

PALACOS®
PERFECTED

COPAL® exchange G

PREFORMED SPACERS FOR SUPPORTING PJI TREATMENT

YOUR ELEMENT OF SUCCESS IN INFECTION MANAGEMENT

COPAL EXCHANGE G PREFORMED SPACERS

MEET YOUR ELEMENT OF SUCCESS IN INFECTION MANAGEMENT.

In addition to being a clinically devastating complication, periprosthetic joint infections (PJI) in the U.S. number over 30,000 annually, with a yearly cost exceeding \$1.62 billion.¹ Which is why it is more important than ever to have an effective, efficient, go-to solution within reach.

For two-stage revision procedures, **COPAL® exchange G** integrates minimized wear² and outstanding stability into an easy-to-use preformed design. All to help orthopedic surgeons increase efficiency, efficacy, and reduce OR time.



FAST

Reduced OR time by up to 15 minutes minimizes further infection risk³ and lessens the economic impact on facilities by up to \$735.^{4,5}*



STABLE

Proven to result in fewer structural complications; including fracture²², instability, and subluxation.⁸



CONSISTENT

Engineered for consistent, reproducible sizing, elution rates, and mechanical stability from batch-to-batch.



SECURE

Receive peace of mind with limited surgeon product liability.⁹



MOBILE

Proven to facilitate patient mobility during 2-stage revision interims^{6,7}



SIMPLE

Ready to use for immediate implantation.

TIME IS MONEY, SAVE MORE.

Preformed spacers like **COPAL® exchange G** have been shown to save facilities up to \$735^{4,5} (or 15 minutes*) in O.R time per case when compared to moulded or handmade spacers.

Cutting O.R time also minimizes patient exposure to potential re-infection³.

*Compared to complete polymerization cycle for a handmade or moulded spacer. Time saved will vary based on environmental factors and cement type.

**When used according to manufacturer IFUs

DESIGNED FOR PATIENT COMFORT

PERFORMED FOR OPTIMIZED PERFORMANCE.

Employing cutting-edge innovation, advanced materials, and groundbreaking manufacturing technologies, **COPAL® exchange G** spacers represent the state-of-the-art for supporting PJI treatment.³

The **COPAL® exchange G** portfolio features a range of sizes to accommodate patient needs. For the hip, choose between a variety of stem lengths, head sizes, and medial widths to fit patients with varying degrees of bone loss, as well as variances in patient natural bone size.

For knees, our spacers provide a range of motion over 90 degrees for increased flexion. The single radius design of the femur and highly congruent articulation of the femoral and tibial components are designed to improve stability and lower the risk of dislocation.

For a full list of dimensions and offerings, please contact a local representative, or scan below.



FORMULATED FOR INNOVATION

PALACOS® Perfected

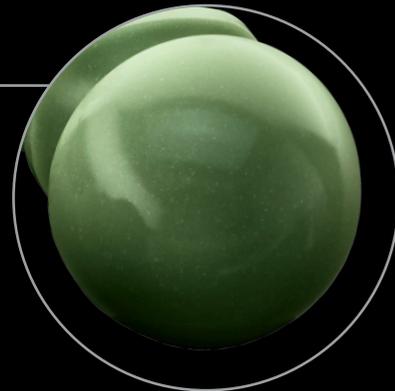
With experience and expertise earned from over 34 million procedures and more than 60 years of manufacturing, PALACOS® cements - optimized for efficacy in COPAL® exchange G spacers - are extensively proven⁹, highly dependable, and widely respected.

Capitalizing on this history of cement innovation, COPAL® exchange G spacers are created using a state-of-the-art, proprietary one-piece moulding process for a remarkably smooth surface (see below).

The only green preformed spacer on the market, COPAL® exchange G spacers are also the only currently available preformed spacer formulated with the radiopacifier calcium carbonate (CaCO₃) instead of the traditional barium sulfate.² As calcium carbonate is water soluble, this radiopacifier choice lessens the potential of hazardous wear particles in the body, while also increasing the antibiotic efficacy of the spacer.¹⁰

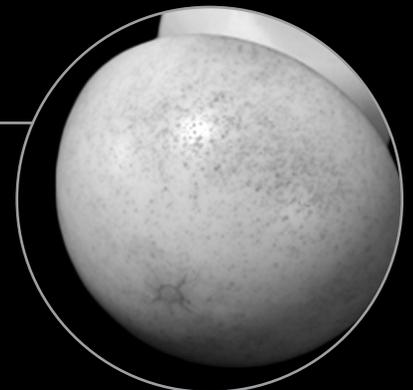
COPAL® exchange G Spacers

- Smooth surface quality is perceived to result in lower friction during articulation***
- Fewer abrasion and wear-particles due to unique cement formula¹⁰
- PALACOS®-green color provides bright contrast against patient bone bed¹¹
- Hydrophilic cement matrix provides extended antibiotic efficacy^{12, 14}



Traditional Preformed Spacers

- Traditional de-moulding processes can result in abrasive articulating surfaces
- Higher surface porosity is perceived to result in increased friction and osteolysis-inducing particles***
- Barium sulfate-based cement formula allows for higher x-ray contrast compared to calcium sulfate-based cements¹¹



***Gathered from US surgeon opinion, 2022

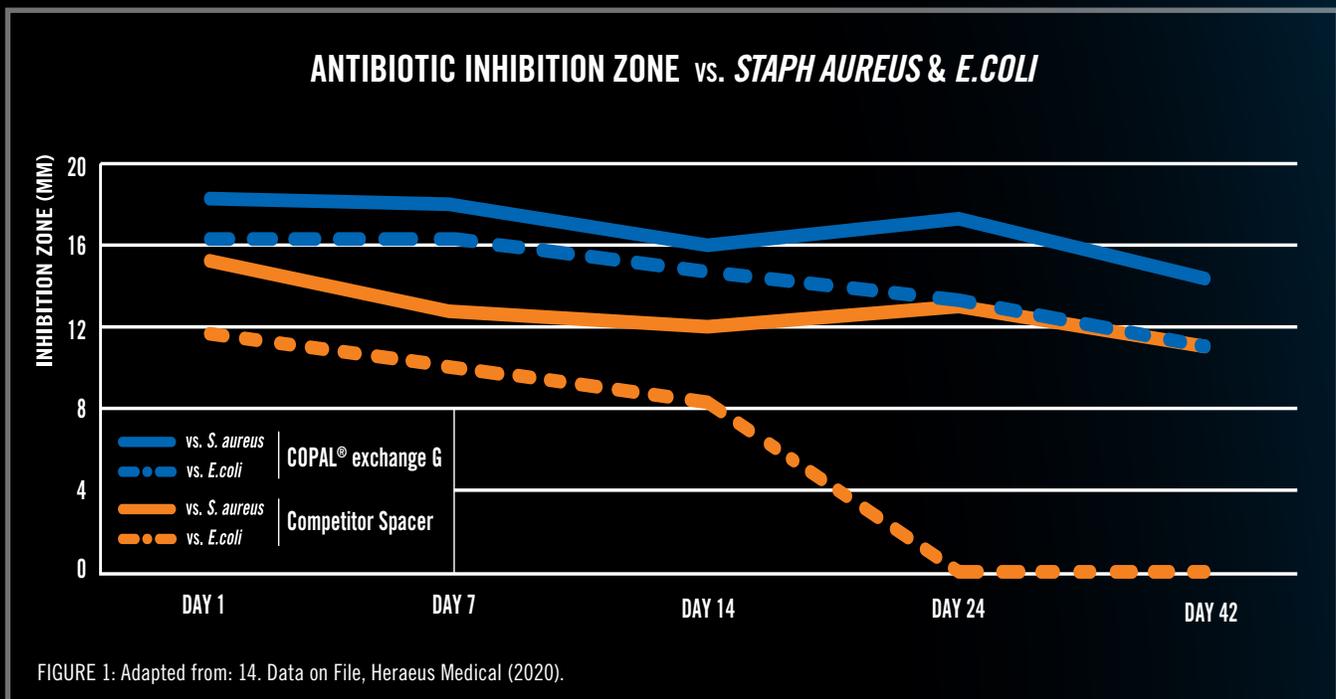
DEVELOPED FOR INFECTION MANAGEMENT SUPPORT

Increase Your Antibiotic Efficacy Against PJI

PJI is notoriously difficult to treat due to its broad spectrum of infection-causing bacteria and the prevalence of prosthesis-bound biofilms. Since the first spacer introduction in the 1980s¹³, the field has been constantly evolving to provide surgeons and patients more effective and efficient treatment methods. **COPAL® exchange G** preformed spacers are proud to continue the path of PJI innovation.

Developed with the same base structure and strong antibiotic profile as PALACOS® cements with gentamicin, **COPAL® exchange G** preformed spacers take increased elution kinetics to the next level - **extending their antibiotic efficacy over 42 days**.¹⁴

Intended to further optimize their elution profile, the cement used in the creation of **COPAL® exchange G** spacers is created with calcium carbonate (CaCO₃) instead of traditional barium sulfate, which allows for an increase in antibiotic release.¹⁰



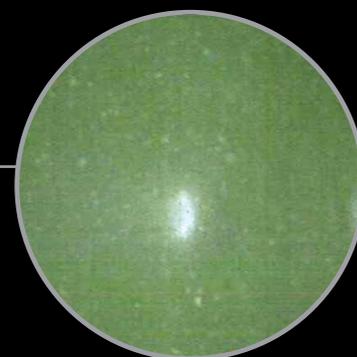
MANUFACTURED FOR WEAR RESISTANCE

Limit Spacer Friction in Knees...

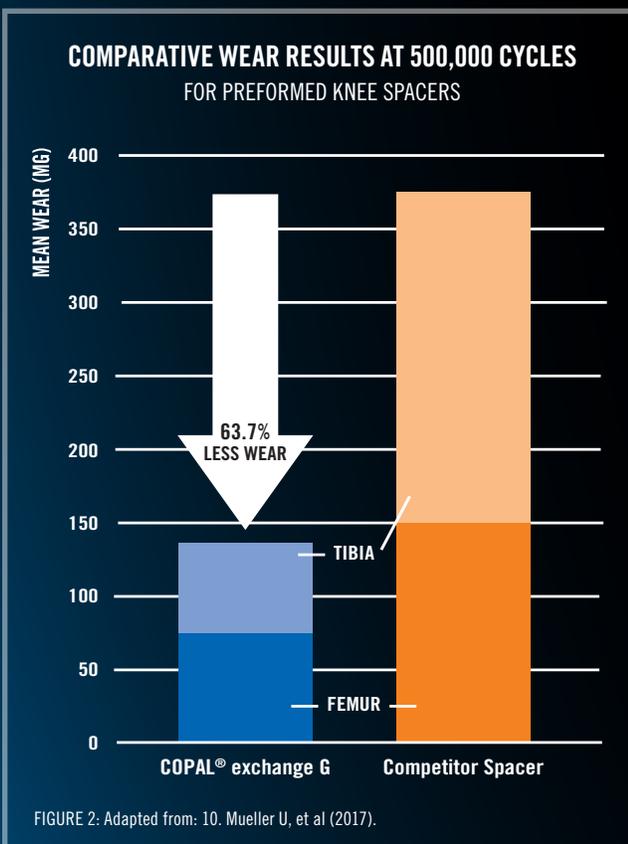
Generally, articulating spacers are preferred over static spacers if the patient's health allows.^{7,13} However, the resulting articulation during joint movement results in increased friction and particle wear over the life of the spacer. The presence of these wear particles in the body have been associated in proinflammatory reactions, osteolysis, and potentially decreased performance of the final prosthesis.^{10,16-18}



Competitive hip spacer head surface pre-testing¹⁹



COPAL[®] exchange G hip spacer head surface pre-testing²⁰



...and Hips.

In comparative testing, **COPAL[®] exchange G** knee spacers were found to minimize this pro-inflammatory and osteolysis-inducing wear by up to 63.7% vs competitor spacers (Fig 2). The released wear particulates were also found to be 1/3 smaller with **COPAL[®] exchange G** than with competitor spacers.¹⁰

COPAL[®] exchange G hip spacers were found to provide increased resistance to in-vitro wear cycles and visually, fewer wear particles and a smoother surface were noted both before and after running testing^{19,20}

15. Guild III, et al. (2014). Articulating vs. static antibiotic impregnated spacers in revision total knee arthroplasty for sepsis. A systematic review. *J. Arthroplasty*, 29(3), 558-63.
 16. Wimhurst, J.A.; Brooks, R.A.; Rushton, N. The effects of particulate bone cements at the bone-implant interface. *J. Bone Jt. Surg. Br. Vol.* 2001, 83, 588-92.
 17. Sun, S.G., et al. Effects of bone cement particles on the function of pseudocapsule-derived fibroblasts. *Acta Orthop.* 2006, 77, 320-8.

TESTED FOR PROVEN PERFORMANCE

Improve Patient Comfort, Increase Patient Mobility.

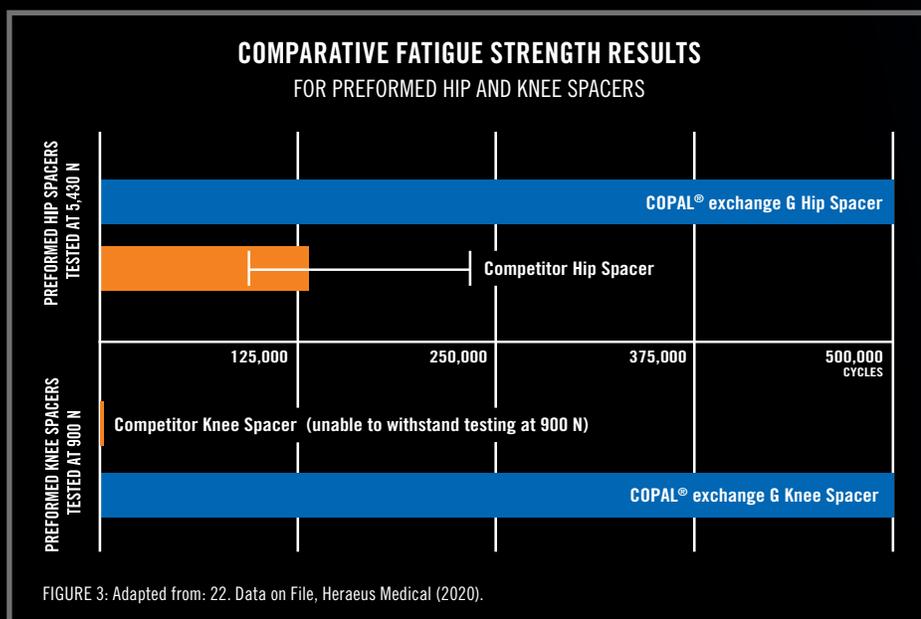
PJI is a devastating complication with serious complications for patient quality of life. With the help of articulating spacers, patients may be able to continue with activities of daily living throughout revision interims.⁷ As traditional spacers are associated with various complications²¹, it is Heraeus Medical's goal to provide a more robust and mechanically stronger solution.

COPAL® exchange G spacers are that solution.

To ensure this, all **COPAL® exchange G** products have undergone rigorous in-vitro compression and fatigue testing.

After 6-months of cyclical fatigue stress (500,000 steps at 1,200 lbs), **COPAL® exchange G** hip spacers showed no visible damage (Fig 3). At that same stress level, competitor hip spacers presented multiple fractures. Under similar in-vitro stress testing conditions (500,000 steps at 200 lbs), **COPAL® exchange G** knees showed no breakage. During testing, competitor spacers were unable to withstand the same amount of stress.²²

Part of the reason for this success is the implant-styled reinforced metal inlay embedded into our hip spacers. This inlay runs from the top of the head to the distal stem, and is strengthened at the neck of the spacer (see x-ray below); providing additional durability to **COPAL® exchange G** spacers.*



*Compared to handmade spacers without metal inlay

COPAL EXCHANGE G PREFORMED SPACERS

Advantages at a Glance:

- ✓ Improve Patient Comfort^{1,22,10}
- ✓ Enhance Stability²²
- ✓ Reduce Friction¹⁰
- ✓ Increase Patient Mobility⁶⁻⁷
- ✓ Reduce Re-Infection Risk^{3-5,14}
- ✓ Increase Antibiotic Efficacy¹⁴
- ✓ Save up to 15 Minutes and \$735 of O.R time⁵⁻⁶



PRODUCT	DESCRIPTION	CONTENT	REF
COPAL® exchange G Hip	Preformed hip spacer with gentamicin	S short: 46 mm head x 135 mm stem	5034793
		M short: 54 mm head x 135 mm stem	5034791
		L short: 60 mm head x 135 mm stem	5034788
		S medium: 46 mm head x 184 mm stem	5147215
		M medium: 54 mm head x 184 mm stem	5147216
		S long: 46 mm head x 251 mm stem	5034792
		M long: 54 mm head x 251 mm stem	5034790
		L long: 60 mm head x 251 mm stem	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

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

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