



Enjoy Mobility

SAPHIR

OPERATING TECHNIQUE



SAPHIR LT

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 NECKlar, 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; Incurable 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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1 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.

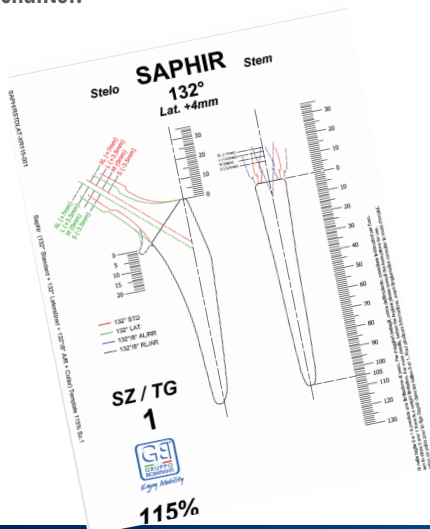
To predetermine the choice of the size and version that will best fit the patient's femur, a choice has to be made concerning filling the canal (femoral stem size), the CCD angle (132° or 126°) and the off-set (STD and Lateralized). There is also the option of an 8° anteverted and 8° retroverted version.

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

2 Femoral neck osteotomy

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

Perform the osteotomy making sure to maintain the correct angle so as not to damage the greater trochanter.



3 Femoral canal preparation

The bone of the greater trochanter area is freed using the special Osteotome (Ref. 120411192). (Fig.2)

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.

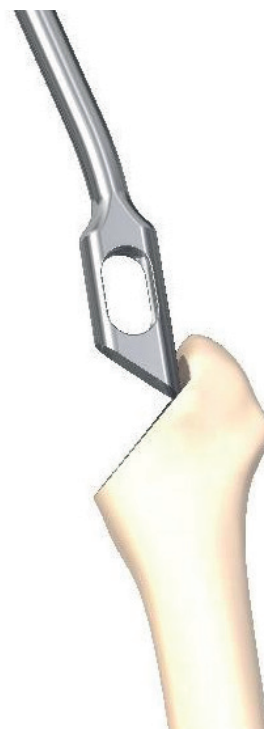
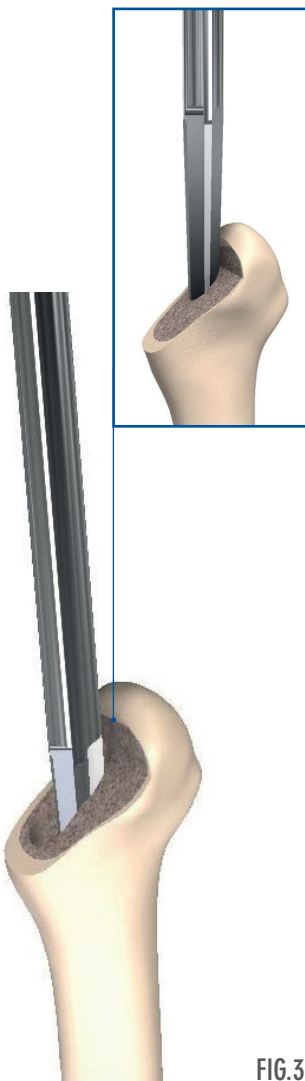


FIG.2

The femoral canal is released by manually introducing the Taper Reamer (Ref. 110381400). (FIG.3)



To avoid stress in the calcar area, a Canal finder (Ref. 120411115) rasp is supplied, which allows the passage of the rasps to be prepared and the housing of the final stem (FIG. 4).



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4 Brocciatura del canale femorale

Once the femur preparatory phase has been completed, the SAPHIR Rasps (Ref. 120411160 ÷ 120411169) mounted on the Rasp handle (Ref. 120411182) are inserted. (Fig.5)

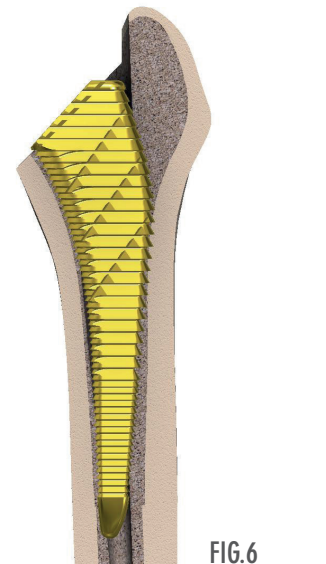
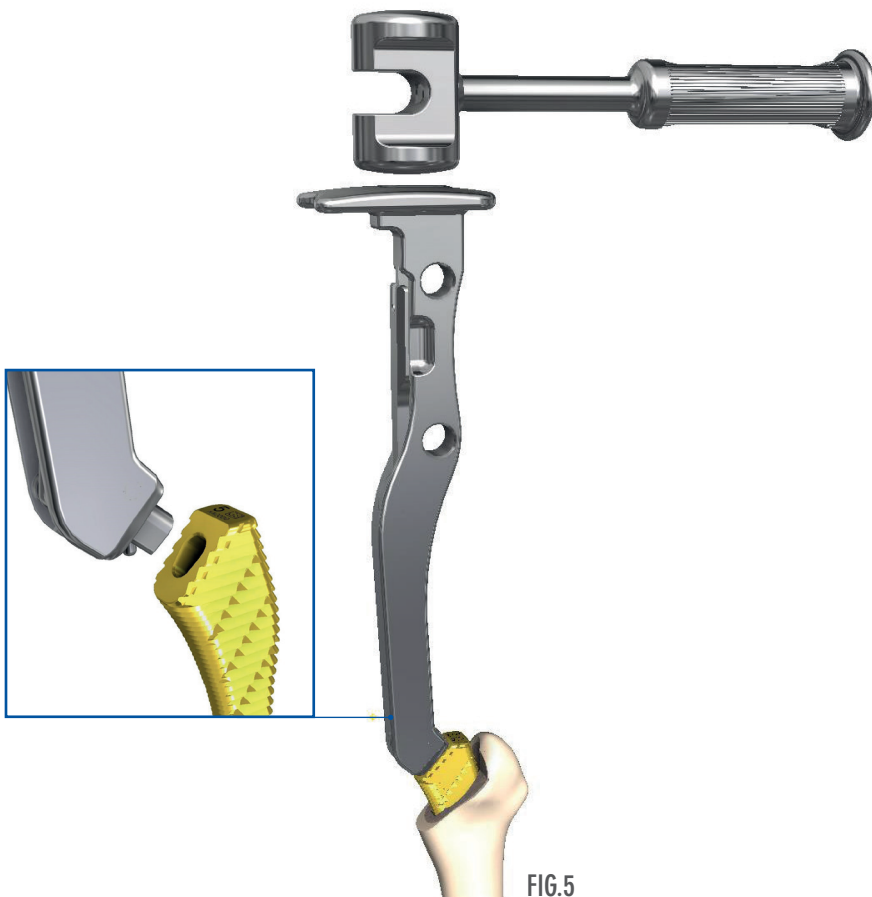
The femoral canal should be prepared by progressively introducing the rasps from size 0 until the planned size is reached and/or the desired fit is achieved.

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.6)

N.B. In the event of an emergency, an emergency rasp Extractor (Ref. 120411174) is available within the SAPHIR instrument set, to be mounted on extractor (Ref. 120411194).

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.



5 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, 120411151, 120411152, 120411153*, 120411154*, 120411155, 120411156, 120411157, 120411158*, 120411159*).

The trial necks, which are available in the SAPHIR instrument set, can be recognized by two NECKour codes. One NECKour, that of the body (FIG.7), indicates the rasp size:

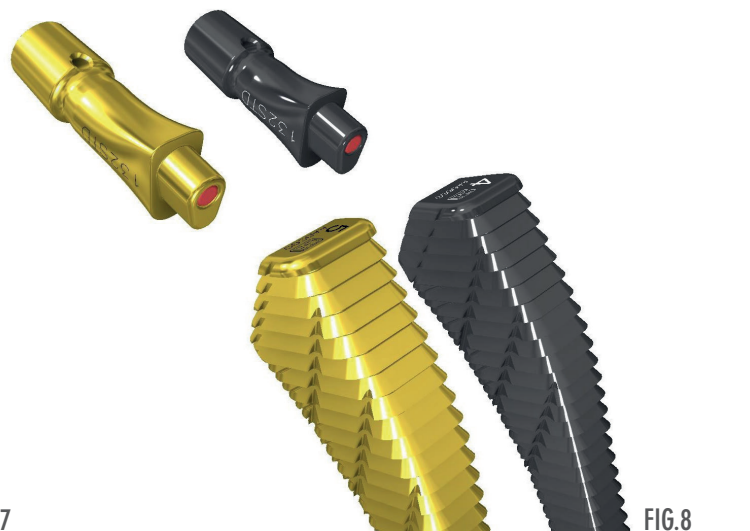
- from size 0 to 4: dark grey
- from size 5 to 9: gold

The NECKoured insert (FIG.8), 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*

NECKORED TRIAL NECK INSERT

Size	STD	LAT	VAR	Ante L	Retro L
	132°	132°	126°	Retro R	Ante R
0	●	●	●	●	●
1	●	●	●	●	●
2	●	●	●	●	●
3	●	●	●	●	●
4	●	●	●	●	●
5	●	●	●	●	●
6	●	●	●	●	●
7	●	●	●	●	●
8	●	●	●	●	●
9	●	●	●	●	●



*Upon request

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6 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. 9)

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

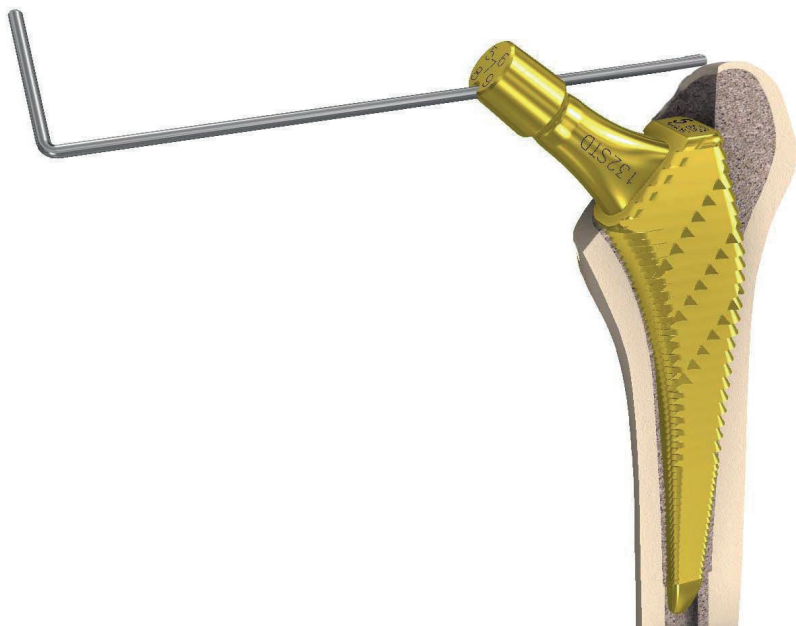


FIG.9

7 Trial reduction

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

Insert the Modular trial neck (Ref. Ref. 120411150, 120411151, 120411152, 120411153*, 120411154*, 120411155, 120411156, 120411157, 120411158*, 120411159*), according to the plan, on the rasp, taking care to respect the coupling NECKour 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.10) To facilitate the trial reduction, the Head pusher (Ref. 120411193), 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.

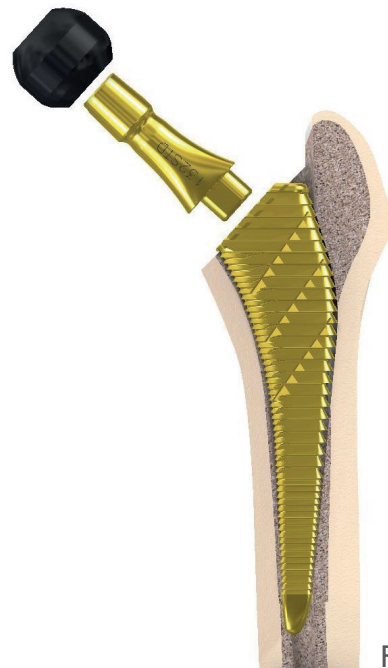


FIG.10

*Upon request

8 Stem insertion

The stem can then be inserted using the impactor (Ref. 120411189), which allows the rotation of the stem to be controlled during insertion. (FIG.11)
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.11

* SAPHIR stem is 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.

9 Positioning of the femoral head

Once the stem has been inserted, it is advisable to perform a further trial reduction and a further check, to select the final head. (FIG.12)
To ensure the proper tightness of the final head, use the appropriate Head Pusher (Ref. 120411193), fitted to the Universal handle.

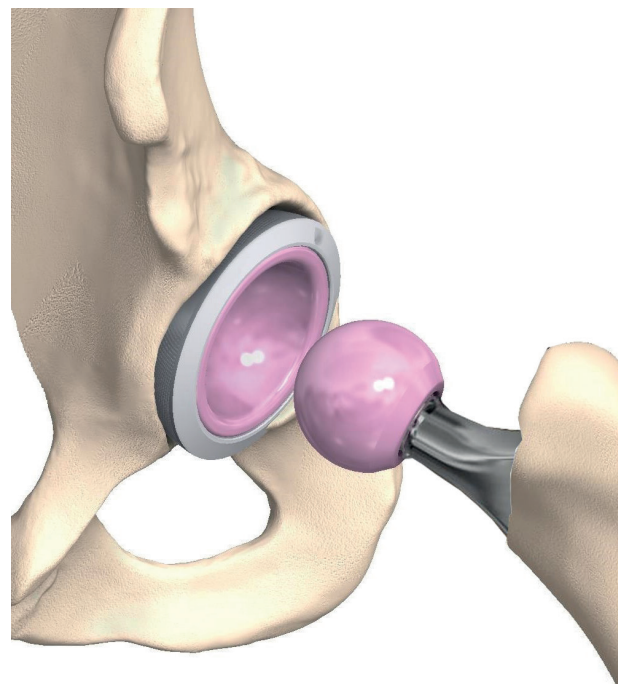


FIG.12

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10 Stem extraction

If it is necessary to extract the stem, use the dedicated Stem Extractor (Ref. 120411194), attaching it onto the universal handle. (FIG.13)

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 hammer.

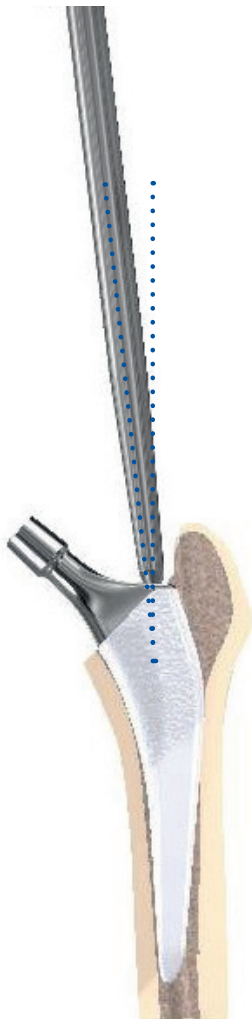
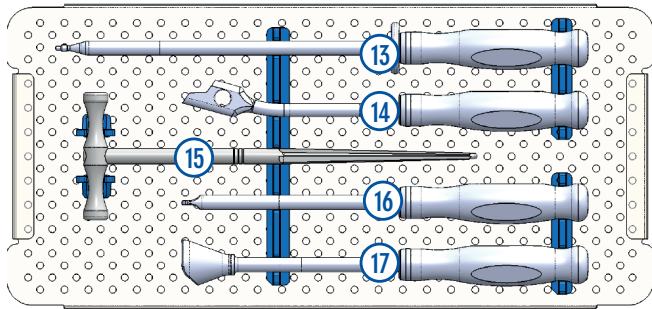
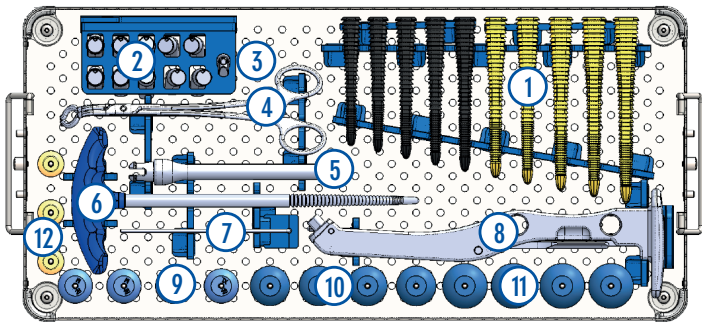


FIG.13

SAPHIR LT INSTRUMENT CODES



Tray and lid for instruments
SAPHIR LT
REF: 120411197, 120411198

①

DESCRIPTION	REF.	SIZE	QNT
Rasp SAPHIR stem	120411160	0	1
	120411161	1	1
	120411162	2	1
	120411163	3	1
	120411164	4	1
	120411165	5	1
	120411166	6	1
	120411167	7	1
	120411168	8	1
120411169	9	1	

②

DESCRIPTION	REF.	NECK	SIZE	QNT
Trial Neck	120411150	132STD	0-4	1
	120411151	132LAT	1-4	1
	120411152	126	0-4	1
	120411153*	132AS/RD*	1-4*	1*
	120411154*	132RS/AD*	1-4*	1*
	120411155	132STD	5-9	1
	120411156	132LAT	5-9	1
	120411157	126	5-9	1
	120411158*	132AS/RD*	5-9*	1*
	120411159*	132RS/AD*	5-9*	1*

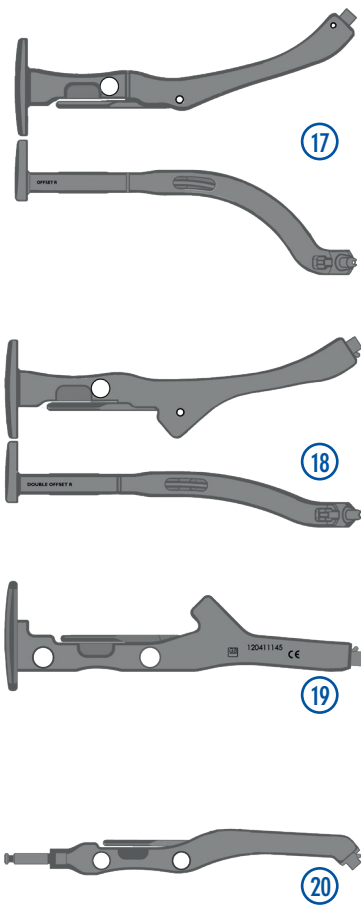
③	Rasp extractor	120411174	1
④	Neck extractor	120411118	1
⑤	T-Bar	120411143	1
⑥	Canal finder rasp	120411115	1
⑦	Trochanterometer	120411176	1
⑧	Rasp handle	120411182	1

DESCRIPTION	REF.	NECK	QNT
⑨ Trial Head (Diam. 28mm)	110380860	S	1
	110380870	M	1
	110380880	L	1
	110380890	XL	1
⑩ Trial Head (Diam. 32mm)	110380960	S	1
	110380970	M	1
	110380980	L	1
⑪ Trial Head (Diam. 36mm)	110380990	XL	1
	110381060	S	1
	110381070	M	1
	110381080	L	1
	110381090	XL	1

DESCRIPTION	REF.	NECK	QNT
⑫ Trial Head (Diam. 22.2mm)*	110381020*	S	1
	110381030*	M	1
	110381040*	L	1

DESCRIPTION	REF.	QNT
⑬ Stem Extractor	120411194	1
⑭ Osteotome	120411192	1
⑮ Taper reamer	110381400	1
⑯ Stem Impactor	120411189	1
⑰ Head pusher	120411189	1

OPTIONAL UPON REQUEST



	DESCRIPTION	REF.	R\L	QNT
17	Saphir Rasp handle offset	120411149*	L	1
		120411148*	R	1
18	Saphir Rasp handle double offset	120411147*	L	1
		120411146*	R	1
19	Rasp handle FF Straight 45°	120411145*	-	1
20	Rasp handle FF Woodpecker	120411171*	-	1

*Upon request

SAPHIR IMPLANT CODES

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

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

SAPHIR UNCEMENTED TI-GROWTH-C®+ HA STANDARD 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

SAPHIR UNCEMENTED TI-GROWTH-C®+ HA AR/RL 8° *

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

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

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

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

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

SAPHIR UNCEMENTED TI-GROWTH-C®+ HA AL/RR 8° *

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

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

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

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

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

*Upon request

SAPHIR IMPLANT CODES

SAPHIR UNCEMENTED 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

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

REF.	SIZE
120440150	0
120440151	1
120440152	2
120440153	3
120440154	4
120440155	5
120440156	6
120440157	7
120440158	8
120440159	9

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

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

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

REF.	SIZE
120440061	1
120440062	2
120440063	3
120440064	4
120440065	5
120440066	6
120440067	7
120440068	8
120440069	9

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

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

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

REF.	SIZE
120440170	0
120440171	1
120440172	2
120440173	3
120440174	4
120440175	5
120440176	6
120440177	7
120440178	8
120440179	9

SAPHIR UNCEMENTED TI-GROWTH-C® AR/RL 8° *

REF.	SIZE
120440081	1
120440082	2
120440083	3
120440084	4
120440085	5
120440086	6
120440087	7
120440088	8
120440089	9

SAPHIR UNCEMENTED TI-GROWTH-C® AL/RR 8° *

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

*Upon request

SAPHIR CEMENTED
STANDARD 132°

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

SAPHIR CEMENTED
AL/RR 8° *

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

SAPHIR CEMENTED
VARIZED 126°

REF.	SIZE
120440220	0
120440221	1
120440222	2
120440223	3
120440224	4
120440225	5
120440226	6
120440227	7
120440228	8
120440229	9

SAPHIR CEMENTED
LATERALIZED 132°

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

SAPHIR CEMENTED
AR/RL 8° *

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

FEMORAL HEAD STAINLESS STEEL
Cone 12/14

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

FEMORAL HEAD CrCo
Cone 12/14

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

FEMORAL HEAD BIOLOX DELTA
Cone 12/14

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

FEMORAL HEAD CERAMIC ZTA
Cone 12/14

REF.	DIAM.	NECK	R.I.C.
110240605	28mm	S	-3.5mm
110240610	28mm	M	0mm
110240615	28mm	L	+3.5mm
110240625	32mm	S	-4mm
110240630	32mm	M	0mm
110240635	32mm	L	+4mm
110240640	32mm	XL	+7mm
110240655	36mm	S	-4mm
110240660	36mm	M	0mm
110240665	36mm	L	+4mm
110240670	36mm	XL	+8mm

*Upon request

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, TraNECK 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.

This document does not constitute medical advice, it does not dispense medical recommendations and it does not convey any diagnostic or therapeutic information.

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