

o r t h o p a e d i c s

SPACER[®] LINE



*Reliability,
Innovation,
Versatility,
Safety...
in the hands of the surgeon.*

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Reliability

SPACER: a great idea from Tecres

Prosthetic infection is one of the most serious complications in orthopedic surgery and is very difficult to treat.

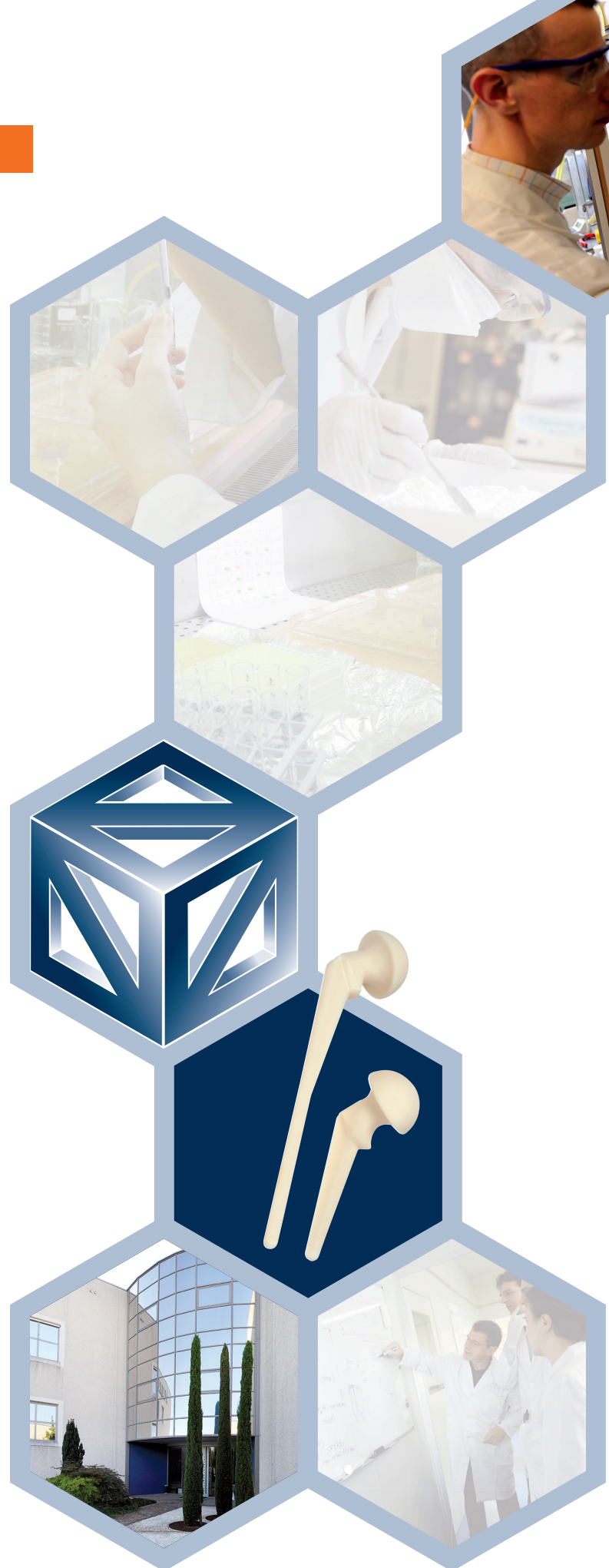
The latest data available in the literature indicate that in the first two years after implanting hip or knee prosthesis, 1,6% will encounter some form of infection.⁽¹⁻²⁾

In recent years, bacteria have developed resistance to classic antibiotics and the problem is now even more difficult to face.

Moreover, resistance to methicillin by Staphylococci (MRS) reaches peaks of 50% in Mediterranean Europe, UK and USA.³⁻⁴

The two-stage revision process is considered the standard for the treatment of prosthetic infections.

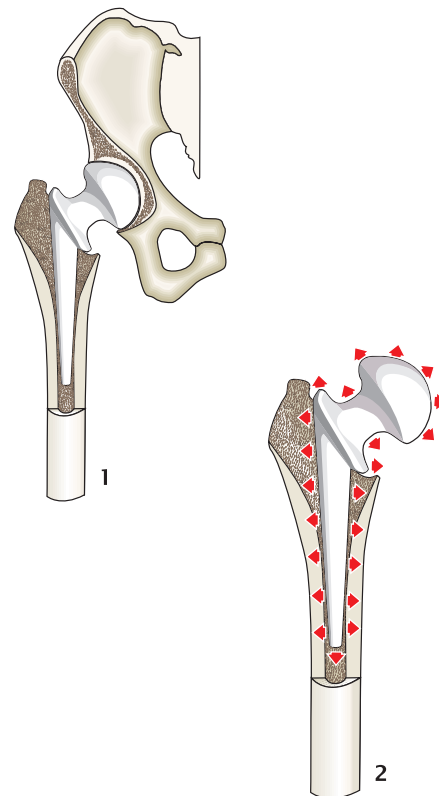
Tecres has successfully produced pre-formed spacers with antibiotic for 15 years.





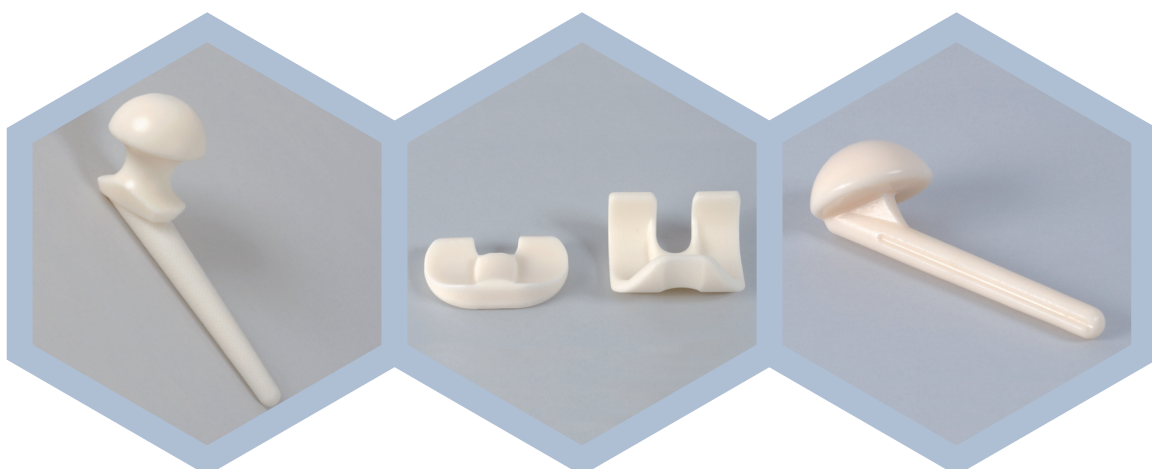
Advantages for surgeons:

- **Saving Time:**
ready to use, with preformed shapes and different sizes.
It makes faster both the surgery first stage and the second one.
- **Safety:**
the devices have mechanical and pharmacological performances standardized and certified.
- **Effectiveness:**
known, extended and long release of antibiotic.
- **Less responsibility:**
using of an industrial device, not an hand-made one.



Advantages for 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.



Research and innovation

Excellent mechanical properties that allow the patient to deambulate with partial weight-bearing

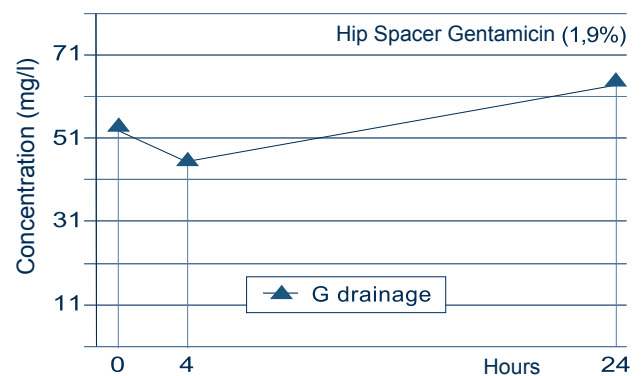
The devices have been tested as permanent prosthesis to support full weight-bearing for 6 months.⁽¹⁰⁻¹¹⁾ The device must be used at partial weight-bearing.⁽¹⁰⁻¹¹⁾

Effectiveness and extended release of antibiotics

At implantation

The release of gentamicin presents high local concentrations (range 40-100 mg/L) in the first 24-48 hours after spacer implant. The concentrations are largely above the susceptibility of bacteria. Serum levels are low (<0.2-0.8 mg/L).⁽⁶⁾ (Fig. 1)

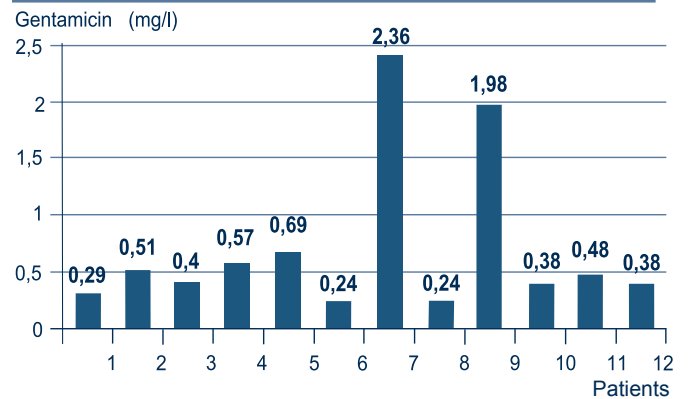
Concentration of antibiotic in drainage in the first 24h (Fig. 1)



At spacer removal

The median intra-articular gentamicin levels were 0.46 mg/L (0.24 to 2.36 mg/L) which would be considered therapeutic. The second stage revision occurred at a median of 99 days following spacer insertion.⁽¹²⁾ (Fig. 2)

Gentamicin levels at 2nd stage revision (Fig. 2)



After use

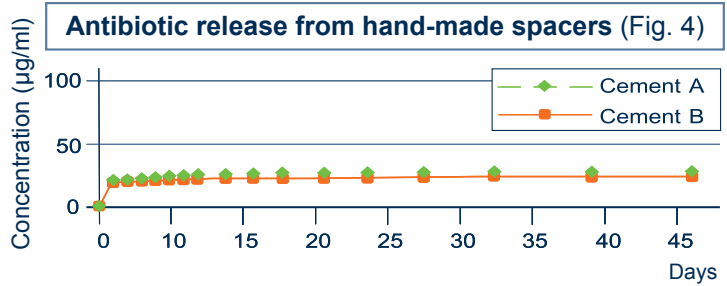
After 12-24 weeks in the hip, the removed spacers still released appreciable amounts (850-1800µg) of gentamicin, representing 0.05%-0.09% of the initial total amount, and in the range 4.7-10.0µg/cm².⁽¹³⁾ (Fig. 3)

Gentamicin release (Fig. 3)

Spacer no.	Duration of implantation (months)	Residual total release µg
1	4.0	1350
2	4.5	1030
3	3.0	1800
4	6.5	1500
5	6.0	850
19	5.0	1320
Mean ±S.D.	4.8 ± 1.3	1308.3 ± 337.0

Commercial cement loaded with antibiotic is unsuitable for spacers

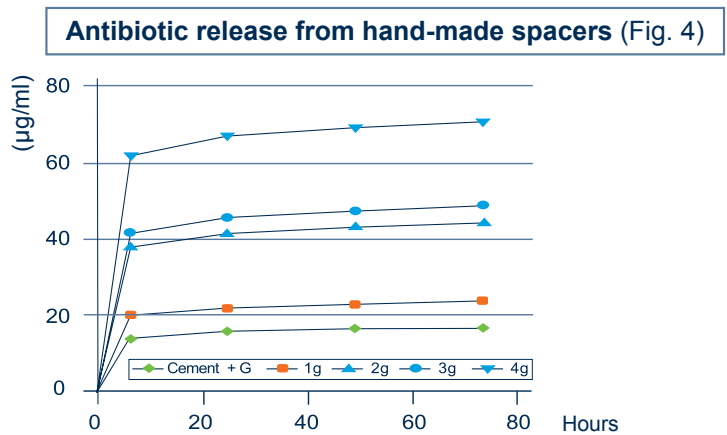
For both the Cement A and Cement B spacers, there was hardly any additional release after the first week. ⁽¹⁴⁾
(Fig. 4)



Increasing the dose of antibiotics in commercial cement:

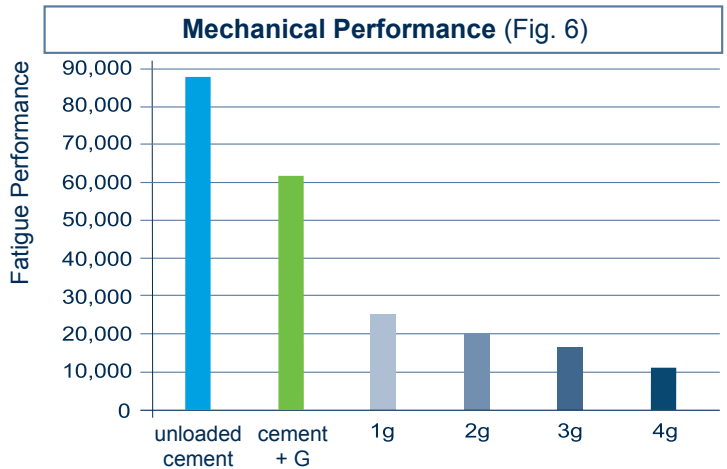
It only influences initial release

Gentamicin release was most rapid during the first 6 h and continued at a much lower rate thereafter. ⁽¹⁵⁾
(Fig. 5)



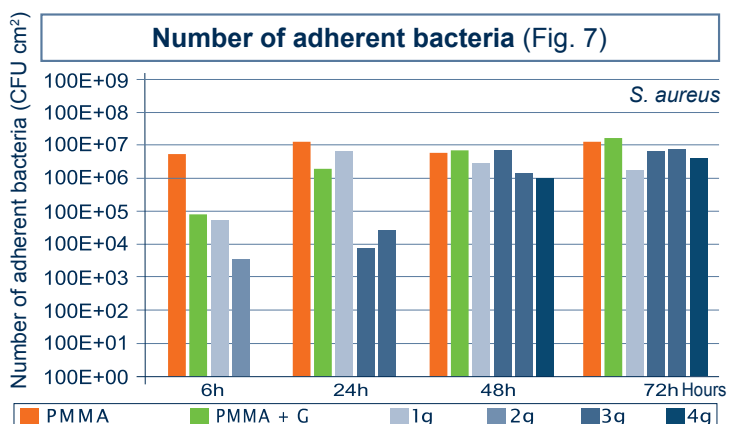
It significantly reduces mechanical performances

When gentamicin was added to unloaded cement (1-4 g), there was a significant reduction in the mechanical performance of the loaded cements compared to unloaded cement. ⁽¹⁵⁾
(Fig. 6)



It does not protect against bacterial adhesion

The incorporation of additional gentamicin did result in an initial reduction in bacterial colonization but this beneficial effect was no longer apparent at 72 h, with the clinical strains forming biofilms on the cements despite the release of high levels of gentamicin. ⁽¹⁵⁾
(Fig. 7)



Versatility

Spacer for Hip

SPACER® G - InterSpace Hip (USA)

The Tecres spacer resembles a femoral prosthesis. It has a load-bearing structure in stainless steel coated with gentamicin bone cement.

Available in 6 sizes (3 head sizes with standard stem and 3 head sizes with XL stem).

The proximal cementation of the neck with bone cement is suggested.

SPACER® G FLAT STEM

Spacer G flat stem resembles Spacer G but has a thinner, flatter stem that fits more easily in the narrow femoral cavity. The top of the stem has been designed to preserve the greater trochanter.

Available in 6 sizes (3 head sizes with standard stem and 3 head sizes with XL stem).

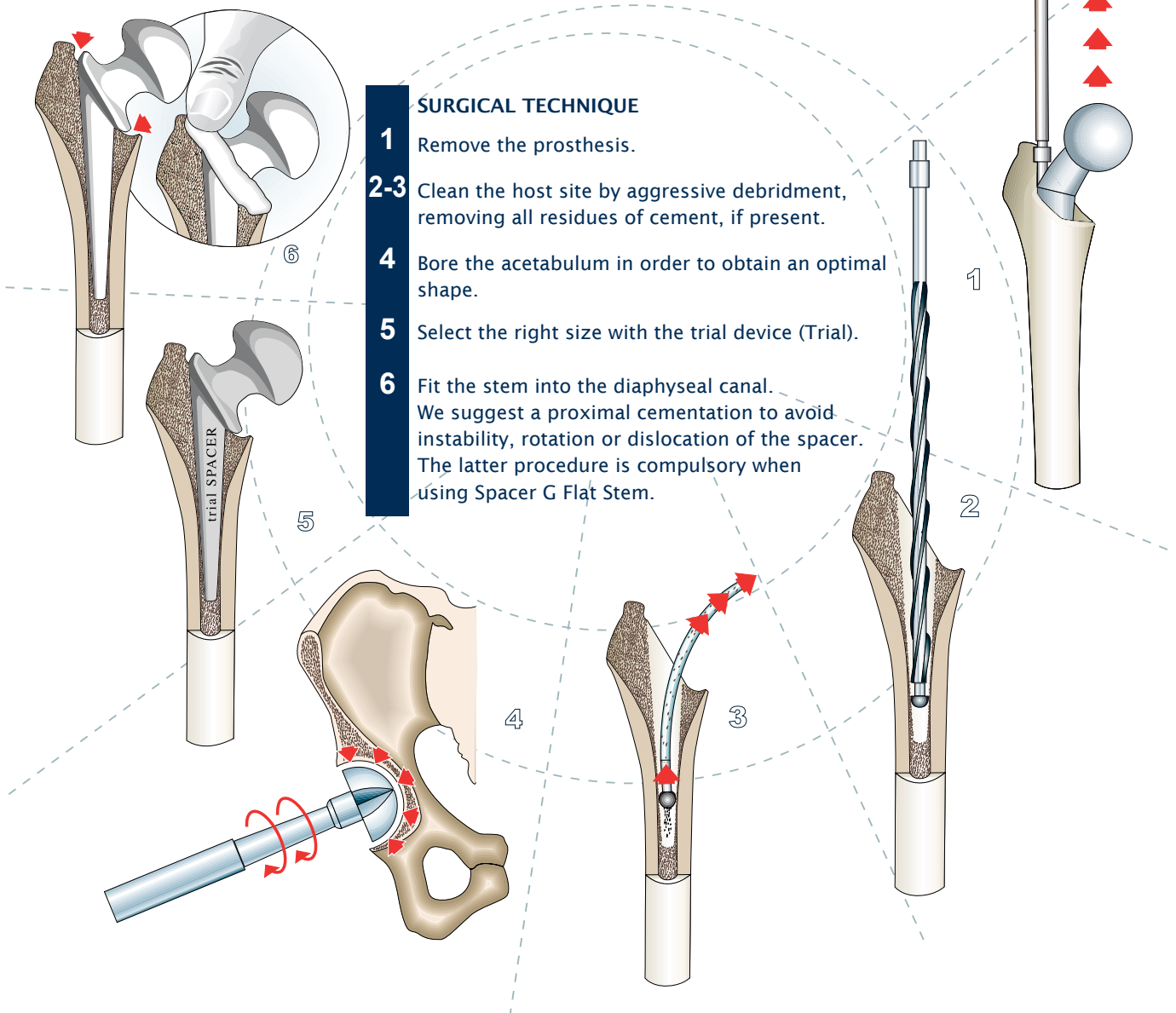
The proximal cementation of the neck with bone cement is compulsory.

VANCOGENX®- SPACE Hip

The exclusive line of spacers with gentamicin and vancomycin for the infections caused by resistant bacteria Gram+ as *S. epidermidis*, MRS, CoNS o Entrococci.

Available in 6 sizes (3 head sizes with standard stem and 3 head sizes with XL stem).

The proximal cementation of the neck with Vancogenx bone cement is compulsory.



Spacer for Knee

SPACER® K - InterSpace Knee (USA)

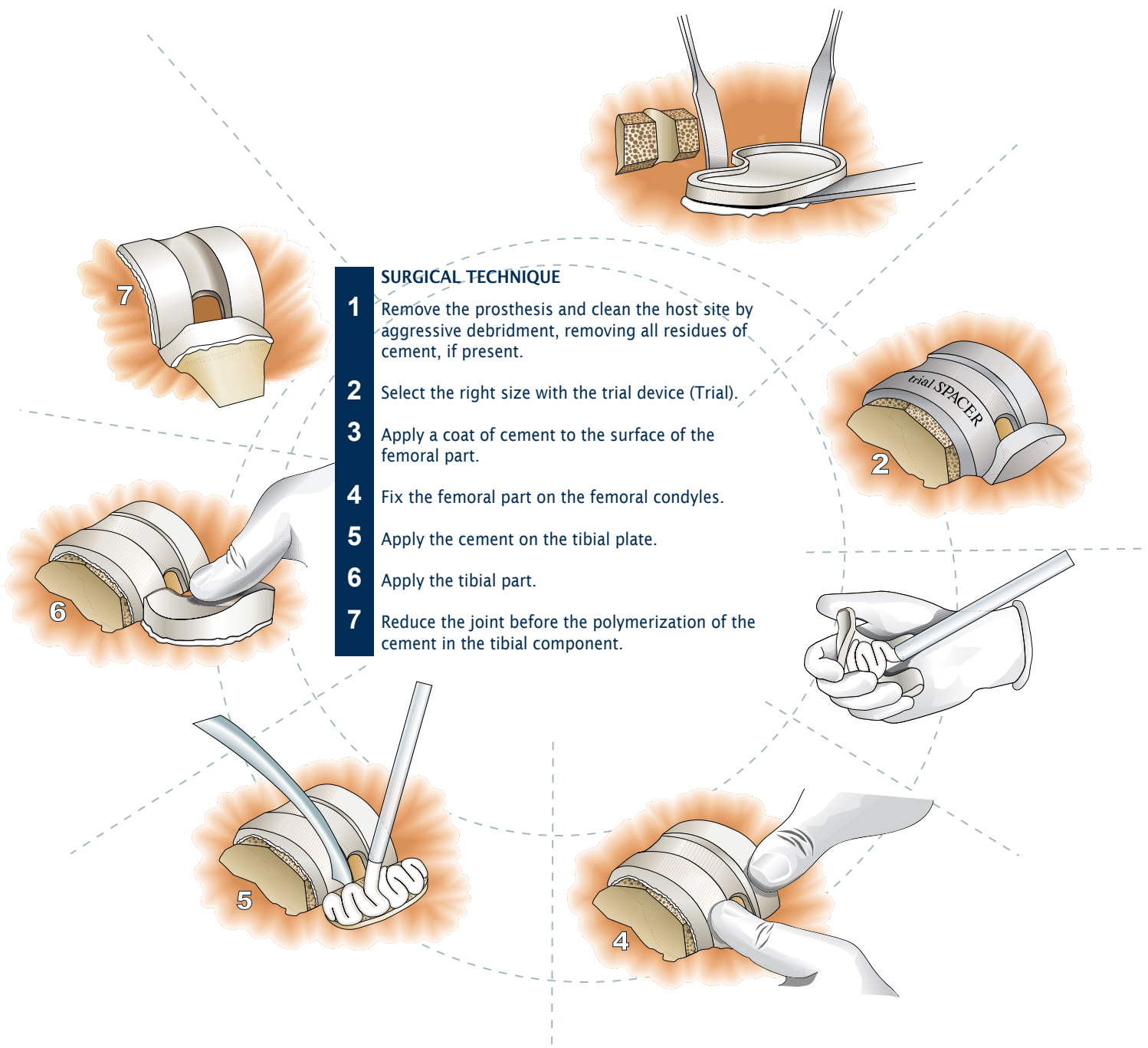
Spacer K resembles a knee prosthesis made in bone cement with gentamicin. It comprises two independent articulating elements. The tibial component has a flat base on which the femoral component articulates. Available in 3 sizes.

The proximal cementation of the neck with bone cement is compulsory.

VANCOGENX®- SPACE KNEE

The exclusive line of spacers with gentamicin and vancomycin, for the infections caused by resistant bacteria Gram+ as *S. epidermidis*, MRS, CoNS o Entrococci. Available in 4 sizes.

The proximal cementation of the neck with Vancogenx bone cement is compulsory.

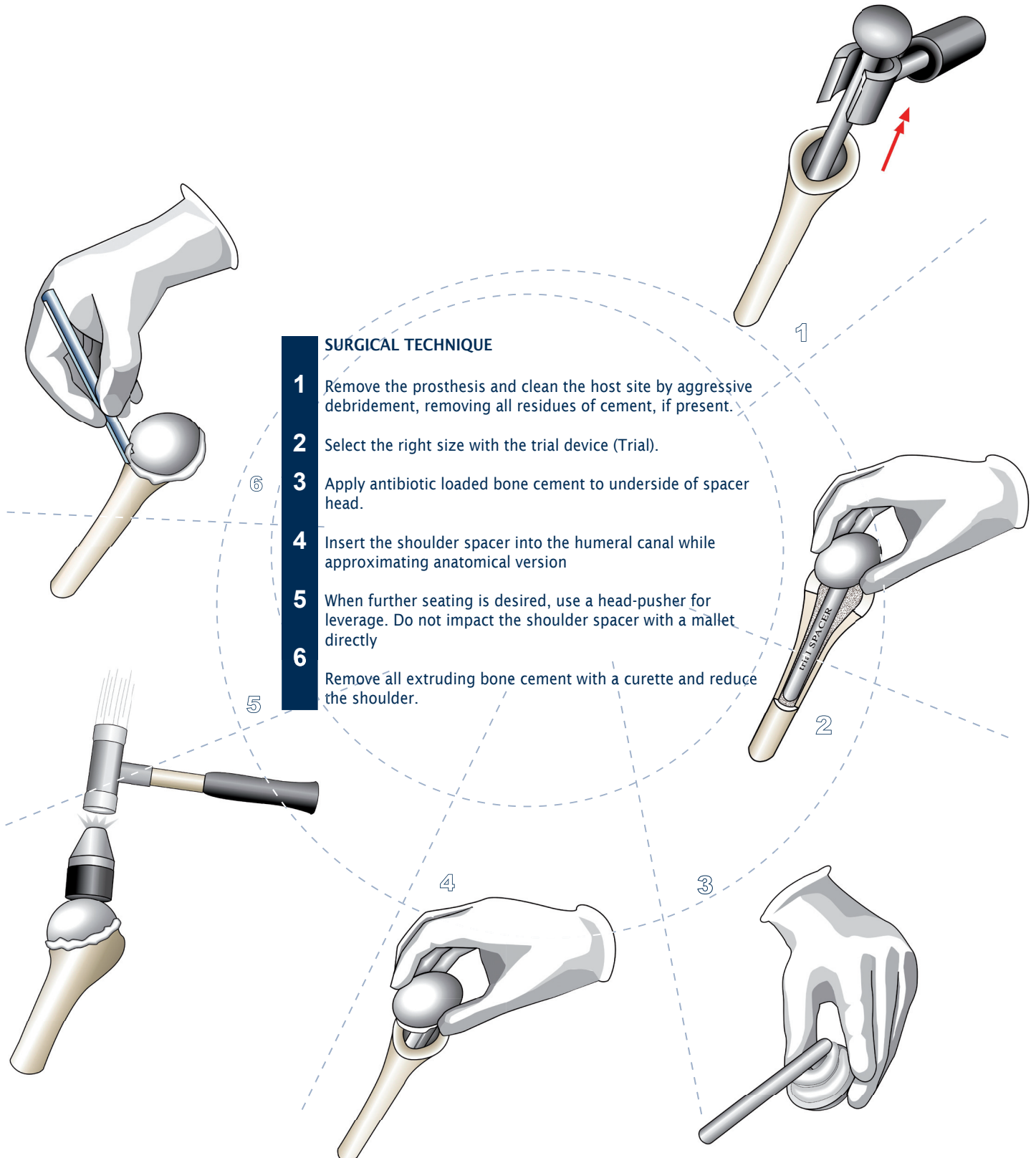


Spacer for Shoulder

SPACER® S - InterSpace Shoulder (USA)

Spacer S resembles a shoulder prosthesis, it has a load-bearing structure in stainless steel coated with gentamicin bone cement. Available in 2 sizes.

The proximal cementation of the neck with bone cement is compulsory



Safety & Effectiveness

Tecres Spacers are the most studied in the world, with more than 500 cases published on peer-reviewed journals.

CLINICAL RESULTS

Journal	1 st Author	Type	N.pts	Cleared at FU (reimplanted)	FU mean (min-max)	Center
J Arthroplasty (2012)	Garcia-Oltra E.	Hip	35	31/32	48 (14 - 85)	Barcelona-2 (SPA)
CORR (2012)	Degen R.M.	Hip	33	28 / 30	43 (24 - 70)	London, ON (CAN)
J Arthroplasty (2012)	Wan Z.	Knee	33	28 / 31	44 (24 - 62)	Houston, TX (USA)
Hip Int (2012)	Romanò C.L.	Hip	183	173/183	60 (24 - 132)	Milan (ITA)
J Arthroplasty (2012)	Neumann D.R.	Hip	42	41 / 42	67 (36 - 120)	Salzburg (AUT)
BMC Infect Dis (2011)	Romanò C.L.	Hip*	20	19 / 20	57 (24 - 104)	Milan (ITA)
Musculoskelet Surg (2011)	D'Angelo F.	Hip	28	27 / 27	53 (18 - 106)	Varese (ITA)
Int Orthop (2011)	Pattyn C.	Hip	61	59 / 61	36 (9 - 84)	Ghent (BEL)
Hip Int (2010)	Gil Gonzalez S.	Hip	35	30 / 35	32 (6 - 65)	Barcelona-1 (SPA)
J Shoulder Elbow Surg (2010)	Coffey M.J.	Shoulder	16	12 / 12	18 (10 - 24)	Dayton, OH (USA)
Int Orthop (2005)	Pitto R.P.	Knee	21	19/19	24 (12 - 43)	Auckland (NZ) Bergamo (ITA)
TOTAL			507	467/492	44 M (6 - 132)	11 ≠ Centers

* *septic arthritis*

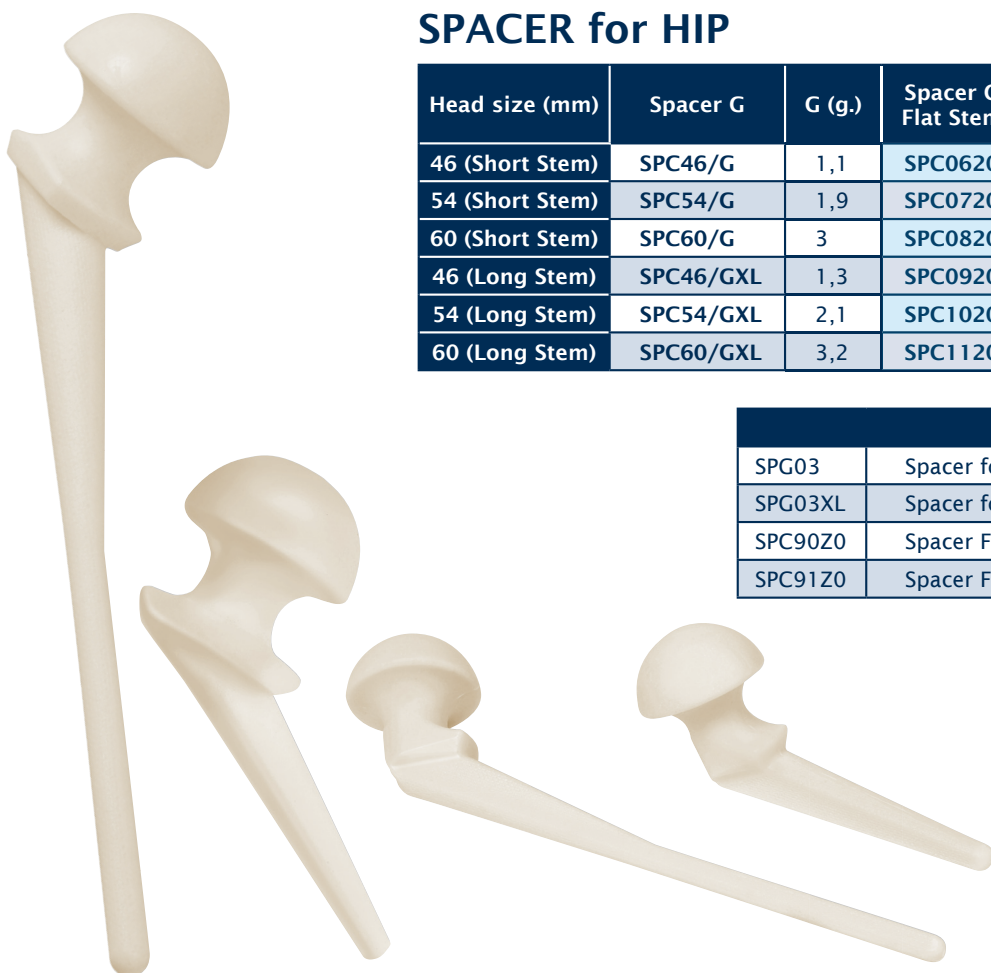
Clinical studies published in peer-reviewed journals by several international centers have demonstrated that the use of a preformed industrial spacer with gentamicin produces excellent results in functional and biological (eradication of infection) point of view. **More than 95% were free from infection at the latest follow-up.**

Ordering information

SPACER for HIP

Head size (mm)	Spacer G	G (g.)	Spacer G Flat Stem	G (g.)	Vancogenx-space hip	G+V (g.)
46 (Short Stem)	SPC46/G	1,1	SPC0620	1,1	SPC0030	1,1 + 1,1
54 (Short Stem)	SPC54/G	1,9	SPC0720	1,6	SPC0130	1,9 + 1,9
60 (Short Stem)	SPC60/G	3	SPC0820	2,6	SPC0230	3 + 3
46 (Long Stem)	SPC46/GXL	1,3	SPC0920	1,2	SPC0330	1,3 + 1,3
54 (Long Stem)	SPC54/GXL	2,1	SPC1020	1,8	SPC0430	2,1 + 2,1
60 (Long Stem)	SPC60/GXL	3,2	SPC1120	2,8	SPC0530	32, + 3,2

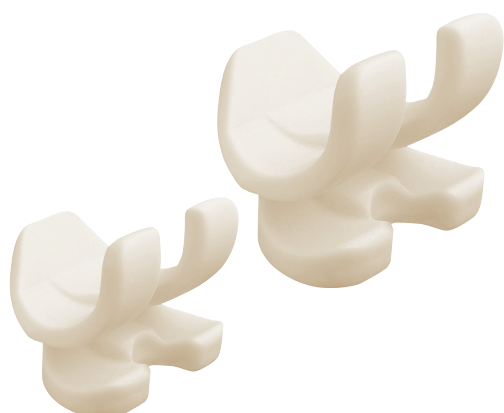
Trial	
SPG03	Spacer for hip (three-size set)
SPG03XL	Spacer for hip XL (three-size set)
SPC9020	Spacer Flat Stem (three-size set)
SPC9120	Spacer Flat Stem XL (three-size set)



SPACER for KNEE

Tibial dimension (mm)	Spacer K	G (g.)	Vancogenx-space Knee	G+V (g.)
60 (Small)	SPK6054/G	0,9	SPK0030	0,9 + 0,9
70 (Medium)	SPK7064/G	1,3	SPK0130	1,3 + 1,3
80 (Large)	SPK8074/G	1,8	SPK0230	1,8 + 1,8
90 (ExtraLarge)	-	-	SPK0330	2,7 + 2,7

Trial	
SPK03	Spacer for knee (three-size set)
SPK03Z0	Spacer for knee XL (one size)



SPACER for SHOULDER

Head size (mm)	Spacer S	G (g.)
41	SPS0020	0,4
46	SPS46/G	0,8

Trial	
SPS90Z0	Spacer for shoulder (two-size set)



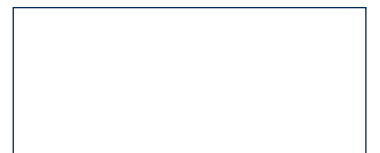
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