External Fixation Systems please be advised that this combination has not been tested in the MR environment and therefore higher heating and serious injury to the patient may occur. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan is required. Immediately abort the scan if the patient reports burning sensation or pain.

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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