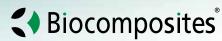
# SYNICEM

PREFORMED TO MAINTAIN SPACE AND AID TREATMENT OF INFECTION





### SYNICEM™

## Preformed spacers to maintain space and aid treatment of infection

The **SYNICEM** spacer range provides a ready-to-use preformed spacer with the performance characteristics you need for your 2-stage revision procedures.

Designed to overcome the challenges of using traditional intra-operative moulded and handmade spacers, **SYNICEM** spacers support revisions of the hip, knee and shoulder to preserve articular space and aid the treatment of infection.



"Mechanical complication rates are higher in 'bespoke' or handmade dynamic spacers which are time-consuming to make and prone to fracture" 1

#### Preformed for improved performance

#### **Preformed spacers**

- ✔ Precision engineered for consistency and structural uniformity
- Designed for dynamic movement and stability
- ✓ Preloaded with gentamicin to aid treatment of infection
- ✓ Case-by-case flexibility and time-saving

#### **Intra-operatively prepared spacers**

- ✗ Inconsistent spacer design and mechanical endurance<sup>1,2</sup>
- ✗ Structural strength varies by antibiotic concentration³
- Unpredictable antibiotic availability due to lack of uniform mixing and irregular porosity, roughness and size<sup>4</sup>
- ✗ Requires dedicated intra-operative time and expertise<sup>1,5</sup>

SYNICEM simplicity Test Match Open and place

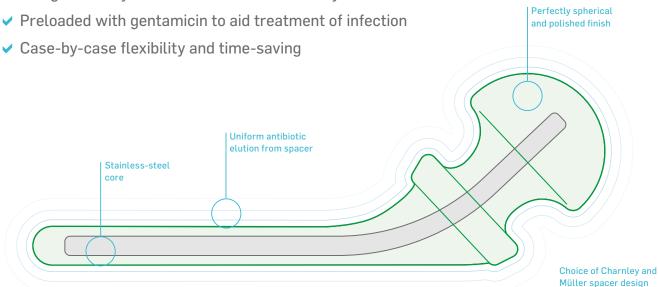
#### Hip

## Specifically designed to support your management of infection in hip revision

Combining convenience, structural uniformity and stability, whilst delivering a high local concentration of gentamicin.

SYNICEM hip spacers maintain joint space and limb length to preserve the abduction and stabilisation structure of the hip.<sup>6</sup>

- Precision engineered for consistency and structural uniformity
- Designed for dynamic movement and stability



### Precision engineered for consistency and structural uniformity

Strictly controlled manufacturing conditions minimise the risk of mechanical failure by eliminating unwanted variation in the shape and structural integrity of the base material.

- Perfectly spherical and polished finish of the femoral head prevents bone stock wear<sup>6</sup>
- Lower complication rates and risk of periprosthetic fracture compared to intra-operatively prepared spacers<sup>1</sup>

### Preloaded with gentamicin to aid treatment of infection

The spacer yields a high local concentration of gentamicin while maintaining low systemic levels to aid the treatment of infection.<sup>6</sup>

### Designed for dynamic movement and stability

Designed to maintain joint space and limb length to preserve the abduction and stabilisation structure after removal of the original implant.<sup>6</sup>

- Choice of Charnley and Müller spacer design
- Uniform stainless-steel core to increase mechanical resistance



### Case-by-case flexibility and time-saving

A comprehensive range of sizes and styles provide case-by-case flexibility, with a reusable spacer tray available to ensure you select the correct size every time.<sup>6</sup>

✓ No moulding required



SYNICEM spacers Ready-to-use in under a minute



Prepared intra-operatively 16 minutes per spacer fitting<sup>5</sup>



Trial spacer tray

#### SYNICEM hip spacers with gentamicin

Model	Model type	Head diameter	Neck angle	Offset	Stem length	Gentamicin content*	Order code
40C	Charnley	40 mm	137°	23.9 mm	127 mm	1.6 grams	880970
48C	Charnley	48 mm	137°	29.5 mm	130 mm	2.5 grams	880980
56C	Charnley	56 mm	137°	32.8 mm	130 mm	3.7 grams	880990
40CXL	Charnley	40 mm	137°	23.9 mm	250 mm	2.1 grams	880991
48CXL	Charnley	48 mm	137°	29.5 mm	250 mm	3.0 grams	880968
56CXL	Charnley	56 mm	137°	32.8 mm	250 mm	4.2 grams	880969
48M	Müller	48 mm	137°	20.7 mm	120 mm	2.7 grams	880975
56M	Müller	56 mm	137°	24.7 mm	127 mm	3.8 grams	880985
Reusable trial	Regular	-			-	-	882036
spacer tray	XL	-			-	-	882038

<sup>\*</sup>May vary by ±5%

#### Knee

## Specifically designed to support your management of infection in knee revision

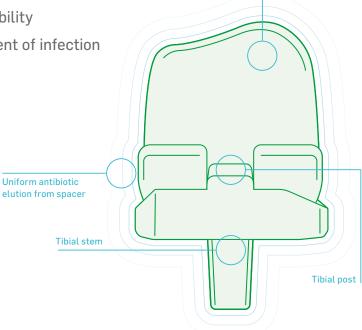
Combining convenience, structural uniformity and stability, whilst delivering a high local concentration of gentamicin. **SYNICEM** knee spacers maintain articular space, limb length and ligament structure.<sup>6</sup>

Precision engineered for consistency and structural uniformity



Preloaded with gentamicin to aid treatment of infection

Case-by-case flexibility and time-saving



Left and right geometries

for each knee

### Precision engineered for consistency and structural uniformity

Strictly controlled manufacturing conditions minimise the risk of mechanical failure by eliminating unwanted variation and ensuring the uniform shape and structural integrity of base material.

✓ Intra-operatively prepared spacers are timeconsuming to make and prone to fracture.¹

### Preloaded with gentamicin to aid treatment of infection

The spacer yields a high local concentration of gentamicin while maintaining low systemic levels to aid the treatment of infection.<sup>6</sup>

### Designed for dynamic movement and stability

Designed to maintain the articular space, limb length and ligament structure after removal of the original implant.<sup>6</sup>

- ✓ Specific left and right geometries for each knee
- Tibial stem ensures stability of the tibial component
- ✓ Tibial post aligns the femoral component

### Case-by-case flexibility and time-saving

A comprehensive range of sizes and styles provide case-by-case flexibility, with a reusable spacer tray available to ensure you select the correct size every time.<sup>6</sup>

✓ No moulding required



SYNICEM spacers Ready-to-use in under a minute

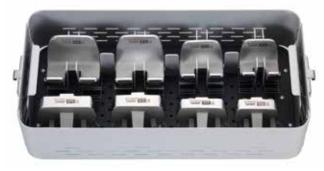


Prepared intra-operatively 14 minutes per spacer fitting<sup>5</sup>





Right knee spacer



Trial spacer tray

#### SYNICEM knee spacers with gentamicin

Model	Stem inclusion	Knee spacer orientation	Femoral medial /lateral	Femoral anterior /posterior	Tibial medial /lateral	Tibial anterior /posterior	Gentamicin content*	Order code
RD58	<b>V</b>	Right	58 mm	45 mm	65 mm	43 mm	3.2 grams	880961
RI58	<b>~</b>	Left	58 mm	45 mm	65 mm	43 mm	3.2 grams	880962
RD65	<b>✓</b>	Right	65 mm	45 mm	73 mm	43 mm	3.5 grams	880963
RI65	<b>✓</b>	Left	65 mm	45 mm	73 mm	43 mm	3.5 grams	880964
RD72	<b>✓</b>	Right	72 mm	54 mm	77.5 mm	50 mm	5.3 grams	881266
RI72	<b>✓</b>	Left	72 mm	54 mm	77.5 mm	50 mm	5.3 grams	881267
RD79	<b>V</b>	Right	79 mm	54 mm	85 mm	50 mm	5.5 grams	880966
RI79	<b>V</b>	Left	79 mm	54 mm	85 mm	50 mm	5.5 grams	880967
Reusable trial spacer tray	-	-					-	882037

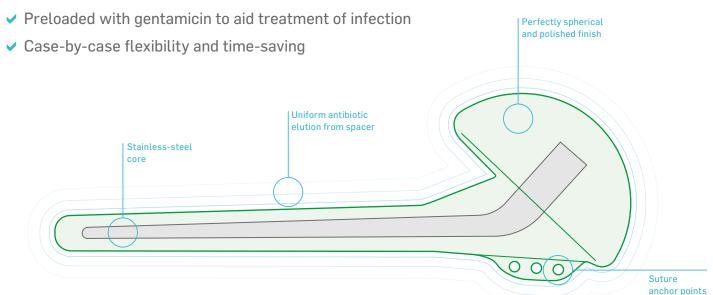
#### Shoulder

## Specifically designed to support your management of infection in shoulder revision

Combining convenience, structural uniformity and stability, whilst delivering a high local concentration of gentamicin.

SYNICEM shoulder spacers reliably stabilise the shoulder, while maintaining the articular space, limb length and muscle structure.<sup>6</sup>

- Precision engineered for consistency and structural uniformity
- Designed for dynamic movement and stability



### Precision engineered for consistency and structural uniformity

Strictly controlled manufacturing conditions minimise the risk of mechanical failure by eliminating unwanted variation in the shape and structural integrity of the base material.

- Perfectly spherical and polished finish of the humeral head prevents bone stock wear<sup>6</sup>
- ✓ Intra-operatively prepared spacers are timeconsuming to make and prone to fracture.¹

### Preloaded with gentamicin to aid treatment of infection

The spacer yields a high local concentration of gentamicin while maintaining low systemic levels to aid the treatment of infection.<sup>6</sup>

### Designed for dynamic movement and stability

Designed to maintain articular space, limb length and muscle structure after removal of the original implant.<sup>6</sup>

- Uniform stainless-steel core to increase mechanical resistance
- Suture anchor points allow rotator cuff to be secured to the spacer

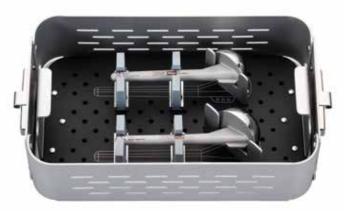
### Case-by-case flexibility and time-saving

A comprehensive range of sizes and styles provide case-by-case flexibility, with a reusable spacer tray available to ensure you select the correct size every time.<sup>6</sup>

✓ No moulding required







Trial spacer tray

#### SYNICEM shoulder spacers with gentamicin

Model	Head diameter	Stem length	Gentamicin content*	Order code
H40	40 mm	120 mm	1.0 grams	881220
H48	48 mm	120 mm	1.5 grams	881221
Reusable trial spacer tray	-	-	-	882039

<sup>\*</sup>May vary by ±5%

#### STIMULAN®

## Perfect partner for your infection management strategy

**STIMULAN** is a truly absorbable calcium sulfate antibiotic carrier specifically designed to support the proactive management of dead space and surgical site infection, with unrivalled flexibility and the broadest surgical application.<sup>7</sup>

- ▼ The only calcium matrix approved for use in bone and soft tissue
- Easily mixed with liquid and powder antibiotics
- Freedom to tailor antibiotic to clinical need



STIMULAN is uniquely recrystallised for consistent and reliable performance in carrying antibiotics to a site of infection

#### The Biocomposites Companion

Your essential guide to making the most of **SYNICEM** spacers and **STIMULAN** – all in one straightforward app.

- ✓ How to prepare: step-by-step videos
- ✓ Top tips: tried and tested advice for surgeons
- ✓ FAQs: common questions answered
- ✓ Product range: what's available

To download your Biocomposites Companion, simply scan the QR code.









- 1. Craig, A., King, S.W., van Duren, B.H., Veysi, V.T., Jain, S., & Palan, J. (2022). Articular spacers in two-stage revision arthroplasty for prosthetic joint infection of the hip and the knee. *EFORT Open Reviews*, 7, 137 152.
- 2. D'Angelo, Fabio, L. Negri, Giovanni Zatti and F. A. Grassi. "Two-stage revision surgery to treat an infected hip implant. A comparison between a custom-made spacer and a pre-formed one." La Chizurgia degli grappi di movimento 90.3 (2005): 271-9
- 3. Dunne, N., Hill, J., McAfee, P., Todd, K., Kirkpatrick, R., Tunney, M., & Patrick, S. (2007). In vitro study of the efficacy of acrylic bone cement loaded with supplementary amounts of gentamicin: effect on mechanical properties, antibiotic release, and biofilm formation. Acta orthopaedica, 78(6), 774–785.
- 4. Quanjun Cui; William M Mihalko; "Antibiotic-impregnated cement spacers for the treatment of infection associated with total hip or knee arthroplasty". The Journal of Bone and Joint Surgery, American Volume, 89(4):871-82, APR 2007.
- Moerenhout, K., Steinmetz, S., Vautrin, M., Picarra, S., Udin, G., & Borens, O. (2021). Economic advantage of 'self-made' antibiotic-loaded spacer compared to prefabricated antibiotic-loaded spacer and spacer molds in two-staged revision arthroplasty. Acta orthopaedica Belgica, 87(3), 557–562.
- 6. Synimed, Synicem Instruction for Use
- 7. Biocomposites, STIMULAN Instruction for Use.

For indications, contraindications, warnings and precautions see Instructions for Use. Concurrent use of locally administered antibiotics may affect setting time, absorption characteristics and/or bone formation. It is the surgeon/healthcare professional's responsibility to give due consideration to the details in the medicinal product marketing authorization in deciding whether it is appropriate for the patient under his/her care. The relevant Summary of Product Characteristics (SmPC) must be consulted. The type and dose of medicinal substance should also be assessed according to the individual natient's clinical circumstance.

This brochure may include the use of STIMULAN or techniques that go beyond the current clearance / approval granted by the relevant regulatory authority. Please contact your local representative for further information.

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Patents granted: GB2367552, EP1204599B1, US6780391, EP2594231B1, US8883063, CNZL201210466117. X, GB2496710, EP3058899B1, US10390954, US10, 588, 748, CNZL201610089710.5

Patents pending: GB1502655.2, GB1704688.9, EP 18275044.8, US 15/933936, CN 108619579A

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- ✓ Precision engineered for consistency and structural uniformity
- ✓ Designed for dynamic movement and stability
- ✓ Preloaded with gentamicin to aid treatment of infection
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At Biocomposites, we are proud to be driving improved outcomes across a wide range of clinical applications for patients and surgeons. Our acquisition of Synimed strengthens our portfolio of pioneering products for use in bone and soft tissue infection. Based in Keele, UK, with global operations across Europe, USA, Canada, Argentina, China and India our products are now used in over 800,000 procedures every year and sold in more than 100 countries around the world.

#### Find out more at biocomposites.com

The Synicem range is manufactured by Synimed and distributed by Biocomposites.

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