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ORTHOPAEDICS



PRIME FLEX

FIXED BEARING
Knee Prosthesis

**PRODUCT
INFORMATION**



0426

FEMORAL COMPONENT



10 Femoral sizes

The femoral component is common for both the mobile and fix bearing options of the **GKS PRIME FLEX** range and it's design was studied to optimize prosthesis performance during flexion: the posterior condyle thickness and curvature range allows ample contact area even at elevated flexion.

Manufactured in Cobalt-Chrome alloy, available in both cemented and cementless version and also with the **BIOLOY®** ultrahard finishing surface.

HaX-Pore HaX-hole

The double **HaX-Pore®** bio-active coating on the bone contact surface of the cementless components promotes osseointegration favouring biological fixation.

JOINT LINER



2 Versions 9 Thicknesses

Manufactured with Ultra high molecular weight polyethylene is also available in **VITAL-E®** version.

The **CR** option is designed to ensure optimal behaviour when the PCL functions are preserved.

The **AS** (Anterior Stabilized) option is anatomically shaped with a high medial anterior lip that avoids posterior slipping of the tibia when the PCL functions are compromised.

Colour coding for correct coupling between Tibial component and Insert.

TIBIA TOP



10 Tibial sizes

The **TOP** Tibial component is manufactured in Titanium alloy, available in cemented and cementless **HaX-Pore®** coated option. It is characterized by a symmetric baseplate providing a conical central core with flanged keel for metaphyseal anchorage which opposes the anterior-posterior tilting movement and torque forces. The distal end can be equipped with a conical Extension Stem.

It is available in 10 sizes divided in 5 couples, each one accepting one size of joint liner and compatible with the GKS PRIME FLEX PS System.

GKS PRIME FLEX - Femoral Component



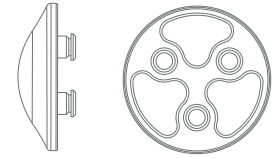
CrCo



BIOLOY®

SIZE	Side	CrCo	CrCo	BIOLOY®	BIOLOY®
		Cemented	HaX-Pore®	Cemented	HaX-Pore®
		Reference	Reference	Reference	Reference
4	RIGHT	54002*	54291*	54078*	54295*
	LEFT	54003*	54292*	54079*	54296*
5	RIGHT	54013	54033	54083	54211
	LEFT	54014	54034	54084	54212
6	RIGHT	54025	54035	54085	54213
	LEFT	54026	54036	54086	54214
7	RIGHT	54017	54037	54087	54215
	LEFT	54018	54038	54088	54216
8	RIGHT	54027	54039	54089	54217
	LEFT	54028	54040	54090	54218
9	RIGHT	54021	54041	54091	54219
	LEFT	54022	54042	54092	54220
10	RIGHT	54006	54045	54095	54221
	LEFT	54007	54046	54096	54222
11	RIGHT	54023	54043	54093	54223
	LEFT	54024	54044	54094	54224
12	RIGHT	54008	54047	54097	54225
	LEFT	54009	54048	54098	54226
13	RIGHT	54004*	54293*	54099*	54297*
	LEFT	54005*	54294*	54100*	54298*

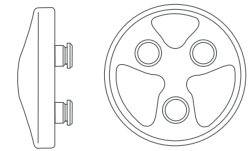
GKS - Patella WING



UHMWPE VITAL-E®

SIZE	Reference	Reference
28mm	53128	53128E
30mm	53130	53130E
32mm	53132	53132E
34mm	53134	53134E
36mm	53136	53136E
38mm	53138	53138E

GKS PRIME FLEX - Patella



UHMWPE

SIZE	Reference
28mm	53028
30mm	53030
32mm	53032
34mm	53034
36mm	53036
38mm	53038

GKS PRIME FLEX - Tibia TOP

Nickel Free

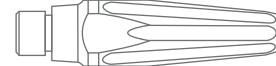


	Cemented	HaX-Pore®
SIZE	Reference	Reference
X S	54471	54491
A	54472	54492
B	54473	54493
C	54474	54494
D	54475	54495
E	54476	54496
F	54477	54497
G	54478	54498
H	54479	54499
I	54480	54500

The correct coupling between Tibial Component and Joint Liner is guided by the colour code reported on the packaging labels.

GKS PRIME FLEX - Tibial Extensions

Nickel Free



Taglia	Reference
40x8mm	54201
40x10mm	54202

Information

INTENDED PURPOSE: GKS PRIME FLEX is a three-compartmental knee prosthesis to be used in Total Knee Replacement procedures. Indicated for primary Total Knee Arthroplasties in cases of advanced osteo-cartilagineous degeneration of the knee joint mainly due to arthrosis, rheumatoid arthritis, post-traumatic factors, and outcomes of corrective osteotomies. Anchorage of the device to the bone may be cementless or cemented, depending upon the selected version.

MATERIALS:

FEMORAL COMPONENT: Cobalt Chromium Molybdenum alloy - ISO5832/4;

TIBIA: Titanium Aluminium Vanadium alloy - ISO5832/3;

ARTICULAR LINER / PATELLA: UHMW PolyEthylene without Calcium Stearate - ISO5834/1/2; Also available in **VITAL-E®** option, added with Vitamin E.

SURFACE FINISHING:

Articular surfaces: achieved through the **MICROLOY®** technological process. **BIOLOY®** version has integral TiNbN coating. Roughness is in compliance with ISO 7207-2 Standards.

Bone-Implant surface:

- **Cemented version:** pelleted surface with depressions for even acrylic cement spreading;
- **Cementless version:** **HaX-Pore®** double coating (300µm Titanium + 60µm Hydroxyapatite $Ca_{10}(OH)_2(PO_4)_6$)

STERILIZATION:

Method: Ethylene Oxyde (EtO) or irradiation (Beta/Gamma rays - minimum dose 25 kGy) or Vaporized Hydrogen Peroxide (VH2O2).

Validity: 5 years (Beta sterilized products) - 10 years (EtO/Gamma/VH2O2 sterilized products).

CLASSIFICATION:

Class III as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendments.

GKS PRIME FLEX - Joint Liners

GKS PRIME FLEX - CR Liners



SIZE	Thickness	UHMWPE	VITAL-E®
		Reference	Reference
XS-A	9mm	54406	54406E
	10mm	54401	54401E
	11mm	54407	54407E
	12mm	54402	54402E
	13mm	54408*	54408E*
	14mm	54403	54403E
	15mm	54409*	54409E*
	17mm	54404	54404E
20mm	54405*	54405E*	
B-C	9mm	54416	54416E
	10mm	54411	54411E
	11mm	54417	54417E
	12mm	54412	54412E
	13mm	54418*	54418E*
	14mm	54413	54413E
	15mm	54419*	54419E*
	17mm	54414	54414E
20mm	54415*	54415E*	
D-E	9mm	54426	54426E
	10mm	54421	54421E
	11mm	54427	54427E
	12mm	54422	54422E
	13mm	54428*	54428E*
	14mm	54423	54423E
	15mm	54429*	54429E*
	17mm	54424	54424E
20mm	54425*	54425E*	
F-G	9mm	54436	54436E
	10mm	54431	54431E
	11mm	54437	54437E
	12mm	54432	54432E
	13mm	54438*	54438E*
	14mm	54433	54433E
	15mm	54439	54439E*
	17mm	54434	54434E
20mm	54435*	54435E*	
H-I	9mm	54446	54446E
	10mm	54441	54441E
	11mm	54447	54447E
	12mm	54442	54442E
	13mm	54448*	54448E*
	14mm	54443	54443E
	15mm	54449*	54449E*
	17mm	54444	54444E
20mm	54445*	54445E*	

GKS PRIME FLEX - Anterior-Stabilized Liners

For the matching between AS Articular Insert and Femoral Component refer to the table below.



SIZE	Compatible FEMUR	RIGHT		LEFT		
		UHMWPE	VITAL-E®	UHMWPE	VITAL-E®	
SIZE	Thickness	Reference	Reference	Reference	Reference	
XS-A	4-5-6	9mm	55121	55121E	55122	55122E
		10mm	55021	55021E	55022	55022E
		11mm	55123	55123E	55124	55124E
		12mm	55023	55023E	55024	55024E
		13mm	55125*	55125E*	55126*	55126E*
		14mm	55025	55025E	55026	55026E
		15mm	55127*	55127E*	55128*	55128E*
		17mm	55027	55027E	55028	55028E
		20mm	55029*	55029E*	55030*	55030E*
		B-C	5-6-7-8	9mm	55129	55129E
10mm	55035			55035E	55036	55036E
11mm	55131			55131E	55132	55132E
12mm	55037			55037E	55038	55038E
13mm	55133*			55133E*	55134*	55134E*
14mm	55039			55039E	55040	55040E
15mm	55135*			55135E*	55136*	55136E*
17mm	55041			55041E	55042	55042E
20mm	55043*			55043E*	55044*	55044E*
D-E	7-8-9 10-11			9mm	55137	55137E
		10mm	55049	55049E	55050	55050E
		11mm	55139	55139E	55140	55140E
		12mm	55051	55051E	55052	55052E
		13mm	55141*	55141E*	55142*	55142E*
		14mm	55053	55053E	55054	55054E
		15mm	55143*	55143E*	55144*	55144E*
		17mm	55055	55055E	55056	55056E
		20mm	55057*	55057E*	55058*	55058E*
		F-G	9-10 11-12	9mm	55145	55145E
10mm	55063			55063E	55064	55064E
11mm	55147			55147E	55148	55148E
12mm	55065			55065E	55066	55066E
13mm	55149*			55149E*	55150*	55150E*
14mm	55067			55067E	55068	55068E
15mm	55151*			55151E*	55152*	55152E*
17mm	55069			55069E	55070	55070E
20mm	55071*			55071E*	55072*	55072E*
H-I	9-10 11-12-13			9mm	55153	55153E
		10mm	55077	55077E	55078	55078E
		11mm	55155	55155E	55156	55156E
		12mm	55079	55079E	55080	55080E
		13mm	55157*	55157E*	55158*	55158E*
		14mm	55081	55081E	55082	55082E
		15mm	55159*	55159E*	55160*	55160E*
		17mm	55083	55083E	55084	55084E
		20mm	55085*	55085E*	55086*	55086E*

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