

PATIENT INFORMATION LEAFLET

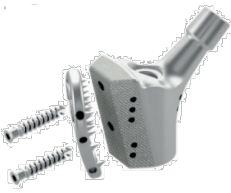




Name of device	PANTHEON Proximal Femur Reconstruction (PFR)
Intended purpose	It is a modular system intended to be used for the reconstruction of the proximal femur in case of severe proximal femoral bone loss in revision hip surgery (due to infection, fracture, failed total hip prosthesis) or in case of bone tumor.
Patient	<p>Hip joint replacement is indicated for patients with the following health conditions:</p> <ul style="list-style-type: none"> • Primary and secondary arthrosis (degeneration of hip joint) • Rheumatoid and degenerative arthritis • Deformities, such as dysplasia • Fractures and necrosis (death) of bone • Revisions, where other devices or treatments have failed • Metastatic diseases (cancer)
Undesirable side effects	<p>Apart from possible per-operation complications, a prosthetic implant can also be subject to:</p> <ul style="list-style-type: none"> ▪ Peri-prosthetic infection with or without loosening ▪ Movement of one or several prosthetic elements due to mechanical overloading, osteoporosis, etc. ▪ Dislocation of the prosthesis or fracture of the bone due to traumatism from physiotherapy ▪ Extra-articular pathology: phlebothrombosis, pulmonary embolism, etc. ▪ Fatigue fracture of prosthetic components can occur as a result of: trauma, strenuous activity, improper alignment or duration of service
Warnings and precautions	<p>The following factors can be critical to the eventual success of the hip joint replacement:</p> <ol style="list-style-type: none"> 1. Patient's weight. An overweight or obese patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small size prosthesis must be used. 2. Patient's occupation or activity. If the patient is involved in an occupation or activity, which calls for substantial walking, running, lifting, or muscle strain, the resultant forces can lead to failure of the fixation, the device or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations. 3. Condition of senility, mental illness, or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications. <p>Patients with renal insufficiency may be sensitive to potential metal ion release. Also, since little is known about the transport of potential metal ion release across the placenta, these devices should be used with caution in women of childbearing age.</p>

PATIENT INFORMATION LEAFLET



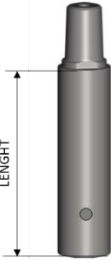
Expected device lifetime	<p>The security and durability of the implant depends also on patient's behaviour, particularly as concerning patient's activity and body weight.</p>
Symptoms of malfunctioning	<p>If you experience any of the following:</p> <ul style="list-style-type: none"> ▪ sudden severe pain in your leg, ▪ you can't put your weight on your leg, ▪ you have pain that does not get better even after taking pain killers, ▪ you have a red, hot, painful and swollen leg particularly around the wound or in your lower leg, <p>contact your GP or the ward immediately.</p>
Materials	<p>All components of the Pantheon Proximal Femur Reconstruction system are manufactured with Titanium alloy according to standard ISO 5832-3.</p>
Vigilance System	<p>The users are party to the setting up of the vigilance system after introduction of medical device on the market. They are obliged by law to report to the competent authorities as well as the manufacturer any incident concerning the medical device liable to cause or having caused serious risk for the patient or user health.</p> <p>The address of the Therapeutic Goods Administration's website to report any serious incident is https://www.tga.gov.au/reporting-adverse-events</p> <p>Manufacturer name & address:</p> <p>Adler Ortho SpA Via dell 'Innovazione 9, 20032 Cormano - (MI), Italy</p> <p>Australian contact details, http://www.adlerortho.com.au/contact-us</p>

PATIENT INFORMATION LEAFLET

Pantheon Proximal Femur Reconstruction - Product List

Reference	Description	Picture
0200210	PANTHEON PROXIMAL BODY FLAT L 50 SHORT	
0200220	PANTHEON PROXIMAL BODY FLAT L 50 MEDIUM	
0200230	PANTHEON PROXIMAL BODY FLAT L 50 LONG	
0200215	PANTHEON PROXIMAL BODY FLAT L 70 SHORT	
0200225	PANTHEON PROXIMAL BODY FLAT L 70 MEDIUM	
0200235	PANTHEON PROXIMAL BODY FLAT L 70 LONG	
0200310	PANTHEON PROXIMAL BODY SMOOTH L 50 SHORT	
0200320	PANTHEON PROXIMAL BODY SMOOTH L 50 MEDIUM	
0200330	PANTHEON PROXIMAL BODY SMOOTH L 50 LONG	
0200315	PANTHEON PROXIMAL BODY SMOOTH L 70 SHORT	
0200325	PANTHEON PROXIMAL BODY SMOOTH L 70 MEDIUM	
0200335	PANTHEON PROXIMAL BODY SMOOTH L 70 LONG	
0200090	PANTHEON PROXIMAL BODY LOCKING SCREW L50	
0200095	PANTHEON PROXIMAL BODY LOCKING SCREW L70	
0280510	PANTHEON SALVAGE CEMENTED STEM L 115 Ø 10	
0280511	PANTHEON SALVAGE CEMENTED STEM L 115 Ø 11	
0280512	PANTHEON SALVAGE CEMENTED STEM L 115 Ø 12	
0280514	PANTHEON SALVAGE CEMENTED STEM L 115 Ø 14	
0280516	PANTHEON SALVAGE CEMENTED STEM L 115 Ø 16	
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0201811	PANTHEON SALVAGE CEMENTLESS STEM HA COATED L 145 Ø 11	

PATIENT INFORMATION LEAFLET

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0200705	PANTHEON SALVAGE PLATE WITHOUT SPIKES LOCKING SCREW		
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0200715	PANTHEON SALVAGE PLATE WITH SPIKES L70		
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0200770	PANTHEON SALVAGE PLATE WITH SPIKES COMPRESSION SCREW LONG		
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0200605	PANTHEON CORTICAL PLATE LOCKING SCREW		
0200910	PANTHEON SHAFT L 35		
0200920	PANTHEON SHAFT L 50		
0200930	PANTHEON SHAFT L 65		
0200940	PANTHEON SHAFT L 80		
0200950	PANTHEON SHAFT L 95		
0200960	PANTHEON SHAFT L 110		
0200965	PANTHEON EXTENSION SHAFT L 120		
0200970	PANTHEON SHAFT L 125		
0200980	PANTHEON SHAFT L 140		

PANTHEON BRIDGING COLLARS



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PATIENT INFORMATION LEAFLET

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PATIENT INFORMATION LEAFLET

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