

SPACER Line



TECRES

ADVANCING HIGH TECHNOLOGY

“Knowing
that our products
every day improve
the lives of many people.
This is our ambition.
This is our reward.”

Giovanni Faccioli, President.

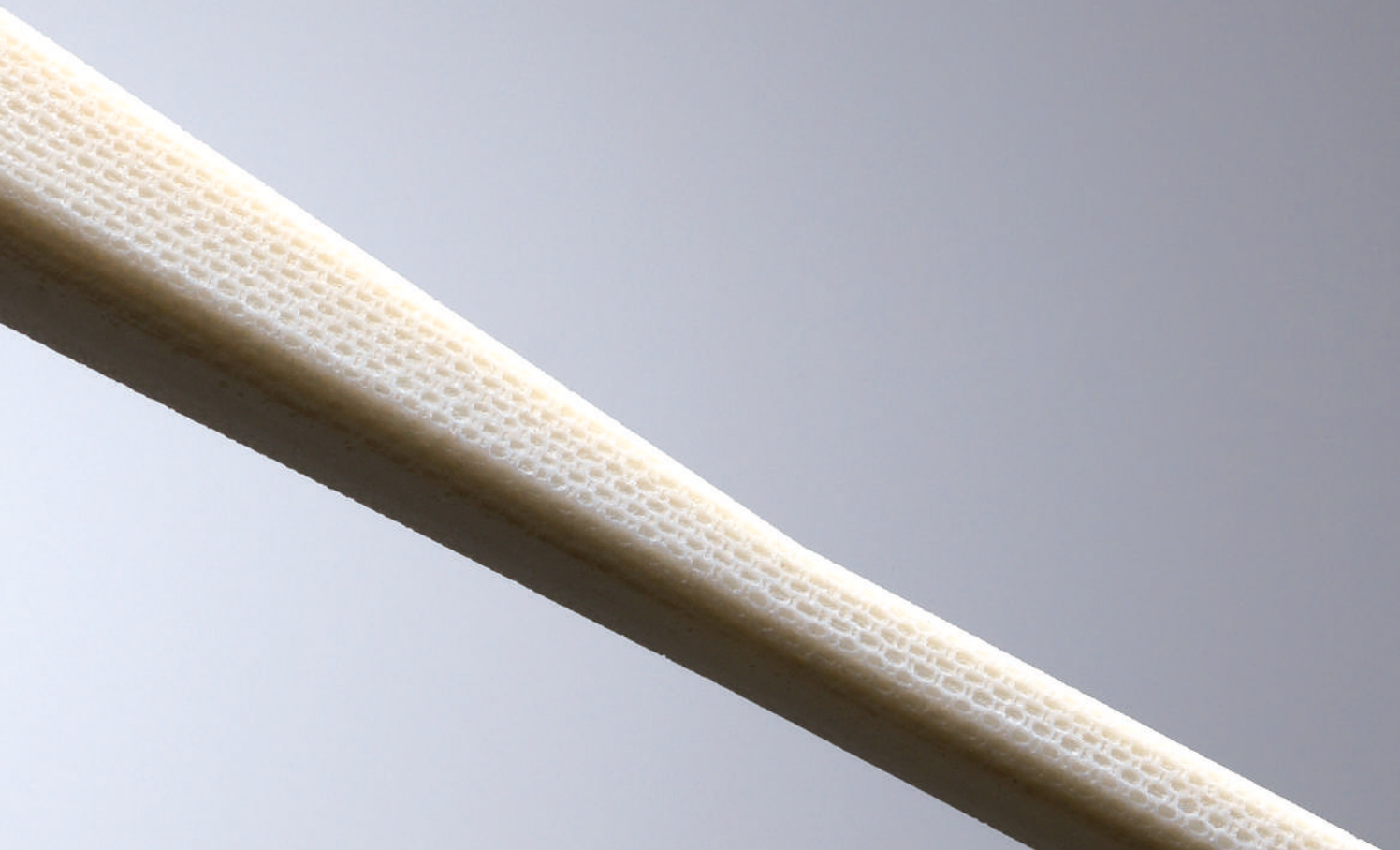


TECRES

Cutting-edge technologies and constant research to improve the lives of many people. This is the vision of Tecres since 1981, operating in synergy with surgeons, Universities and Research Institutes in order to invent, realize and provide the market with safe, effective and innovative products. We are specialized in acrylic resins since 1986 with medical applications in fields such as orthopaedics, spinal surgery and neurosurgery. Our excellence and reliability are recognized in more than 70 Countries around the world.



Spacer® Line:
The Exclusive Preformed
Antibiotic Loaded Spacer



PERIPROSTHETIC JOINT INFECTION

Periprosthetic joint infection (PJI) remains one of the most challenging complications in total joint arthroplasty (TJA). Overall, the reported incidence of PJI ranges between 0.5% and 3%¹.

Two-stage revision

Two-stage revision surgery consists of the removal of the infected prosthetic implant, thorough surgical debridement and implantation of a temporary antibiotic spacer followed by several weeks of systemic antibiotic therapy; eventually, after the eradication of the infection, the spacer is removed and replaced by a new prosthesis. This option is the most widespread and has been shown to have a great efficacy in eradicating chronic periprosthetic infections.

Tecres Preformed Spacers

Tecres in 1996 introduced the first preformed Gentamicin bone cement spacer device for the hip (Spacer®-G). In the following years, the family of spacers was implemented with knee (Spacer®-K) and shoulder (Spacer®-S) devices. Eventually, in 2010 Tecres introduced the dual antibiotic spacer line with the antibiotic combination Gentamicin/Vancomycin for the hip (Vancogenx-Space® Hip) and for the knee (Vancogenx-Space® Knee).

The use of a preformed commercial spacer, with standardized mechanical and pharmacological properties is an option which provides mechanical, biological and pharmacological safety and performance. Such devices maintain the correct joint space, allow a good range of joint mobility, promote early rehabilitation by providing a means to avoid muscular retraction, allow the patient greater function during the treatment period, allow partial weight-bearing with crutches when the residual bone stock is adequate², provide high and inhibitory local concentration of antibiotic in the site of infection at implantation³ which is maintained over time⁴.

Tecres spacers represent today the most studied and published spacer devices with over 100 publications in peer-reviewed journals.



CLINICAL ADVANTAGES OF A PREFORMED SPACER

SAFETY

FEATURES
IN COMPARISON
WITH
HAND-MADE
SPACERS

- Negligible risk of device breakage (mechanical strength)^{5,6}
- Negligible risk of systemic toxicity (controlled and known antibiotic release)^{3,4}
- Negligible risk of bone defect increase (device ergonomics, joint surface smoothness and hardness)^{7,8,9,10}
- Shorter operatory times (reduced anaesthesiological risk)^{9,11}
- Reduced hospital stay^{2,12}

PERFORMANCE

- Joint spacing and mobility^{8,9,6,13}
- Partial weight-bearing with crutches^{2,14}
- Easier second stage revision surgery¹¹
- Reduction of functional recovery times after revision prosthesis implantation^{13,14,15}
- Help to oppose the present infection with the controlled and effective release of antibiotic directly in the infection site all over the implantation period^{3,4}

QUALITY OF LIFE

- Possibility of physical therapy (muscle tonicity, no joint stiffness)^{8,13,16,17}
- Self-independence (psychological benefit)^{8,14}
- Basic movements for daily routine without the need of help⁸
- Earlier hospital dismissal is generally allowed^{12,18,19}

ANTIBIOTIC FEATURES

- Broad spectrum of activity against Gram p.ve and Gram n.ve bacteria²⁰
- Bacterial adhesion prevention²¹
- High local antibiotic concentration in the joint all over the implantation period^{3,4,22}
- Low serum level^{3,4}
- Standardized and known local antibiotic release³
- Synergistic antimicrobial effect (Vancogenx®-Space)³



CLINICAL RESULTS OF TECRES SPACERS

The relevant clinical information extracted from 34 peer-reviewed papers (28 different hospitals, more than 1,400 unique patients) is given in the table below. Infection eradication rate at a mean follow-up of 56 months exceeds 91%.

	Author	Year	Type	Antibiotic	Journal	Pts	Reimplanted	"Infection free at FU"	Mean FU (M)	City
1	Bertazzoni E	2004	Hip	G	Acta Orthop Scand	20	17	17/17	49	Verona (ITA)
2	Pitto RP	2005	Knee	G	Int Orthop	21	19	19/19	24	Auckland (NZ), Bergamo (ITA)
3	Coffey MJ	2010	Shoulder	G	J Shoulder Elbow Surg	16	12	12/12	18	Dayton, OH (USA)
4	Gil Gonzalez S	2010	Hip	G	Hip Int	35	35	30/35	32	Barcelona #1 (SPA)
5	Pignatti G	2010	Hip	G	Open Orthop J	36	36	36/36	64	Bologna (ITA)
6	Pattyn C	2010	Hip	G	Int Orthop	61	61	59/61	34	Ghent (BEL)
7	D'Angelo F	2011	Hip	G	Musculoskelet Surg	28	27	27/27	53	Varese (ITA)
8	Romanò CL	2011	Hip	G	BMC Infect Dis	20	20	19/20	57	Milan #1,2 (ITA)
9	Degen RM	2012	Hip	G	Clin Orthop Relat Res.	33	32	31/32	43	London, ON (CAN)
10	Neumann DR	2012	Hip	G	J Arthroplasty	42	42	41/42	67	Salzburg (AUT)
11	Romanò CL	2012	Hip	G	Hip Int	183	183	173/183	60	Milan #1,2 (ITA)
12	Wan Z	2012	Knee	G	J Arthroplasty	33	31	28/31	44	Houston, TX (USA)
13	Castelli CC	2014	Knee	G+GV	Int Orthop	50	50	46/50	84	Bergamo (ITA)
14	Corona P	2014	Hip + Knee	G+GV	Clin Orthop Relat Res.	41	37	34/37	35	Barcelona #3 (SPA)
15	Vasso M	2016	Knee	G	Knee Surg Sports T A	29	29	24/29	120	Roma (ITA)
16	Buchalter DB	2017	Shoulder	G	J Shoulder Elbow Surg	18	18	14/18	60	New York, NY (USA)
17	Markzak D	2017	Hip	GV	Int Orthop	47	47	41/47	52	Lodz (POL)
18	Nodzo SR	2017	Knee	G	Knee	58	58	48/58	75	New York, NY (USA)
19	Vecchini E	2017	Knee	G	J Knee Surg	16	16	16/16	74	Verona (ITA)
20	Corona P	2018	Hip + Knee	GV	Eur J Orthop Surg Traumatol	23	23	19/23	48	Barcelona #3 (SPA)
21	Akhtar A	2019	Knee	G	Indian J Orthop	27	27	24/27	43	London (UK)
22	Garcia-Oltra E	2019	Hip	G	Acta Orthop Belg	67	52	48/52	57	Barcelona #2 (SPA)
23	Pellegrini A	2019	Shoulder	G	Orthop Traumatol Surg Res.	23	11	11/11	96	Milan #1,2 (ITA)
24	Patrick M	2019	Shoulder	G	J Shoulder Elbow Surg	47	27	25/27	> 12M	Gainesville, FL (USA)
25	Bialecki J	2020	Hip	G	Orthopaedic Reviews	71	71	66/71	70	Otwock (POL)
26	Burastero G	2020	Hip	GV	PLOS 1	148	148	133/148	56	Pietra Ligure (ITA)
27	Corrò S	2020	Hip + Knee	GV	J Arthroplasty	108	108	98/108*	46	Barcelona #3 (SPA)
28	Cronin KJ	2020	Shoulder	G	J Shoulder Elbow Surg	12	0		67	Lexington, KY (USA)
29	Golgeloglu F	2020	Knee	GV	Indian J Orthop	56	56	46/56	48	Tunceli (TUR)
30	Rollo G	2020	Hip	GV	J Clinical Orthop Trauma	26	26	26/26	26	Lecce (ITA)
31	Veltman ES	2020	Hip	G	Work J Orthop	55	55	43/55	51	Amsterdam (NL)
32	Woon CYL	2020	Knee	G	Knee Surg Sports T A	28	28	25/28	> 24M	New York, NY (USA)
33	Meshram P	2021	Shoulder	G	Sem Arthrop	17	17	14/17	62	Baltimore, MD (USA)
34	Russo A	2021	Hip + Knee	GV	Int Orthop	47	47	43/47	86	Pietra Ligure (ITA)

Note: in 48 patients the shoulder spacer was kept as definitive. Infection eradication in 42/48 (87.5%)

1.542

1.466

91,1%

56,6 M

28 CENTERS

RANGE OF PRODUCTS

HIP SPACER

The device includes a load-bearing structure in stainless steel. It is available in two design variants, with a standard tapered stem or with a rectangular flat stem

Sizes: each design variant is available in 3 head sizes and 2 stem length options

Antibiotic: Gentamicin or Gentamicin/Vancomycin



Spacer-G: with Gentamicin, round stem

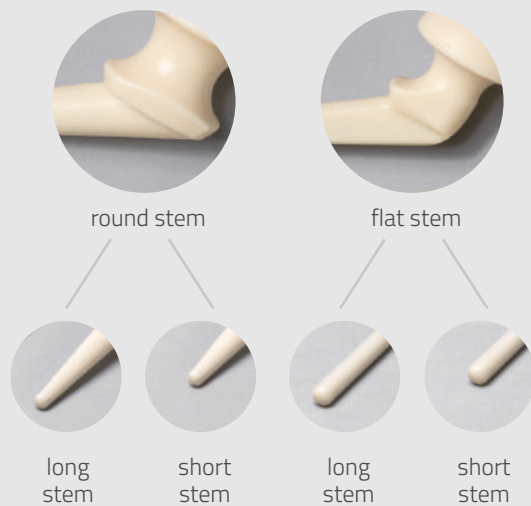
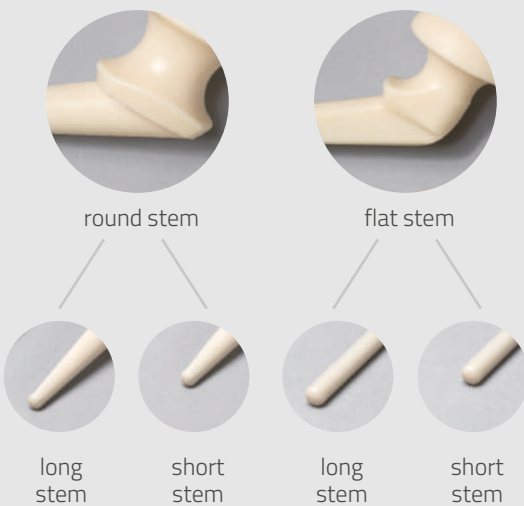
Spacer-G Flat Stem: with Gentamicin, flat stem

Vancogenx-Space Hip: with Gentamicin+Vancomycin, round stem

Vancogenx-Space Hip Flat stem: with Gentamicin+Vancomycin, flat stem

Spacer-G: with Gentamicin

Vancogenx-Space Hip: with Gentamicin+Vancomycin



SHOULDER SPACER

The device includes a load-bearing structure in stainless steel.

Sizes: the design is available in 2 head sizes

Antibiotic: Gentamicin

Spacer-S: with Gentamicin, 2 different head sizes



KNEE SPACER

The device is made with antibiotic loaded bone cement. It is made of two independent articulating components.

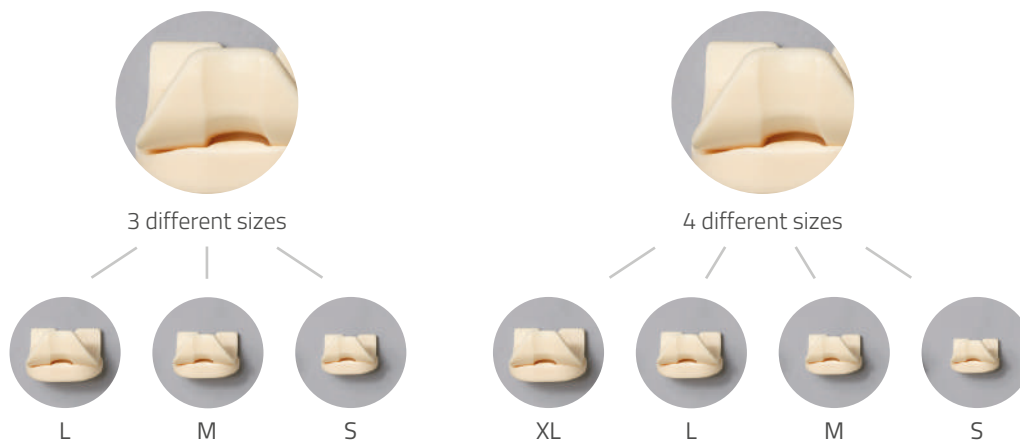
Sizes: the device is available in 3 (gentamicin) or 4 (gentamicin/vancomycin) sizes

Antibiotic: Gentamicin or Gentamicin/Vancomycin



Spacer-K: with Gentamicin, 3 different sizes

Vancogenx-Space Knee: with Gentamicin+Vancomycin, 4 different sizes



Surgical Technique:
scan the QR code and watch the video tutorial
Surgical Technique is available on Tecres website

ATS SPACER

The device is made with antibiotic loaded bone cement. It is intended to be used always together with Tecres Knee Spacer, in case of patient with a severe tibial bone defect.

Sizes: The device is available in 4 variants. 2 thickness options and 2 width options guarantee a perfect fit every time

Antibiotic: Gentamicin or Gentamicin+Vancomycin

Spacer®-K ATS: with Gentamicin

Vancogenx-Space® Knee ATS: with Gentamicin+Vancomycin



VANCOGENX-SPACE®

Periprosthetic infections (PJI) due to MRSA (methicillin-resistant *Staphylococcus aureus*), MRSE (methicillin-resistant *Staphylococcus epidermidis*), and other resistant pathogens represent a serious and widespread problem.

For this reason Tecres developed the Vancogenx® line.

Vancogenx®-Space: hip and knee spacer devices that combine the mechanical and functional characteristics of Tecres spacers with the pharmacological effectiveness of the Vancomycin-Gentamicin combination.

Vancogenx®-Space spacer devices were developed from Vancogenx® bone cement technology.

VANCOGENX®-SPACE: SYNERGY

When combined, Gentamicin and Vancomycin have a synergistic action against bacteria.^{8,23,24}

Their range of action covers approximately 90% of the pathogenic agents generally isolated in surgical infections.^{24,25}

The Gentamicin and Vancomycin combination is the most commonly used and published in literature on bone cement spacers for the treatments of orthopaedic infections.

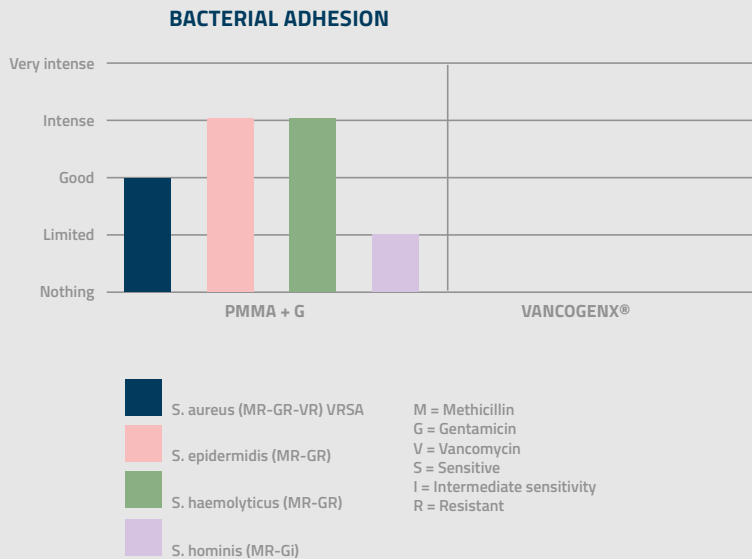
	GRAM+				GRAM-		
	MRS (Methicillin resistant staphylococci)	MSS (Methicillin susceptible Staphylococci)	Enterococci	Streptococci	Cutibacteria	Enterobacteriaceae	Pseudomonas spp.
Gentamicin	Medium	Low	Medium		-	Medium	
Vancomycin	High				Medium	-	-
Gentamicin and Vancomycin	SYNERGISTIC			HIGH	MEDIUM		

VANCOGENX®-SPACE: EFFECTIVENESS

Vancogenx® bone cement has been shown to be able to prevent bacterial adhesion²⁴ (in vitro tests) and as a coadjuvant in treatment of the infection (in vivo animal tests).²⁶

Bacterial anti-adhesion

Vancogenx® exerts an anti-adhesion action by inhibiting bacterial proliferation²¹

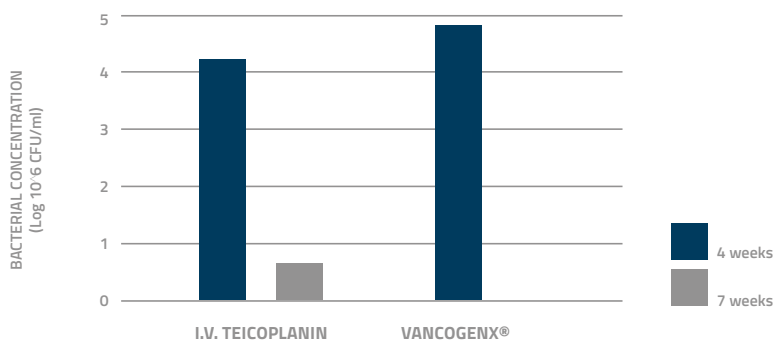


The chart shows the adhesion of clinical isolates to PMMA loaded with gentamicin and the Vancomycin-Gentamicin combination (Vancogenx®). The Gentamicin-Vancomycin combination prevents bacteria from adhering to the PMMA.²⁴

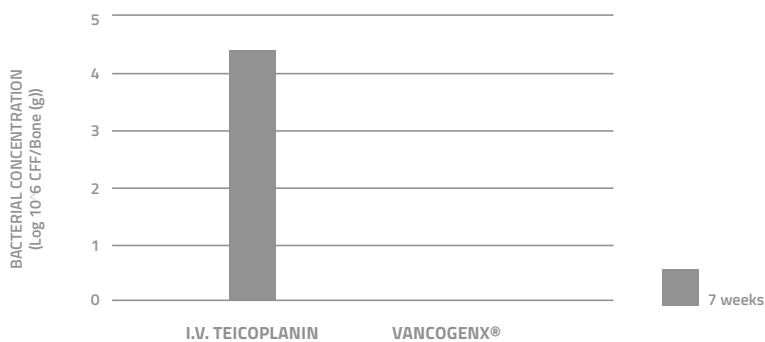
Coadjuvant in the treatment of infection

In vivo animal studies* have proven Vancogenx®'s therapeutic efficacy in experimental osteomyelitis models. The results of the study indicate that local therapy with Vancogenx® is able to eradicate infection and provides better results than systemic therapy with teicoplanin.²⁶ Following surgical debridement, the local therapy achieved with Vancogenx® eradicates infection and provides better results than systemic therapy.

MICROBIOLOGICAL ANALYSIS OF THE CULTURE SWAB



BACTERIAL LOAD IN THE BONE



Description of the study: an MRSA osteomyelitis was induced in the femur of New Zealand rabbits. After 4 weeks the animals were subjected to surgical debridement of the femoral canal and divided into various groups to represent different treatment options, among which: insertion of an SS nail covered with Vancogenx® (group 1) and a one-week systemic treatment with I.V. Teicoplanin (group 2). After 3 weeks the animals were sacrificed, and the femurs explanted to assess the outcomes of the infection: local therapy with Vancogenx® was able to eradicate the infection (from a radiological, histological and microbiological point of view) providing better results than systemic therapy with I.V. Teicoplanin.



ORDERING INFORMATION

SPACER FOR HIP

Spacer®-G Gentamicin Loaded

STEM	HEAD SIZE (mm)	ROUND STEM	FLAT STEM
SHORT STEM	46	SPC46/G	SPC0620
	54	SPC54/G	SPC0720
	60	SPC60/G	SPC0820
LONG STEM	46	SPC46/GXL	SPC0920
	54	SPC54/GXL	SPC1020
	60	SPC60/GXL	SPC1120

Vancogenx®-Space Hip Gentamicin + Vancomycin Loaded

STEM	HEAD SIZE (mm)	ROUND STEM	FLAT STEM
SHORT STEM	46	SPC0030	SPC0630
	54	SPC0130	SPC0730
	60	SPC0230	SPC0830
LONG STEM	46	SPC0330	SPC0930
	54	SPC0430	SPC1030
	60	SPC0530	SPC1130

Trial Set (3-size set)

SHORT ROUND STEM	SPG03
LONG ROUND STEM	SPG03XL
SHORT FLAT STEM	SPC90Z0
LONG FLAT STEM	SPC91Z0

SPACER FOR KNEE

Spacer®-K Gentamicin Loaded

TIBIAL WIDTH (mm)	CODE
60 - small	SPK6054/G
70 - medium	SPK7064/G
80 - large	SPK8074/G

Vancogenx®-Space Knee Gentamicin + Vancomycin Loaded

TIBIAL WIDTH (mm)	CODE
60 - small	SPK0030
70 - medium	SPK0130
80 - large	SPK0230
90 - extralarge	SPK0330

Trial Set

TRIAL SET (SMALL-MEDIUM-LARGE)	SPK03
TRIAL EXTRALARGE	SPK03Z0

ATS

Spacer®-K ATS Gentamicin Loaded

TIBIAL WIDTH (mm)	THICKNESS (mm)	CODE	Spacer®-K pairing
60	7	SPK0420	S or M
60	12	SPK0520	S or M
80	7	SPK0620	L
80	12	SPK0720	L

Vancogenx®-Space Knee ATS Gentamicin+Vancomycin loaded

TIBIAL WIDTH (mm)	THICKNESS (mm)	CODE	Vancogenx-Space® Knee
60	7	SPK0430	S or M
60	12	SPK0530	S or M
80	7	SPK0630	L or XL
80	12	SPK0730	L or XL

TRIAL SET (all sizes): SPK90Z0

SPACER FOR SHOULDER

Spacer®-S Gentamicin Loaded

HEAD SIZE (mm)	CODE
41	SPS0020
46	SPS46/G

Trial Set

TWO-SIZE	SPS90Z0
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