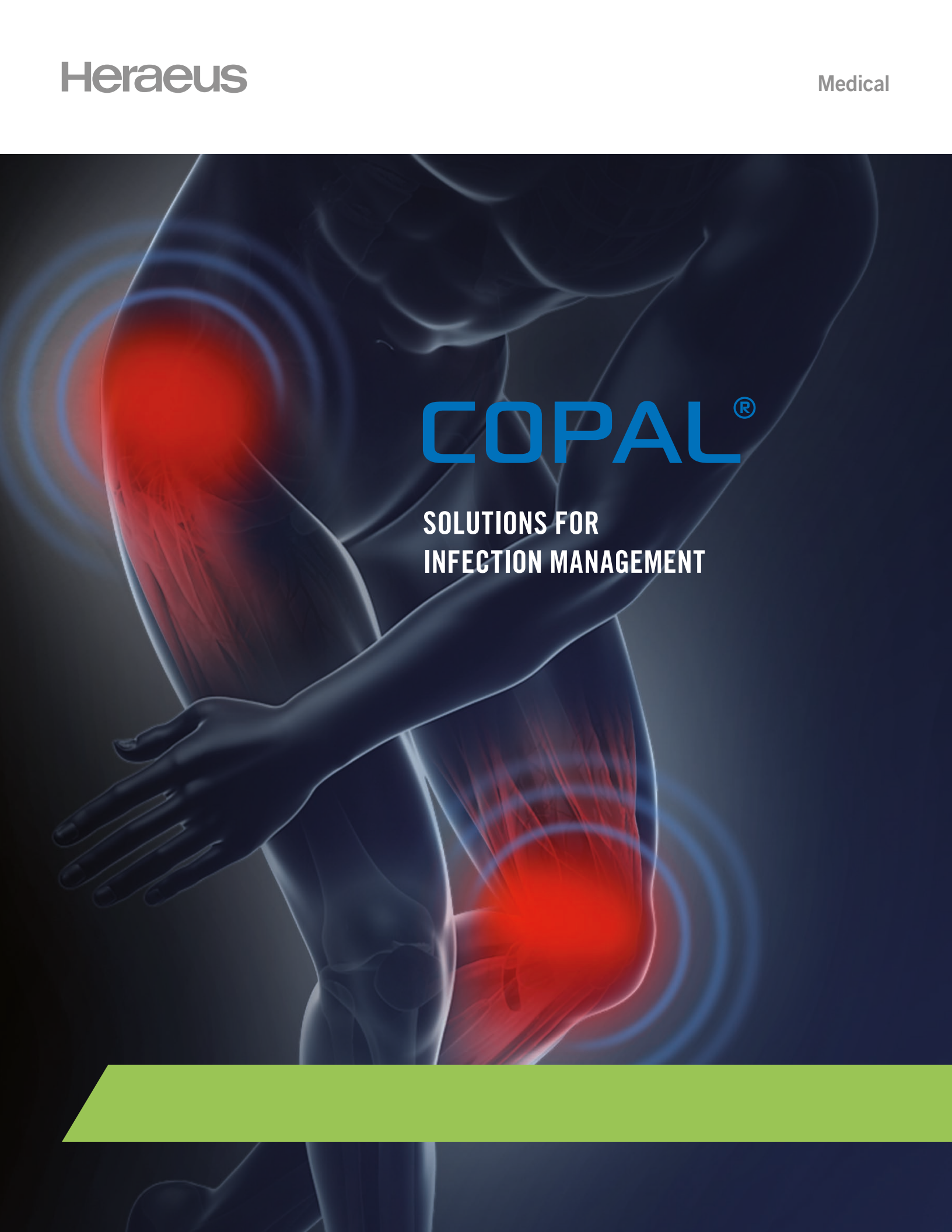




COPAL[®]

**SOLUTIONS FOR
INFECTION MANAGEMENT**

RISING NUMBERS OF REVISIONS

FINANCIAL BURDEN FOR PATIENT AND HEALTHCARE SYSTEM

With the projected growth of total joint arthroplasty (TJA) in hip and knee, the numbers of revisions in total hip arthroplasty (THA) and total knee arthroplasty (TKA) are also expected to increase.¹⁻⁴ Common reasons for revisions after TKA and THA can be, amongst others, infections and mechanical loosening.⁵ The rise of revision procedures imposes growing financial burden for both patient and healthcare system.⁶

COSTS FOR REVISION TJA

Up to

\$58,061

overall costs for revision THA^{*6}



+ 35%^{*6}

Up to

\$52,745

overall costs for revision TKA^{*6}



+ 32%^{*6}

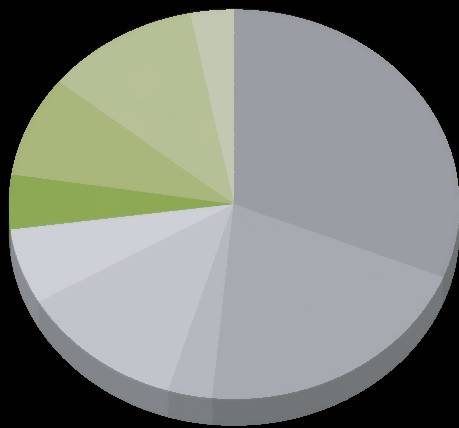
* From 2009–2018

PERIPROSTHETIC JOINT INFECTION

A DEVASTATING COMPLICATION

The risk of infection after primary implantation of a hip or knee prosthesis is 1% and 2%, respectively.⁷ Comorbidities and related circumstances may increase the individual risk of infection.⁸⁻¹¹ According to the National Joint Registry UK, infections belong to the most common reasons for revisions.¹²

MICROBIOLOGIC ETIOLOGY OF PJI



- CoN *Staphylococci* (ex *S. lugdunensis*)
- *S. aureus* complex
- *S. lugdunensis*
- *Streptococci*
- *Enterococci*
- *Corynebacteria*
- Aerobic Gram-negative bacteria
- Anaerobic bacteria
- Other

The pathogenesis of periprosthetic joint infections (PJI) is related to microorganisms growing in biofilms rendering it difficult to eradicate the infection. Essential strategies are needed to minimize the overall incidence of infection in orthopedic surgery.

The combination of two antibiotics in bone cement can provide local effective antimicrobial therapy against PJI associated pathogens.^{13,14}

Figure 1: Microorganisms related to PJI (Hip and Knee as example)

COPAL® G+V

ADDED PROTECTION FOR INFECTION MANAGEMENT

EFFECTIVE AGAINST MOST PJI RELATED PATHOGENS

COPAL® G+V (gentamicin and vancomycin) is a PMMA bone cement intended for fixation of COPAL® exchange G hip spacer to the host bone.

COPAL® G+V is a high-viscosity bone cement providing high local concentrations of gentamicin and vancomycin with a low systemic burden.¹⁵

The broad spectrum of locally eluted antibiotics supports the effective eradication of most PJI related pathogens and MRSA/MRSE.¹⁶⁻¹⁸

COPAL® G+V bone cement shows higher cumulative antibiotic elution of vancomycin (in vitro) over period of 42 days compared to Spectrum® GV bone cement (OsteoRemedies).



COPAL® G+V: INCREASED ANTIBIOTIC ELUTION

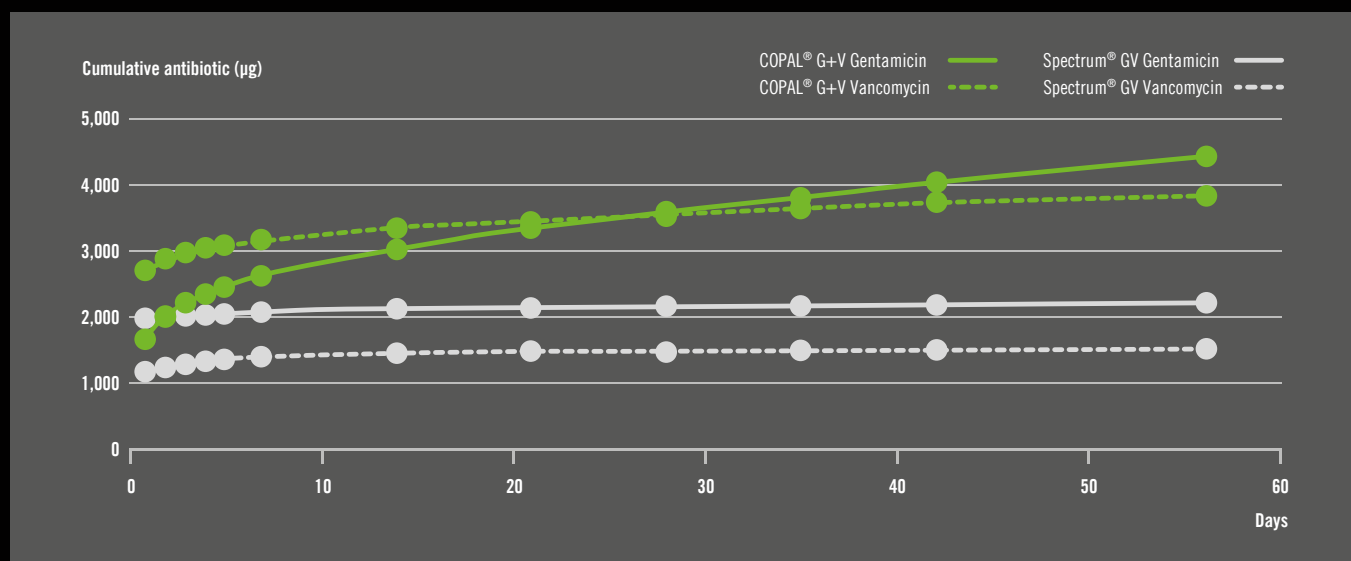


Figure 2: Cumulative gentamicin and vancomycin release (µg/specimen)

COPAL[®] exchange G

DESIGNED FOR PATIENT COMFORT

PREFORMED FOR OPTIMIZED PERFORMANCE

For two-stage revision procedures, the COPAL[®] exchange G preformed PMMA spacers containing gentamicin allows for antibiotic protection¹⁹ and immediate implantation. All to help orthopedic surgeons facilitate infection eradication and implant placement during second-stage revision.²⁰⁻²⁴

EFFICIENT

COPAL[®] exchange G as an antibiotic eluting spacers provide predictable, consistent local antibiotic release over time to prevent bacterial adhesion with high antimicrobial activity against PJI over 42 days.²⁵⁻²⁹

STABLE

COPAL[®] exchange G spacers show high compression strength and fatigue strength.*¹⁹

SIMPLE

Ready to use for immediate implantation and safe in handling.¹⁹



* Compared to Spacer[®] K (Tecres)

COPAL[®] knee moulds

INDIVIDUAL SPACER SOLUTIONS

MOULDING YOUR FUTURE WITH FLEXIBILITY

CUSTOMIZABLE: PATIENT FOCUS

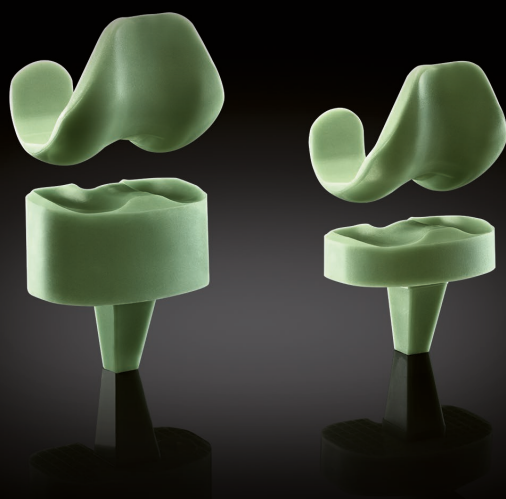
- COPAL[®] knee moulds provide customization to the individual patient situation
- Modularity allows for 36 reconstruction options
- Articulation of COPAL[®] knee moulds provides limited patient mobility during spacer interval.³⁰

ANATOMICAL: PROSTHESIS-LIKE SPACER DESIGN

- COPAL[®] knee moulds' design is based on actual articulating knee prostheses
- Modular tibial spacer design allows for improved fit and joint space preservation

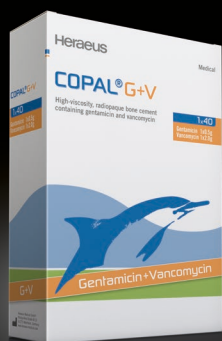
RELIABLE: HERAEUS MEDICAL QUALITY

- Reproducible spacer design and quality based on a rigid material preventing deformation under heat or pressure
- Safe in handling: spacer construction without scalpel
- COPAL[®] knee moulds is fillable with PALACOS[®] R+G bone cements



COPAL[®]

FOR INFECTION MANAGEMENT



COPAL[®]G+V

- High-viscosity bone cement with gentamicin and vancomycin
- Broad spectrum of activity supporting PJI treatment
- Effective against most PJI related pathogens and MRSA/MRSE
- High local antibiotic elution with low systemic load
- For fixation of COPAL[®] exchange G hip spacer to the host bone



COPAL[®]exchange G

- High antimicrobial activity against PJI over 42 days
- Ready to use for immediate implantation
- Quick and easy handling
- Different sizes to accommodate surgeons needs



COPAL[®]knee moulds

- Customizable for individual approach
- Modularity allows for 36 reconstruction options
- Prosthesis-like spacer design
- Fillable with PALACOS[®] R+G bone cements

PRODUCT	DESCRIPTION	CONTENT	REF
COPAL® G+V	High-viscosity bone cement with gentamicin and vancomycin	1x40	5184267
COPAL® exchange G hip	Preformed hip spacer with gentamicin	S short: 46 mm head x 135 mm stem M short: 54 mm head x 135 mm stem L short: 60 mm head x 135 mm stem	5034793 5034791 5034788
		S medium: 46 mm head x 184 mm stem M medium: 54 mm head x 184 mm stem	5147215 5147216
		S long: 46 mm head x 251 mm stem M long: 54 mm head x 251 mm stem L long: 60 mm head x 251 mm stem	5034792 5034790 5034785
COPAL® exchange G knee	Preformed knee spacer with gentamicin	S: 54 mm femur x 54 mm tibia M: 64 mm femur x 64 mm tibia L: 74 mm femur x 74 mm tibia	5034798 5034797 5034796
COPAL® exchange G trial set hip	Trials to determine spacer sizing	S: with short, medium and long stem M: with short, medium and long stem L: with short and long stem	5092608 5092613 5092614
COPAL® exchange G trial set knee	Trials to determine spacer sizing	Set includes sizes S, M, L	5092607
COPAL® knee moulds	Moulds for temporary spacers	S: 60 mm Femur ML S: 65 mm Tibia ML	5159868
		M: 70 mm Femur ML M: 75 mm Tibia ML	5159869
		L: 80 mm Femur ML L: 85 mm Tibia ML	5159870
COPAL® knee moulds trials	Trials to determine spacer sizing (Trial base starts at 12 mm with 5 mm increments up to 37 mm)	S M L	5159874 5164923 5165924

Simply order from Heraeus.

1. Kurtz et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 2007. | 2. Sloan M et al. Projected volume of primary total joint arthroplasty in the U.S., 2014 to 2030. J Bone Joint Surg Am 2018. | 3. Schwartz et al. Projections and Epidemiology of Revision Hip and Knee Arthroplasty in the United States to 2030 2020. | 4. Shichman et al. Projections and Epidemiology of Revision Hip and Knee Arthroplasty in the United States to 2040–2060 2023. | 5. Kamath et al. Quantifying the Burden of Revision Total Joint Arthroplasty for Periprosthetic Infection 2015. | 6. Heo et al. Trends in Costs and Professional Reimbursements for Revision Total Hip and Knee Arthroplasty 2024. | 7. Corvec S. et al. Epidemiology and new developments in the diagnosis of prosthetic joint infection. Int J Artif Organs. 2012 | 8. Berberich et al. Dual antibiotic loaded bone cement in patients at high infection risks in arthroplasty: Rationale of use for prophylaxis and scientific evidence 2021. | 9. Lenguerrand E et al. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Risk factors associated with revision for prosthetic joint infection following knee replacement: an observational cohort study from England and Wales Lancet Infect Dis 2019. | 10. Marmor et al. Patient-specific risk factors for infection in arthroplasty procedure. Orthop Traumatol Surg Res 2016. | 11. Kunutsor SK et al. Patient-Related Risk Factors for Periprosthetic Joint Infection after Total Joint Arthroplasty: A Systematic Review and Meta-Analysis. PLoS One 2016. | 12. NJR 20th Annual report 2023, p. 125 and p. 206. | 13. Sprowson et al. Bone Joint J. 2016. | 14. Berberich et al. Patients at a high risk of PJI: Can we reduce the incidence of infection using dual antibiotic-loaded bone cement 2022. | 15. Kendoff DO et al. Bioavailability of gentamicin and vancomycin released from an antibiotic containing bone cement in patients undergoing a septic one-stage total hip arthroplasty (THA) revision: a monocentric open clinical trial. Hip Int. 2016. | 16. EMA Assessment Report Vancomycin: EMA/645288/2017. | 17. Brodt, HR. Antibiotika-Therapie: Klinik und Praxis der antiinfektiösen Behandlung. Stuttgart: Schattauer Verlag 2012. | 18. Cara A et al. Antibiotics in Bone Cements Used for Prosthesis Fixation: An Efficient Way to Prevent Staphylococcus aureus and Staphylococcus epidermidis Prosthetic Joint Infection. Front. Med. 2021. | 19. Kuehn KD et al. PMMA Bone Cement -What is the role of local Antibiotics? Maitrise Orthopedique 2016. | 20. Data on File, Heraeus Medical (2020). | 21. Burnett, RSJ et al. Technique and timing of two-stage exchange for infection in TKA. Clinical Orthopaedics and Related Research® 2007. | 22. Castelli CC et al. Key points in two-stage revision for infected knee arthroplasty: bone loss, quality of life between stages and surgical approach at second stage. Infection and Local Treatment in Orthopedic Surgery 2007. | 23. Pattyn C et al. Preformed gentamicin spacers in two-stage revision hip arthroplasty: functional results and complications. International orthopaedics 2011. | 24. Soffiatti R. The preformed spacers: from the idea to the realization of an industrial device. In: Meani E, et al [ed]. Infection and local treatment in Orthopedic surgery. Berlin: Springer-Verlag 2007; 201–4. | 25. Mutimer J et al. Measurements of in vivo intra-articular gentamicin levels from antibiotic loaded articulating spacers in revision total knee replacement. The Knee 2009. | 26. Bertazzoni Minelli, E et al. Antimicrobial activity of gentamicin and vancomycin combination in joint fluids after antibiotic-loaded cement spacer implantation in two-stage revision surgery. Journal of chemotherapy 2015. | 27. Romano CL et al. Two-stage revision surgery with preformed spacers and cementless implants for septic hip arthritis: a prospective, nonrandomized cohort study. BMC Infect Dis. 2011. | 28. Bertazzoni Minelli E et al. Release of gentamicin and vancomycin from temporary human hip spacers in two stage revision of infected arthroplasty. J Antimicrob Chemother. 2004. | 29. Data on File, Heraeus Medical (2020). As tested in vitro for S. aureus and E. coli bacteria. | 30. For further instructions on limited patient mobility, please consult the Instructions for Use of COPAL® knee moulds.

Figure 1: adapted from Tai et al. Microbiology of Hip and Knee Periprosthetic Joint Infections: A Database Study 2022, Figure 2: Data on File, Heraeus Medical (2024)

For more information, visit www.heraeus-medical-usa.com or call 1.833.PALACOS.

