

ORTHOPAEDICS

# 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

Tecres introduced in 1996 the first industrial made, preformed orthopaedic Spacer, designed to help treat prosthetic infections.

Prosthetic infection is one of the most serious complications in orthopedic surgery and is very difficult to treat. The latest data available in literature indicate that in the first two years after implanting hip or knee prosthesis, 1,6% will encounter some form of infections. The two-stage revision process is considered the standard for the treatment of prosthetic infections<sup>1-2</sup>.





# ADVANTAGES

## ADVANTAGES FOR THE SURGEONS

**Saving Time:** ready to use, with preformed shapes and different sizes. It makes faster both the first and the second stage.

**Safety:** the devices have mechanical and pharmacological performances standardized and certified.

**Effectiveness:** known, extended and long release of antibiotic.

**Less responsibility:** using an industrial device, not an hand-made one.

## ADVANTAGES FOR THE PATIENTS

**Better quality of life:** Spacer allows deambulation with partial weight-bearing and permits to make some basic daily activities, this allows the patient to be independent.

**Possibility to make physiotherapy**

**Reduction of functional recovery time:** faster discharge from hospital.

## MECHANICAL AND PHARMACOLOGICAL PROPERTIES

Tecres Preformed Spacers guarantee excellent mechanical properties that allow the patient to deambulate with partial weight-bearing. The precise quantity of antibiotic mixed inside PMMA allows excellent mechanical performances together with a prolonged antibiotic release, also thanks to the special stem surface.

## SAFETY AND EFFECTIVENESS

Clinical results of more than 700 patients in 15 hospitals around the world demonstrated that more than 94% of Two-Stage Exchange made with Tecres Spacer were free from infection at the latest follow-up.

## CLINICAL RESULTS

	AUTHOR	TYPE	PTS	REIMPLANTED	CLEARED AT FU	MEAN FU (M)	SITE
1	Magnan B	Hip	10	8	8/8	35 (24-48)	Verona (ITA)
2	Pitto RP	Knee	21	19	19/29	24 (12-43)	Auckland (NZ), Bergamo (ITA)
3	Gil Gonzalez S	Hip	35	35	30/35	32 (6-65)	Barcelona-1 (SPA)
4	Coffey MJ	Shoulder	16	12	12/12	18 (10-29)	Dayton, OH (USA)
5	Pattyn C	Hip	61	61	59/61	34 (9-84)	Ghent (BEL)
6	D'Angelo F	Hip	28	27	27/27	53 (18-106)	Varese (ITA)
7	Romanò CL*	Hip	20	20	19/20	57 (24-104)	Milan - 1,2 (ITA)
8	Neumann DR	Hip	42	42	41/42	67 (36-120)	Salzburg (AUT)
9	Romanò CL	Hip	183	183	173/183	60 (24-132)	Milan - 1,2 (ITA)
10	Degen RM	Hip	33	30	28/30	43 (24-70)	London, ON (CAN)
11	Wan Z	Knee	33	31	28/31	44 (24-62)	Houston, TX (USA)
12	Garcia-Oltra E	Hip	35	32	31/32	48 (14-85)	Barcelona-2 (SPA)
13	Corona PS	Hip & Knee	41	38	33/38	35 (12-65)	Barcelona-3 (SPA)
14	Castelli CC	Knee	50	50	46/50	84 (24-156)	Bergamo (ITA)
15	Vecchini E	Knee	19	16	16/16	74 (10-112)	Verona (ITA)
16	Burastero G	Hip	71	71	67/71	39 (8-52)	Albenga (ITA)
17	Vasso M	Knee	29	24	24/24	120 (84-168)	Roma (ITA)
	<b>TOTAL</b>		<b>727</b>	<b>699</b>	<b>94,6%</b>	<b>51,1 months</b>	

# SPACER LINE

## HIP SPACER

Hip Spacer resembles a femoral prosthesis. It has a load-bearing structure in stainless steel coated with antibiotic loaded bone cement. The Tecres Spacer is available in 3 different head sizes in the following variants:



**Spacer G:** with Gentamicin, round stem

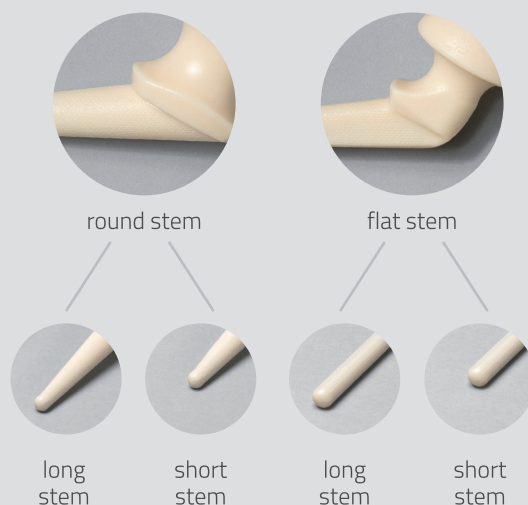
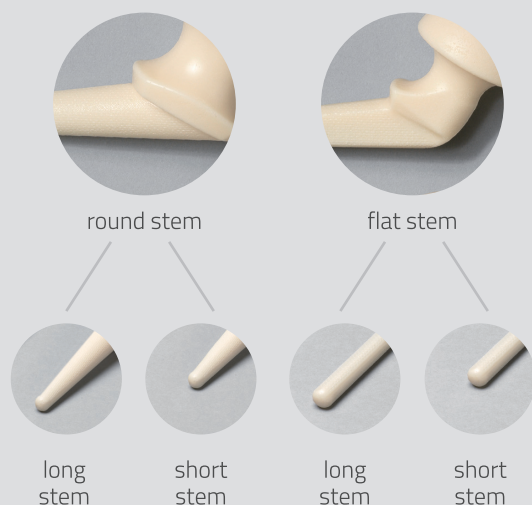
**Spacer G Flat Stem:** with Gentamicin, flat stem

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

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

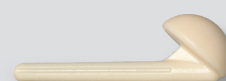
**Spacer G:** with Gentamicin

**Vancogenx Space Hip:** with Gentamicin+Vancomycin

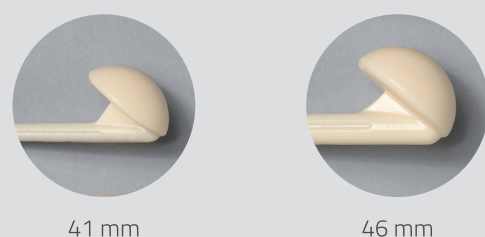


## SHOULDER SPACER

Shoulder Spacer resembles a shoulder prosthesis, it has a load-bearing structure in stainless steel, coated with Gentamicin bone cement. Available in the following version



**Spacer S:** with Gentamicin, 2 different sizes



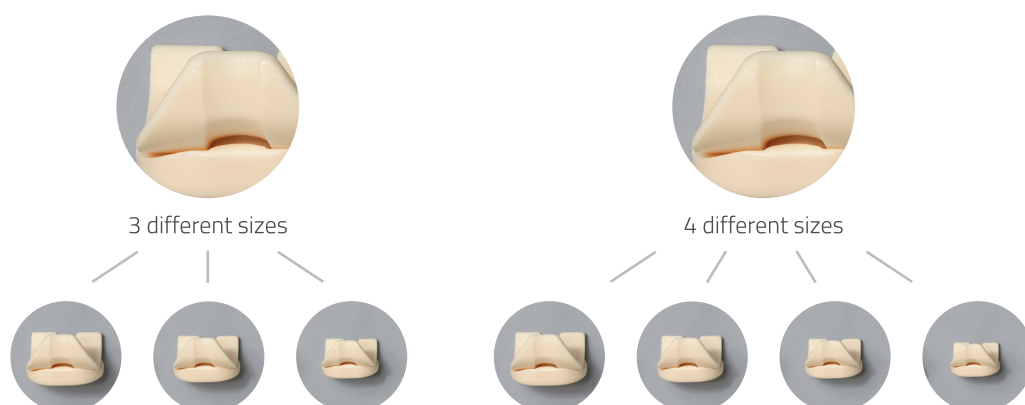
## KNEE SPACER

Knee Spacer resembles a knee prosthesis made in bone cement loaded with antibiotic. It comprises two independent articulating elements. The tibial component has a flat base on which the femoral component articulates. Available in the following variants:



**Spacer K:** with Gentamicin, 3 different sizes

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



Scan the QR code and watch the video tutorial



# 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 - Genta + Vanco 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		Vancogenx Space Knee - Genta + Vanco Loaded	
TIBIAL DIMENSION (mm)	CODE	TIBIAL DIMENSION (mm)	CODE
60 - small	SPK6054/G	60 - small	SPK0030
70 - medium	SPK7064/G	70 - medium	SPK0130
80 - large	SPK8074/G	80 - large	SPK0230
		90 - extralarge	SPK0330

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

SPACER FOR SHOULDER			
Spacer S - Gentamicin Loaded		Trial	
HEAD SIZE (mm)	CODE	TWO-SIZE	
41	SPS0020		
46	SPS46/G		SPS90Z0

# BIBLIOGRAPHY

1. Ong KL, Kurtz SM, Lau E, Bozic KJ, Berry DJ, Parvizi J. **Prosthetic joint infection risk after total hip arthroplasty in the Medicare population.** *J Arthroplasty.* 2009 Sep; 24 (6 Suppl):105-9. Epub 2009 Jun 2.
2. Kurtz SM, Ong KL, Lau E, Bozic KJ, Berry D, Parvizi J. **Prosthetic joint infection risk after TKA in the Medicare population.** *Clin Orthop Relat Res.* 2010 Jan;468(1):52-6. Epub 2009 Aug 8.
3. EARSS Annual Report - Antimicrobial resistance surveillance in Europe 2009. **Annual report of the European Antimicrobial Resistance Surveillance Network (EARS-Net)** [http://www.ecdc.europa.eu/en/publications/Publications/Forms/ECDC\\_DispForm.aspx?ID=580](http://www.ecdc.europa.eu/en/publications/Publications/Forms/ECDC_DispForm.aspx?ID=580)
4. Evans R et al. **Orthopaedic infection: community-associated and healthcare-associated methicillin-resistant.** *Staphylococcus aureus (MRSA) - AAOS 2008*
5. Magnan B et al. **Preformed acrylic bone cement spacer loaded with antibiotics: use of two-stage procedure in 10 patients because of infected hips after total replacement.** *Acta Orthop Scand.* 2001 Dec;72(6):591-4.
6. Bertazzoni Minelli E et al. **PMMA as Drug delivery system and in vivo. Release from Spacers.** In "Infection and local treatment in orthopedic surgery" Meani E, Romanò C, Crosby L, Hofmann G Eds. Springer Verlag 2007.
7. Romanò CL et al. **Long-stem versus short-stem preformed antibiotic-loaded cement spacers for two-stage revision of infected total hip arthroplasty.** *Hip Int.* 2010 Jan-Mar;20(1):26-33.
8. Pitto RP et al. **Pre-formed articulating knee spacer in two-stage revision for the infected TKA.** *Int Orthop.* 2005 Oct;29(5):305-8.
9. Pattyn C et al. **Preformed gentamicin spacers in two-stage revision hip arthroplasty: functional results and complications.** *Int Orthop.* 2010 Nov 30. [Epub ahead of print]
10. Baleani M et al. **The mechanical behaviour of a pre-formed hip.** *Hip International / Vol. 13 no. 3, 2003 / pp. 159-162.*
11. Villa T et al. **Experimental evaluation of the biomechanical performances of a PMMA-based knee spacer.** *Knee.* 2007 Mar;14(2):145-53. Epub 2007 Jan 4.
12. Mutimer J et al. **Measurements of in vivo intra-articular gentamicin levels from antibiotic loaded articulating spacers in revision total knee replacement.** *Knee.* 2009 Jan;16(1):39-41. Epub 2008 Sep 10.
13. Bertazzoni Minelli E et al. **Release of gentamicin and vancomycin from temporary human hip spacers in two-stage revision of infected arthroplasty.** *J Antimicrob Chemoter.* 2004 Feb;53(2):329-34.
14. Moojen DJ et al. **In vitro release of antibiotics from commercial PMMA beads and articulating hip spacers.** *J Arthroplasty.* 2008 Dec;23(8):1152-6.
15. Dunne N et al. **In vitro study of the efficacy of acrylic bone cement loaded with supplementary amounts of gentamicin.** *Acta Orthopaedica* 2007; 78 (6): 774-'3f785.
16. Degen Rm et al. **Does a prefabricated gentamicin-impregnated, load bearing spacer control periprosthetic hip infection?.** *Clin Orthop Relat Res.* 2012 Apr 24. [Epub ahead of print]
17. Wan Z et al. **Preformed articulating knee spacers in 2-stage total knee revision arthroplasty. Minimum 2-year follow-up.** *J Arthroplasty.* 2012 Mar 14. [Epub ahead of print].
18. Neumann DR et al. **Two-stage cementless revision of late total hip arthroplasty infection using a premanufactured spacer.** *J Arthroplasty.* 2011 Dec 15. [Epub ahead of print].
19. Romanò CL et al. **Two stage revision surgery with preformed spacers and cementless implants for septic hip arthritis: a prospective, non-randomized cohort study.** *BMC Infect Dis.* 2011 May 16;11(1):129. [Epub ahead of print]
20. D'Angelo F et al. **The use of a preformed spacer in two-stage revision of infected hip arthroplasties.** *Musculoskelet Surg.* 2011 Apr 9. [Epub ahead of print]
21. Gil Gonzalez S et al. **Two-stage revision of hip prosthesis infection using a hip spacer with stabilising proximal cementation.** *Hip Int.* 2010 May 27;20 (Suppl 7) (S7):128-134. [Epub ahead of print]
22. Coffey MJ, Ely EE, Crosby LA. **Treatment of glenohumeral sepsis with a commercially produced antibiotic-impregnated cement spacer.** *J Shoulder Elbow Surg.* 2010 Sep; 19 (6):868-73. Epub 2010 Apr 14.
23. García-Oltra E, Bori G, Tomas X, Gallart X, García S, Soriano A **Radiological evaluation of acetabular erosion after antibiotic-impregnated polymethylmethacrylate spacer (Spacer-G).** *J Arthroplasty.* 2013 Jun;28(6):1021-4.
24. Castelli CC, Gotti V, Ferrari R. **Two-stage treatment of infected total knee arthroplasty: two to thirteen year experience using an articulating preformed spacer.** *Int Orthop.* 2014 Feb;38(2):405-12. Epub 2014 Jan 26.
25. Corona PS, Barro V, Mendez M, Cáceres E, Flores X. **Industrially prefabricated cement spacers: do vancomycin- and gentamicin-impregnated spacers offer any advantage?** *Clin Orthop Relat Res.* 2014 Mar;472(3):923-32. Epub 2013 Oct 19.
26. Magnan B, Regis D, Biscaglia R, Bartolozzi P. **Preformed acrylic bone cement spacer loaded with antibiotics: use of two-stage procedure in 10 patients because of infected hips after total replacement.** *Acta Orthop Scand.* 2001 Dec;72(6):591-4







## Tecres is specialized in biomaterials in the following medical sectors



**Orthopaedics:** bone cement, bone cement extractor, screw augmentation, endorthesis screws, reinforced bone substitute, custom made devices



**Spinal surgery:** Vertebroplasty resins and kit



**Neurosurgery:** cranial bone cement, custom made prosthesis



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