



OPERATING TECHNIQUE

SAPHIR stem has been designed with different intraoperative needs in mind and it is available in a wide range of sizes and versions, with progression of the extramedullary part (the neck) in homothetic increments.

SAPHIR prosthesis is a shortened stem, category 5, according to the classification of the French Society of Hip and Knee Surgery (SFHG), with a trapezoidal section in its proximal region, quadrangular section in the distal part and with a blunt distal tip.

SAPHIR stem, with and without collar, is available in two uncemented versions: the first with double HAP coating and Ti-Growth C[®]; the second with Ti-Growth C[®] plasma spray in the proximal section and glassbead treatment in the distal section. The stem is also available in a cemented version, in a high nitrogen content steel alloy.



INDICATIONS

The indications are tied to hip pathologies that require an arthroplasty to reduce or eliminate pain and / or improve joint function. The general guidelines are: Non-inflammatory degenerative joint disease such as primary or secondary osteoarthritis; Aseptic necrosis of the femoral head; Rheumatoid Arthritis; Post-traumatic Arthritis; Correction of functional deformity; Outcomes of fractures of the femoral neck; Outcomes of traumatic dislocations of the hip; Failures of osteotomy; Outcomes of arthrodesis.

CONTRAINDICATIONS

SAPHIR stem, in addition to the absolute and relative contraindications mentioned below, is also absolutely contraindicated, in sizes 0 and in sizes 1 for all versions in which they are available, in patients with a body mass greater than 48 kg.

The hip joint surgery is absolutely contraindicated in cases of: systemic or local infection, sepsis, and osteomyelitis. It is relatively contraindicated in case of: Osteoporosis; Patient uncooperative or suffering from neurological disorders, unable to follow directions; Systemic disorders and / or metabolic problems that lead to a progressive deterioration of bone support; Neurological or neuromuscular disorders that could create an unacceptable risk to the prostheses instability or lead to a failure of prostheses fixation; Osteomalacia; Active infection or suspected latent infection in the hip joint; Distant focus of infection that could spread to the implant site; Vascular insufficiency, muscular atrophy, neuromuscular diseases; Incomplete or insufficient presence of soft tissue around the knee joint; Obesity; Inadequate bone stock for the prostheses support or fixation; Skeletal immaturity; Local or disseminated neoplastic diseases; Incorrigible severe deformities.

MATERIALS

UNCEMENTED SAPHIR: Titanium Ti6Al4V (ISO 5832-3) CEMENTED SAPHIR: High Nitrogen Stainless Steel (ISO 5832-9)

UNCEMENTED SAPHIR COATINGS:

- Stem completely coated with hydroxyapatite (HAP) with double coating of HAP and Ti-Growth-C[®] in the proximal area
- Proximal coating of Ti-Growth-C[®] and distal finish: micro-beading

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Preoperative planning

In order to make the most of the different available variants of the SAPHIR stem (10 stem sizes for 5 different neck models), making a pre-operative plan by superimposing the templates on AP and ML radiographs is recommended.

To predetermine the choice of the size and version that will best fit the patient's femur, a choice has to be made concerning filling the canal (femoral stem size), the CCD angle (132° or 126°) and the off-set (STD and Lateralized). There is also the option of an 8° anteverted and 8° retroverted version.

The preoperative choice of a certain stem size is indicative; the final size will be determined intraoperatively on the basis of the actual positioning (sinking and off-set) achieved.

Femoral neck osteotomy

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After joint exposure, depending on the access route the surgeon chooses to take and prior to dislocation, joint length and off-set measurements can be taken using the Off-set/length gauge (Ref. 120411180A \div 120411180F).*

Once the joint is dislocated, it is possible to proceed with the osteotomy.

A 135° resection guide (Ref. 120411185) is available in the SAPHIR instruments set: it should be positioned in the direction of the femoral axis, referring to the reference points and dimensions from the pre-operative plan. (FIG.2)

* When using Off-set/length gauge, please refer to MESOFFLONG-OT-XXX.





FIG.2

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Femoral canal preparation

The bone of the greater trochanter area is freed using the special Modular Osteotome (Ref. 120411177) fitted to the Saphir Universal handle (Ref. 120411172). (FIG.3)

The removal of the underlying bone at the apex of the greater trochanter allows for better insertion of the rasps without forcing the bone, thus limiting the risk of fracture.

The femoral canal is released by manually introducing the Taper Reamer (Ref. 120411186) fitted to the appropriate "T" Handle (Ref. 120411187). (FIG.4)





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Once the canal has been properly reamed, the reamer can remain in place to allow guided positioning of the Trochanter Reamer (Ref. Size 0-4: 120411183; Ref. Size 5-9: 120411184) chosen according to the planned SAPHIR stem size.

(FIG.5)

To avoid stress in the calcar area, a Modular "canal finder" rasp is supplied (Ref. 120411178), which allows the passage of the rasps to be prepared and the housing of the final stem (FIG. 7).



Broaching of the femoral canal

Once the femur preparatory phase has been completed, the SAPHIR Rasps (Ref. 120411160 - 120411169) mounted on the Rasp handle (Ref. 120411182) are inserted. (FIG.8)

The femoral canal should be prepared by progressively introducing the rasps from size 0 until the planned size is reached and/or the desired fit is achieved.

To check the fit of the rasp, check that the rasp does not move by forcing the Rasp Holder handle left in place to rotate (internal and external). (FIG.9) N.B. In the event of an Emergency, an emergency rasp Extractor is available within the SAPHIR instrument set (Ref. 120411174)

N.B. Saphir rasps have been specially designed to allow the possibility of freely approaching cup preparation while leaving the rasp in place, in the case of a "Femur first" approach.





OPERATING TECHNIQUE

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Trial necks

Once the best rasp size has been confirmed, which will determine the choice of the final SAPHIR stem size, it is possible to proceed with the trial reduction by choosing the trial neck of the planned size and version (Ref. 120411150 - 120411159).

The trial necks, which are available in the SAPHIR instrument set, can be recognized by two colour codes.

One colour, that of the body (FIG.10) , indicates the rasp size:

- from size 0 to 4: dark grey
- from size 5 to 9: gold

The coloured insert (FIG.11), placed at the level of the morse taper in the direction of the rasp, determines the version of the final stem:

- STD 132°: Red
- Lat 132°: Green
- Var 126°: Yellow
- Ante Left Retro Right: Blue
- Retro Left Ante Right: Brown





Trochanterometer

On the upper apex of the necks, at the level of the morse taper for housing the head, there is a transverse hole in the ML direction, inside which it is possible to house the Trochanterometer (Ref. 120411176). (FIG. 12)

The trochanterometer allows the surgeon to evaluate the height of the final implant with head M, referring to the apex of the greater trochanter.

Trial reduction

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Leave the last rasp in place and proceed with the trial reduction.

Insert the Modular trial neck (Ref. 120411150 - 120411159), according to the plan, on the rasp, taking care to respect the coupling colour code.

The Trial head, available in four diameters and four lengths (Ref. 28mm 110380860 - 110380890; Ref. 32mm 110380960 - 110380990; Ref. 36mm 110381060 - 110381090) can now be fitted onto the trial neck. (FIG.13)

To facilitate the trial reduction, the Modular head pusher (Ref. 120411179), contained in the SAPHIR instrument set, can be used.

After the surgeon has carefully assessed the 3 important parameters: stability throughout the entire range of motion, leg length and soft tissue tension, the surgeon will validate the final implant.

If necessary, he can optimize the implant by replacing the neck or the trial head or both.





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Stem insertion

Once the trial reduction has been carried out, remove the Trial Head, Trial Neck and finally the Rasp, in that order.

The stem can then be inserted using the special impactor (Ref. 120411175) mounted on the Universal handle (Ref. 120411172), which allows the rotation of the stem to be controlled during insertion. (FIG.14)

The impactor has been specially designed to be orientable on the Varo-Valgus plane and tapered near the greater trochanter to avoid contact and stress on the latter. (FIG.15)

*SAPHIR stem is also absolutely contraindicated, in sizes 0 and in sizes 1, for all versions in which they are available, in patients with a body mass greater



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Positioning of the femoral head

Once the stem has been inserted, it is advisable to perform a further trial reduction and a further check with the length gauge to select the final head. (FIG.16)

To ensure the proper tightness of the final head, use the appropriate Impactor (Ref. 120411179), fitted to the Universal handle.



Stem extraction

If it is necessary to extract the stem, use the dedicated Stem Extractor (Ref. 120411190), attaching it onto the universal handle. (FIG.17)

The extractor has a threaded end which is screwed into the threaded hole of the stem. To complete the extraction, tap the base of the universal handle with the Diapason hammer (Ref. 12041118) contained in the SAPHIR instrument set.



SAPHIR INSTRUMENT CODES



1 120411160 0 1 120411161 1 1 1 120411162 2 1 120411163 3 1 120411164 4 1 120411165 5 1 120411166 6 1 120411166 6 1 120411166 6 1 120411166 6 1 120411167 7 1 120411168 8 1 120411169 9 1 120411169 9 1 120411169 9 1 120411169 9 1 103 T Bar 120411181 - 103 Saphir Universal handle 120411172 - 1 10 Rasp handle 120411182 - 2 10 DESCRIPTION REF. NECK QNT 10380800 S 1 1 10380800		DESCRIPTION	REF.	SIZE	QNT
1 120411161 1 1 120411162 2 1 120411163 3 1 120411164 4 1 120411165 5 1 120411164 4 1 120411165 5 1 120411166 6 1 120411167 7 1 120411167 7 1 120411167 7 1 120411167 7 1 120411167 7 1 120411167 7 1 120411167 7 1 120411169 9 1 1 120411167 7 1 3 T Bar 120411173 - 1 4 Saphir Universal handle 120411172 - 1 5 Clamp 120411182 - 1 6 Rasp handle 120411182 - 1 101381020* S			120411160	0	1
1 120411162 2 1 120411163 3 1 120411164 4 1 120411165 5 1 120411166 6 1 120411166 6 1 120411166 6 1 120411166 6 1 120411166 6 1 120411166 6 1 120411167 7 1 120411168 8 1 120411169 9 1 120411169 9 1 3 T Bar 120411173 - 4 Saphir Universal handle 120411172 - 1 5 Clamp 120411182 - 2 6 Rasp handle 120411182 - 2 7 Trial head (Diam. 22.2mm) 110381020* S 1 10380800 S 1 1 1 8 Trial head (Diam. 28mm)			120411161	1	1
1 120411163 3 1 120411164 4 1 120411165 5 1 120411165 5 1 120411166 6 1 120411165 5 1 120411166 6 1 120411167 7 1 120411168 8 1 120411169 9 1 120411169 9 1 120411169 9 1 120411169 9 1 120411173 - 1 1 120411173 - 1 1 120411172 - 1 1 120411172 - 1 1 120411181 - 1 1 120411182 - 2 1 120411182 - 2 1 10381020* S 1 1 10381020* S 1 1 10380800 S 1 1 10380860 S			120411162	2	1
1 Rasps SAPHIR Stem 120411164 4 1 120411165 5 1 120411166 6 1 120411167 7 1 120411167 7 1 120411168 8 1 120411169 9 1 120411169 9 1 120411169 9 1 120411169 9 1 120411169 9 1 1103 T Bar 120411173 - 1103 Saphir Universal handle 120411172 - 1 110 Saphir Universal handle 120411182 - 2 1105 Clamp 120411182 - 2 1105 Clamp 110381020* S 1 101 Tial head 110381030* M 1 101 Trial head 110380800 S 1 10380870 M 1 1 1			120411163	3	1
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120411167 7 1 120411168 8 1 120411169 9 1 120411169 9 1 120411169 9 1 120411169 9 1 120411169 9 1 120411173 - 1 120411173 - 1 120411172 - 1 120411172 - 1 120411181 - 1 120411181 - 1 120411182 - 2 120411182 - 2 120411182 - 2 120411182 - 2 120411182 - 2 10381020* NECK QNT 110381030* M 1 110380300* M 1 110380860 S 1 110380870 M 1 110380890 XL 1 110380960 S 1 110380980 L 1 <td></td> <td></td> <td>120411166</td> <td>6</td> <td>1</td>			120411166	6	1
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6 Rasp handle 120411182 - 2 DESCRIPTION REF. NECK QNT 7 Trial head (Diam. 22.2mm) 110381020* S 1 110381040* L 1 1 110380860 S 1 110380870 M 1 110380880 L 1 110380880 L 1 110380890 XL 1 110380960 S 1 110380970 M 1 110380980 L 1 110380980 L 1 110380980 L 1 110380980 L 1	(5)	Clamp	120411118		1
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Trial head 110381020* S 1 (Diam. 22.2mm) 110381040* M 1 110381040* L 1 110380860 S 1 110380860 S 1 110380870 M 1 110380880 L 1 110380880 L 1 110380890 XL 1 110380960 S 1 110380970 M 1 (Diam. 32mm) 110380980 L 1	Ŭ	DESCRIPTION	REF.	NECK	QNT
Trial head (Diam. 22.2mm) 110381030* M 1 110381040* L 1 110380860 S 1 110380860 S 1 110380870 M 1 110380870 M 1 110380880 L 1 110380890 XL 1 110380960 S 1 110380970 M 1 10380980 L 1 110380980 L 1			110381020*	S	1
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3 Trial head 110380860 S 1 (Diam. 28mm) 110380870 M 1 110380880 L 1 110380890 XL 1 110380960 S 1 110380970 M 1 110380970 M 1 110380980 L 1 110380980 L 1	\smile		110381040*	L	1
Trial head (Diam. 28mm) 110380870 M 1 110380880 L 1 110380890 XL 1 110380960 S 1 110380970 M 1 110380970 M 1 10380970 M 1 10380980 L 1 110380980 L 1			110380860	S	1
(Diam. 28mm) 110380880 L 1 110380890 XL 1 110380960 S 1 110380970 M 1 (Diam. 32mm) 110380980 L 1	@	Trial head	110380870	М	1
110380890 XL 1 110380960 S 1 110380960 S 1 110380970 M 1 (Diam. 32mm) 110380980 L 1	(Diam. 28mm)	(Diam. 28mm)	110380880	L	1
Trial head 110380960 S 1 9 (Diam. 32mm) 110380970 M 1 110380980 L 1 110380900 VI 1			110380890	XL	1
Trial head 110380970 M 1 (Diam. 32mm) 110380980 L 1			110380960	S	1
y (plain, 321111) 110380980 L 1	\bigcirc	Trial head	110380970	M	1
3311/1010101	Y	(Diam. 52mm)	110380980	L	1

Tray and lid for instruments SAPHIR REF: 120411195, 120411196

	DESCRIPTION	REF.	NECK	QNT
		110381060	S	1
\sim	Trial head	110381070	М	1
(10)	(Diam. 36mm)	110381080	L	1
		110381090	XL	1
	DESCRIPTION	REF.	SIZE	QNT
(11)	Trochanter Reamer	120411183	0-4	1
(12)	Trochanter Reamer	120411184	5-9	1
(13)	Modular head pusher	120411179	-	1
(14)	Impactor	120411175	-	1
(15)	Canal finder rasp	120411178		1
(16)	Modular Osteotome	120411177		1
(17)	Trochanterometer	120411176	-	1
(18)	135° resection guide	120411185	-	1
(19)	« T » Handle	120411187	-	1
20	Stem Extractor	120411190	-	1
(21)	Taper reamer	120411186	-	1
$(\widetilde{22})$	Rasp extractor	120411174	-	1
(23)	Palpator*	120411180D	-	1
(24)	Trocar depth gauge*	120411180B	-	1
(25)	Locking screw*	120411180F	-	3
(26)	Graduated rod*	120411180A	-	1
(27)	Locking system*	120411180E	-	1
28	Support depth gauge*	120411180C		1
	DESCRIPTION	REF.	NECK	SIZE
		120411150	132STD	0-4
		120411151	132LAT	1-4
		120411152	126	0-4
		120411153	132AG/RD	1-4
\bigcirc	Trial Nask	120411154	132RG/AD	1-4
Ð	mat Neck	120411155	132STD	5-9
		120411156	132LAT	5-9
		120411157	126	5-9
		120411158	132AG/RD	5-9
		120411159	132RG/AD	5-9

SAPHIR INSTRUMENT CODES



SAPHIR IMPLANT CODES

UNCEMENTED HA+TI-GROWTH-C® SAPHIR STANDARD 132°

REF.	SIZE
120440000	0
120440001	1
120440002	2
120440003	3
120440004	4
120440005	5
120440006	6
120440007	7
120440008	8
120440009	9

UNCEMENTED HA+TI-GROWTH-C® SAPHIR LATERALIZED 137°

AILKALIZLU IJZ		
REF.	SIZE	
120440011	1	
120440012	2	
120440013	3	
120440014	4	
120440015	5	
120440016	6	
120440017	7	
120440018	8	
120440019	9	

UNCEMENTED HA+TI-GROWTH-C® SAPHIR VARIZED 126°

REF.	SIZE	
120440020	0	
120440021	1	
120440022	2	
120440023	3	
120440024	4	
120440025	5	
120440026	6	
120440027	7	
120440028	8	
120440029	9	

UNCEMENTED HA+TI-GROWTH-C® SAPHIR ANTE R / RETRO L (AR/RL)*

REF.	SIZE
120440031	1
120440032	2
120440033	3
120440034	4
120440035	5
120440036	6
120440037	7
120440038	8
120440039	9

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UNCEMENTED HA+TI-GROWTH-C® SAPHII ANTE L / RETRO R (AL/RR)*

	,	
	SIZE	REF.
	4	100110011
	1	120440041
	2	120440042
	3	120440043
	4	120440044
	5	120440045
	6	120440046
	7	120440047
P	8	120440048
14	9	120440049

R	CEMENTED SAPHIR RETRO R / ANTE L (RR/AL)*

	()
REF.	SIZE
120440231	1
120440232	2
120440233	3
120440234	4
120440235	5
120440236	6
120440237	7
120440238	8
120440239	9

CEMENTED SAPHIR RETRO R / ANTE L (RR/AL)*

REF.	SIZE
120//02/1	1
120440241	1
120440242	2
120440243	3
120440244	4
120440245	5
120440246	6
120440247	7
120440248	8
120440249	9

120440120	0
120440121	1
120440122	2
120440123	3
120440124	4
120440125	5
120440126	6
120440127	7
120440128	8
120440129	9

UNCEMENTED HA+TI-GROWTH-C® SAPHIR VARIZED 126° WITH COLLAR* SI7F

120440116	0
120440117	7
120440118	8
120440119	9

REF.	SIZE
120440111	1
120440112	2
120440113	3
120440114	4
120440115	5
120440116	6
120440117	7
120440118	8
120440119	9

UNCEMENTED HA+TI-GROWTH-C® SAPHIR LATERALIZED 132° WITH COLLAR*

REF.	SIZE
120440100	0
120440101	1
120440102	2
120440103	3
120440104	4
120440105	5
120440106	6
120440107	7
120440108	8
120440109	9

UNCEMENTED HA+TI-GROWTH-C® SAPHIR STANDARD 132° WITH COLLAR*

CEMENTED SAPHIR STANDARD 132°

1161.	OILL
120440211	1
120440212	2
120440213	3
120440214	4
120440215	5
120440216	6
120440217	7
120440218	8
120440219	9

CEMENTED SAPHIR

REF.

120440220

120440221

120440222

120440223

120440224

120440225

120440226

120440227

120440228

SIZE

0

2

3

4

5

6 7

8

120440229 9

1

VARIZED 126°

RFF SI7F

CEMENTED SAPHIR LATERALIZED 132°

REF.	SIZE
120440200	0
120440201	1
120440202	2
120440203	3
120440204	4
120440205	5
120440206	6
120440207	7
120440208	8
120440209	9

SAPHIR IMPLANT CODES

UNCEMENTED SAPHIR TI-GROWTH-C® STANDARD 132° *

REF.	SIZE
120440050	0
120440051	1
120440052	2
120440053	3
120440054	4
120440055	5
120440056	6
120440057	7
120440058	8
120440059	9

UNCEMENTED SAPHIR TI-GROWTH-C® LATERALIZED 132° *

REF.	SIZE
120440061	1
120440062 120440063	2 3
120440064	4
120440065 120440066	5 6
120440067	7
120440068 120440069	8
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UNCEMENTED SAPHIR TI-GROWTH-C $^{\otimes}$ VARIZED 126 $^{\circ}$ *

REF.	SIZE
100440070	0
120440070	U
120440071	1
120440072	2
120440073	3
120440074	4
120440075	5
120440076	6
120440077	7
120440078	8
120440079	9

UNCEMENTED SAPHIR TI-GROWTH-C[®] ANTE R / RETRO L (AR/RL)*

REF.	SIZE
120///0081	1
120440001	2
120440083	3
120440084	4
120440085	5
120440086	6
120440087	7
120440088	8
120440089	9

UNCEMENTED SAPHIR TI-GROWTH-C[®] STANDARD 132° WITH COLLAR *

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REF.	SIZE
120440150	0
120440151	1
120440152	2
120440155	4
120440155	5
120440156	6
120440157	7
120440158	8
120440159	9

UNCEMENTED SAPHIR TI-GROWTH-C[®] LATERALIZED WITH COLLAR *

REF.	SIZE
120440161	1
120440162	2
120440163	3
120440164	4
120440165	5
120440166	6
120440167	7
120440168	8
120440169	9

UNCEMENTED SAPHIR TI-GROWTH-C® VARIZED 126° WITH COLLAR *

SIZE
0
1
2
3
4
5
6
7
8
9

UNCEMENTED SAPHIR TI-GROWTH-C® RETRO R / ANTE L (RR/AL)*

REF.	SIZE
120440091	1
120440092	2
120440093	3
120440094	4
120440095	5
120440096	6
120440097	7
120440098	8
120440099	9

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CrCo HEAD Cone 12/14

COILE 12/14			
REF.	DIAM.	NECK	R.I.C.
110207105E	22.2mm	S	-2mm
110207110E	22.2mm	М	0
110207115E	22.2mm	L	+2mm
110210105E	28mm	S	-3.5mm
110210110E	28mm	М	0mm
110210115E	28mm	L	+3.5mm
110210120E	28mm	XL	+7mm
110220105E	32mm	S	-4mm
110220110E	32mm	М	0mm
110220115E	32mm	L	+4mm
110220120E	32mm	XL	+7mm
110367705	36mm	S	-4mm
110367710	36mm	М	0mm
110367715	36mm	L	+4mm
110367720	36mm	XL	+8mm

CERAMIC HEAD Cone 12/14

REF.	DIAM.	NECK	R.I.C.
110240205	28mm	S	-3.5mm
110240210	28mm	М	0mm
110240215	28mm	L	+3.5mm
110240305	32mm	S	-4mm
110240310	32mm	М	0mm
110240315	32mm	L	+4mm
110240320	32mm	XL	+7mm
110240405	36mm	S	-4mm
110240410	36mm	М	0mm
110240415	36mm	L	+4mm
110240420	36mm	XL	+8mm

STAINLESS STEEL FEMORAL HEAD Cone 12/14

REF.	DIAM.	NECK	R.I.C.
110205105E	28mm	S	-3.5mm
110205110E	28mm	М	0mm
110205115E	28mm	L	+3.5mm
110205120E	28mm	XL	+7mm
110205205E*	32mm	S	-4mm
110205210E*	32mm	М	0mm
110205215E*	32mm	L	+4mm
110205220E*	32mm	XL	+7mm

Web Site



Use the QR-Code to visit Gruppo Bioimpianti website

IFU

Use the QR-Code to view complete product informations, including instructions for use, indications and contraindications, precautions and warnings



Erivan R, Villatte G, Dartus J, Mertl P, Piriou P, Tracol P, Vernizeau M, Mulliez A, Puch J, Girard J, Descamps S, Boisgard S et la Société française de chirurgie de la hanche et du genou (SFHG) *French Hip & Knee Society classification of short-stem hip prostheses: Inter- and intraobserver reproducibility* Orthop Traumatol Surg Res. 2022 Feb;108(1):103126. doi: 10.1016/j. otsr.2021.103126. Epub 2021 Oct 23.

This surgical technique is exclusively intended for medical professionals, especially physicians and surgeons.

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