

GKS PRIME FLEX RK - Revision Cones

MANUFACTURING - DISTRIBUTION:

permedica S.p.a.
via Como, 38/39 - IT23807 Merate (Lc) - ITALY

REGISTERED TRADEMARKS:



QUALITY CERTIFICATIONIS:



INTENDED PURPOSE

The GKS PRIME FLEX RK Femoral and Tibial revision cones are devices to be used in knee prosthesis revision surgeries in the presence of serious bone defects in order to provide adequate reinforcement / support to the bone structure thus allowing the positioning, within them, of cemented prosthetic components.

Anchorage of the device to the bone is achieved by means of press-fit cementless fixation.

TECHNICAL INFORMATION

DESIGN:

FEMORAL CONES: to be used to fill any bone defects located at the femoral metaphysis; available in 4 sizes (XS, Small, Medium e Large).

TIBIAL CONES: to be used to fill any bone defects located at the tibial metaphysis; available in cylindrical version (2 diameters), conical (3 sizes: Small, Medium and Large) and "Stepped" with asimmetrical cone (2 sizes: Medium and Large). The cylindrical version can also be used in the femoral metaphysis in combination with a femoral cone as a proximal extension.

MATERIALS

Titanium alloy Ti6Al4V - ISO5832/3; ASTM F 2924.

The device DOES NOT CONTAIN any ferromagnetic materials.

SURFACE FINISHING - COATINGS:

TRASER® high roughness random trabecular surface with rough and irregular pores shape, achieved through SLM (Selective Laser Melting) technology; average pores size 500µm, average porosity percentage 70%.

STERILIZATION:

Method: products are sterilized by Irradiation (*R - nominal dose 25 kGy*) or vaporized Hydrogen Peroxide (*VH2O2*).

Validity: 10 years.

PACKAGING:

Outer: rigid carton box, with polypropylene protection film;

Inner: double plastic bi-laminated envelopes polyamide / PE, vacuum-packed (*R* sterilized products); double Tyvek envelopes and bi-laminated BOPET / PE (*VH2O2* sterilized products).

Identification labels reporting all necessary information regarding the product can be found both on the outer or inner package; extra detachable labels for application to the clinical chart and patient Implant Card are enclosed.

CLASSIFICATION:

Class IIb 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.

PRODUCT TECHNICAL INFORMATION SHEET

FURTHER INFORMATION

The GKS PRIME FLEX RK femoral and tibial cones are devices that have the function of filling bone defects at the metaphyseal level of the tibia and femur in order to create the necessary support for the stabilization of a prosthetic component (tibial plate or femoral component) which is fixed inside it with the aid of bone cement, regardless of the orientation of the cone. Therefore, their use can also be extended to the femoral and tibial prosthetic components of other systems, not necessarily produced by Permedica, as long as their dimensional compatibility is verified pre-operatively. The surgeon is required to verify the coupling of the tibial / femoral cone with the relative prosthetic component according to the general indications provided by the surgical technique.

The GKS PRIME FLEX RK are available in different types and sizes for the femoral and tibial compartment.

The instruments include dedicated broaches for each type and size of implant capable of ensuring adequate housing through press-fit insertion, even in the case of using two superimposed cones; sterilizable trial implants allow to verify the suitability of the prepared site.

AVAILABLE SIZES *References with asterisk are available on request

GKS PRIME FLEX RK - TIBIAL CONES

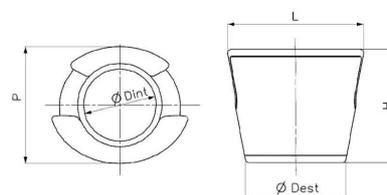
Nickel Free



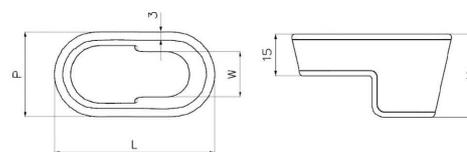
SIZE	conical reference	L	P	H	Ø Est	Ø Int
SMALL	48802	27mm	27mm	30,0mm	21mm	17mm
MEDIUM	48803	37mm	31mm	32,5mm	25mm	20mm
LARGE	48804	47mm	35mm	35,0mm	30mm	23mm



SIZE	cylindrical reference	L	P	H	Ø Est	Ø Int
25mm	48805	25mm	25mm	30mm	25mm	20mm
29mm	48806	29mm	29mm	30mm	29mm	23mm



SIZE	stepped reference	L	P	H	W
MEDIUM	48851	58mm	31mm	30mm	16,5mm
LARGE	48852	69mm	35,5mm	30mm	20,5mm

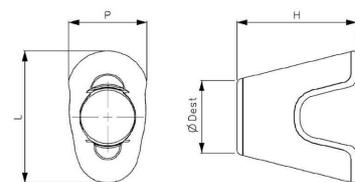


GKS PRIME FLEX RK - FEMORAL CONES

Nickel Free



SIZE	conical reference	L	P	H	Ø Est	Ø Int
XS	48900	31mm	18mm	33mm	21mm	17mm
SMALL	48901	36mm	22mm	35mm	23mm	18mm
MEDIUM	48902	40mm	26mm	35mm	25mm	18mm
LARGE	48903	48mm	29mm	45mm	27x24mm	18mm



ANALYTICAL PRODUCTS LIST

REF	description	class	EMDN Code
48802	GKS PRIME FLEX RK: TIBIAL CONE Nickel Free - CONICAL SMALL	IIb	P09098002
48803	GKS PRIME FLEX RK: TIBIAL CONE Nickel Free - CONICAL MEDIUM	IIb	P09098002
48804	GKS PRIME FLEX RK: TIBIAL CONE Nickel Free - CONICAL LARGE	IIb	P09098002
48805	GKS PRIME FLEX RK: TIBIAL CONE Nickel Free - CYLINDRICAL Ø 25mm	IIb	P09098002
48806	GKS PRIME FLEX RK: TIBIAL CONE Nickel Free - CYLINDRICAL Ø 29mm	IIb	P09098002
48851	GKS PRIME FLEX RK: TIBIAL CONE Nickel Free - STEPPED MEDIUM	IIb	P09098002
48852	GKS PRIME FLEX RK: TIBIAL CONE Nickel Free - STEPPED LARGE	IIb	P09098002
48900	GKS PRIME FLEX RK: FEMORAL CONE Nickel Free - XS	IIb	P09098002
48901	GKS PRIME FLEX RK: FEMORAL CONE Nickel Free - SMALL	IIb	P09098002
48902	GKS PRIME FLEX RK: FEMORAL CONE Nickel Free - MEDIUM	IIb	P09098002
48903	GKS PRIME FLEX RK: FEMORAL CONE Nickel Free - LARGE	IIb	P09098002

RELATED DOCUMENTS

Product Information Sheet: **SI029EN**

Surgical Technique: **TC095EN**

Instruments Technical Information Sheet: **SSP061EN**