MRI

Galaxy Fixation



Frame Removal

Untighten the clamps by turning the drop back to the open position (12 o'clock) using the 30017 Allen Wrench or the T-Wrench hexagon 5-5 QC (93162). Then turn counterclockwise the knurled knob by hand. Disassemble the frame removing clamps and rods. Remove bone screws with AO Quick Connection manually with the T-Wrench hexagon 5-5 QC (93162). Remove bone screws that have been cut to length manually with the Universal T-Wrench (91150).

Instrumentation		
Part #	Description	
93162	T-WRENCH HEXAGON 5-5 QC	
	or	
91150	UNIVERSAL T-WRENCH	
30017	ALLEN WRENCH 5mm	

MRI SAFETY INFORMATION

In case you are building a MRI conditional frame, the frame shall be accompanied by a MRI Patient Card. MRI Patient Cards are available for download at ifu.orthofix.it. It is the responsibility of the clinician to provide the MRI Patient Card to the patient.



Outside the MRI bore MRI Safety Information				
may result in serious injury. CAUTION: All GALAXY FIXATION components must be outside the bore to avoid risk of excessive RF heating.				
Device Name	GALAXY FIXATION			
Static Magnetic Field Strength (B0)	1.5T or 3.0T			
Maximum Spatial Field Gradient	15T/m or 1500gauss/cm			
RF Excitation	Circularly Polarized (CP)			
RF Transmit Coil Type	Volume RF body coil			
Operating Mode	First level Operating Mode			
Maximum Whole-Body SAR	4W/kg (first level control mode)			
Maximum Head SAR	3.2W/kg (first level control mode)			
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF with less than 2 degrees Celsius temperature rise.			
MR Image Artifact	The presence of this implant may produce an image artifact.			
Device Positioning	GALAXY FIXATION components must not extend into the MRI bore. Therefore, MR scanning of body parts where the GALAXY FIXATION is located is contraindicated.			

Non-clinical testing has demonstrated that the GALAXY FIXATION Components are MR Conditional and are labeled MR CONDITIONAL "MR" according to the terminology specified in ASTM F2503 "Standard Practice for Marking Medical Devices and Other Items in the Magnetic Resonance Environment".

Displacement Information

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

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 seven configurations of Galaxy Fixation/Gemini. 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 2°C. In non-clinical testing the worst scenarios produced the following temperature rises during MRI under the conditions reported above:

GALAXY FIXATION	1.5Tesla System	3.0Tesla System
Minutes of scanning	15	15
Calorimetry measured values, whole body averaged SAR (W/kg)	2.2W/Kg	2.5W/Kg
Highest temperature rise less than (°C)	2°C	2°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 Fixation/Gemini Components are placed outside the MR bore.

Under the scan conditions defined above, the Galaxy Fixation™ Wrist Frames are expected to produce a maximum temperature rise of 1°C after 15 minutes of continuous scanning.

MR Patient Safety

MRI in patients with Galaxy Fixation/Gemini can only be performed under these parameters. Never scan the Galaxy Fixation/ Gemini directly. Using other parameters, MRI could result in serious injury to the patient. When the Galaxy Fixation/Gemini 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. Galaxy Fixation/Gemini can only be guaranteed for MRI when using the following components to build a frame:

* The following components are listed in non-sterile configuration. Please consider that the same MRI information and performance are applicable to the same components in sterile configuration if available (code number preceded by 99-, e.g. 99-93030)

RODS*	
Part #	Description
932100	ROD 100mm LONG, 12mm DIAMETER
932150	ROD 150mm LONG, 12mm DIAMETER
932200	ROD 200mm LONG, 12mm DIAMETER
932250	ROD 250mm LONG, 12mm DIAMETER
932300	ROD 300mm LONG, 12mm DIAMETER
932350	ROD 350mm LONG, 12mm DIAMETER
932400	ROD 400mm LONG, 12mm DIAMETER
99- 932450	ROD 450mm LONG, 12mm DIAMETER, STERILE**
99- 932500	ROD 500mm LONG, 12mm DIAMETER, STERILE**
99- 932550	ROD 550mm LONG, 12mm DIAMETER, STERILE**
99- 932600	ROD 600mm LONG, 12mm DIAMETER, STERILE**
99- 932650	ROD 650mm LONG, 12mm DIAMETER, STERILE**
939100	ROD 100mm LONG, 9mm DIAMETER
939150	ROD 150mm LONG, 9mm DIAMETER
939200	ROD 200mm LONG, 9mm DIAMETER
939250	ROD 250mm LONG, 9mm DIAMETER
939300	ROD 300mm LONG, 9mm DIAMETER
936060	ROD 60mm LONG, 6mm DIAMETER
936080	ROD 80mm LONG, 6mm DIAMETER
936100	ROD 100mm LONG, 6mm DIAMETER
936120	ROD 120mm LONG, 6mm DIAMETER
936140	ROD 140mm LONG, 6mm DIAMETER
936160	ROD 160mm LONG, 6mm DIAMETER
936180	ROD 180mm LONG, 6mm DIAMETER
936200	ROD 200mm LONG, 6mm DIAMETER

GALAXY FIXATION CLAMPS*		
Part #	Description	
93010	LARGE CLAMP	
93110	MEDIUM CLAMP	
93310	SMALL CLAMP	
93020	MULTI-SCREW CLAMP	
93030	LARGE-MEDIUM TRANSITION CLAMP	
93120	MEDIUM MULTI-SCREW CLAMP	
93040	LARGE DOUBLE MULTISCREW CLAMP	
93140	MEDIUM DOUBLE MULTISCREW CLAMP	

GALAXY FIXATION WRIST*		
Part #	Description	
93320	SMALL MULTI-SCREW CLAMP-LONG	
93330	SMALL MULTI-SCREW CLAMP-SHORT	
93350	WRIST MODULE	

ELBOW HINGE*	
Part #	Description
93410	ELBOW HINGE
GALAXY TI-HEX CONNECING POSTS*	

Part #	Description
93031	GALAXY TL-HEX CONNECTING POST L50mm D12mm
93032	GALAXY TL-HEX CONNECTING POST L100mm D12mm

** Special order only

* Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Orthofix representative if you have questions about the availability of Orthofix products in your area.

XCALIBER CONICAL BONE SCREWS*				
Part #	Shaft Ø	Thread Ø	Total L	Thread L
912630	6mm	6 - 5.6mm	260mm	30mm
912640	6mm	6 - 5.6mm	260mm	40mm
912650	6mm	6 - 5.6mm	260mm	50mm
912660	6mm	6 - 5.6mm	260mm	60mm
912670	6mm	6 - 5.6mm	260mm	70mm
912680	6mm	6 - 5.6mm	260mm	80mm
912690	6mm	6 - 5.6mm	260mm	90mm
911530	6mm	6 - 5.6mm	150mm	30mm
911540	6mm	6 - 5.6mm	150mm	40mm
911550	6mm	6 - 5.6mm	150mm	50mm
911560	6mm	6 - 5.6mm	150mm	60mm
911570	6mm	6 - 5.6mm	150mm	70mm
911580	6mm	6 - 5.6mm	150mm	80mm
911590	6mm	6 - 5.6mm	150mm	90mm

GEMINI CLAMPS*		
Part #	Description	
94100	GALAXY FIXATION GEMINI UNIVERSAL SINGLE CLAMP	
94200	GGALAXY FIXATION GEMINI DOUBLE UNIVERSAL MUL- TIPIN CLAMP	
94300	GALAXY FIXATION GEMINI UNIVERSAL MULTIPIN CLAMP	
99-94010	GALAXY FIXATION GEMINI SINGLE CLAMP STERILE	
99-94020	GGALAXY FIXATION GEMINI MULTIPIN CLAMP STERILE	
99-94030	GALAXY FIXATION GEMINI TRANSITIONAL SINGLE CLAMP STERILE	
99-94040	GALAXY FIXATION GEMINI DOUBLE MULTIPIN CLAMP STERILE	
99-94140	GALAXY FIXATION GEMINI DOUBLE MULTIPIN CLAMP MEDIUM STERILE	

BONE SCREWS*				
Part #	Shaft Ø	Thread Ø	Total L	Thread L
10190	6mm	4,5 - 3.5mm	70	20
10191	6mm	4,5 - 3.5mm	80mm	20mm
10108	6mm	4,5 - 3.5mm	80mm	30mm
10135	6mm	4,5 - 3.5mm	100mm	20mm
10136	6mm	4,5 - 3.5mm	100mm	30mm
10105	6mm	4,5 - 3.5mm	100mm	40mm
10137	6mm	4,5 - 3.5mm	120mm	20mm
10138	6mm	4,5 - 3.5mm	120mm	30mm
10106	6mm	4,5 - 3.5mm	120mm	40mm
35100	4mm	3.3 - 3mm	70mm	20mm
35101	4mm	3.3 - 3mm	80mm	35mm
M310	3mm	3-2.5mm	50mm	18mm
M311	3mm	3-2.5mm	60mm	20mm
M312	3mm	3-2.5mm	60mm	25mm
M313	3mm	3-2.5mm	60mm	30mm
M321	3mm	3-2.5mm	70mm	15mm
M314	3mm	3-2.5mm	70mm	20mm
M315	3mm	3-2.5mm	70mm	25mm
M316	3mm	3-2.5mm	70mm	30mm
M317	3mm	3-2.5mm	100mm	30mm

TRANSFIXING PINS*		
Part #	Description	
1-92050	SS TRANSFIXING PIN L 260mm D 4mm THREAD D 5XL50mm QC	
1-92080	SS TRANSFIXING PIN L 260mm D 4mm THREAD D 5XL80mm QC	
1-93050	TRANSFIX PIN 50mm QC	
1-93080	TRANSFIX PIN 80mm QC	

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XCALIBER C	YLINDRICAL B	ONE SCREWS	÷		XCALIBER CYLINDRICAL BONE SCREWS*				
Part #	Shaft Ø	Thread Ø	Total L	Thread L	Part #	Shaft Ø	Thread Ø	Total L	Thread L
941625	6mm	6mm	180mm	25mm	942535	6mm	5mm	260mm	35mm
941630	6mm	6mm	180mm	30mm	942540	6mm	5mm	260mm	40mm
941635	6mm	6mm	180mm	35mm	942545	6mm	5mm	260mm	45mm
941640	6mm	6mm	180mm	40mm	942550	6mm	5mm	260mm	50mm
941645	6mm	6mm	180mm	45mm	942560	6mm	5mm	260mm	60mm
941650	6mm	6mm	180mm	50mm	942570	6mm	5mm	260mm	70mm
941660	6mm	6mm	180mm	60mm	942580	6mm	5mm	260mm	80mm
941670	6mm	6mm	180mm	70mm	942590	6mm	5mm	260mm	90mm
941680	6mm	6mm	180mm	80mm	944540	6mm	5mm	150mm	40mm
941690	6mm	6mm	180mm	90mm	943420	6mm	4mm	100mm	20mm
942625	6mm	6mm	260mm	25mm	943430	6mm	4mm	100mm	30mm
942630	6mm	6mm	260mm	30mm	943440	6mm	4mm	100mm	40mm
942635	6mm	6mm	260mm	35mm	944420	6mm	4mm	120mm	20mm
942640	6mm	6mm	260mm	40mm	944430	6mm	4mm	120mm	30mm
942645	6mm	6mm	260mm	45mm	944440	6mm	4mm	120mm	40mm
942650	6mm	6mm	260mm	50mm	945420	6mm	4mm	150mm	20mm
942660	6mm	6mm	260mm	60mm	945425	6mm	4mm	150mm	25mm
942670	6mm	6mm	260mm	70mm	945430	6mm	4mm	150mm	30mm
942680	6mm	6mm	260mm	80mm	945435	6mm	4mm	150mm	35mm
942690	6mm	6mm	260mm	90mm	945440	6mm	4mm	150mm	40mm
941525	6mm	5mm	180mm	25mm	946420	6mm	4mm	180mm	20mm
941530	6mm	5mm	180mm	30mm	946430	6mm	4mm	180mm	30mm
941535	6mm	5mm	180mm	35mm	946440	6mm	4mm	180mm	40mm
941540	6mm	5mm	180mm	40mm	947320	6mm	4mm	100mm	20mm
941545	6mm	5mm	180mm	45mm	947325	6mm	4mm	100mm	25mm
941550	6mm	5mm	180mm	50mm	948315	4mm	3mm	120mm	15mm
941560	6mm	5mm	180mm	60mm	948320	4mm	3mm	120mm	20mm
941570	6mm	5mm	180mm	70mm	948325	4mm	3mm	120mm	25mm
942525	6mm	5mm	260mm	25mm	948330	4mm	3mm	120mm	30mm
942530	6mm	5mm	260mm	30mm	948335	4mm	3mm	120mm	35mm

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TL-HEX GALAXY FIXATION Hybrid System

The TL-HEX GALAXY FIXATION Hybrid System has not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. It has not been tested for heating, migration, or image artifact

in the MR environment. The safety of the TL-HEX GALAXY FIXATION Hybrid System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

TL-EVO GALAXY FIXATION Hybrid System

The TL-EVO GALAXY FIXATION Hybrid System has been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment.

Outside the MRI bore							
MRI Safety Information							
A person with the TL-EVO	GALAXY FIXATION Hybrid System may be safely scanned under the following conditions. Failure to						
follow these conditions may result in serious injury.							
CAUTION: All TL-EVO GALAXY FIXATION Hybrid System components must be outside the bore to avoid risk of excessive RF							
heating.							
Device Name	TL-EVO GALAXY FIXATION Hybrid System						
Static Magnetic Field Strength (B0)	1.5T or 3.0T						
Maximum Spatial Field Gradient	15T/m or 1500gauss/cm						
RF Excitation	Circularly Polarized (CP)						
RF Transmit Coil Type	Volume RF body coil						
Operating Mode	First level Operating Mode						
Maximum Whole-Body SAR	4W/kg (first level control mode)						
Maximum Head SAR	3.2W/kg (first level control mode)						
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF with less than 2 degrees Celsius temperature rise.						
MR Image Artifact	The presence of this implant may produce an image artifact.						
Device Positioning	TL-EVO GALAXY FIXATION Hybrid System components must not extend into the MRI. Therefore, MR scanning of body parts where the TL-EVO GALAXY FIXATION Hybrid System is located is contraindicated.						

Non-clinical testing has demonstrated that the TL-EVO GALAXY FIXATION Hybrid System components are MR Conditional according to the terminology specified in ASTM F2503 "Standard Practice for Marking Medical Devices and Other Items in the Magnetic Resonance Environment".

TL-EVO GALAXY FIXATION Hybrid System can only be guaranteed for MRI when using the following TL-EVO components to build a frame:

TrueLok EVO Components				
Part #	Description			
99-882140	TrueLok Evo Rx 5/8 Modular Ring D140mm Sterile			
99-882160	TrueLok Evo Rx 5/8 Modular Ring D160mm Sterile			
99-882180	TrueLok Evo Rx 5/8 Modular Ring D180mm Sterile			
99-882200	TrueLok Evo Rx 5/8 Modular Ring D200mm Sterile			
99-885000	TrueLok Evo Nut with Washer Sterile			
99-885001	TrueLok Evo Wire Fixation Bolt Sterile			
99-885002	TrueLok Evo 8Mm Half Pin Fixation Bolt Sterile			
99-885003	TrueLok Evo Bolt L16.5mm Sterile			
99-885004	TrueLok Evo 2 Holes Post Sterile			
99-885005	TrueLok Evo 3 Holes Post Sterile			

TrueLok EVO Components				
Part #	Description			
99-885006	TrueLok Evo 4 Holes Post Sterile			
99-885007	TrueLok Evo Half Pin Fixation Bolt Sterile			
54-1215	Bayonet Wire With Stopper			
54-1216	Bayonet Wire			
93031	Galaxy TL-Hex Connecting Post L50			

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Electronic Instructions for use available at the website http://ifu.orthofix.it

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days): tel +39 045 6719301, fax +39 045 6719370, e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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