

EXACTECH | SPACERS

Operative Technique



InterSpace[®]

Hip, Knee and Shoulder

The first commercially available
preformed spacer technology.

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INTRODUCTION

Infected arthroplasty is the most devastating complication for the patient and surgeon. Kapadia et al. found that the mean episode cost, length of hospitalization, and median readmissions was significantly higher in an infected group when compared to the matched cohort of patients with periprosthetic infections and those who underwent primary total joint arthroplasty: \$88,623 vs \$25,659, 7.6 vs 3.29 days, and 2 vs 0, respectively.¹ Oftentimes, the diagnosis is difficult with only a small percentage identified based on history and physical examination.

As a result, it becomes necessary to validate the infection with laboratory testing and aspirating the patient's joint. In the past, the options available to a surgeon treating a septic revision were limited to long and costly procedures, and the patient was forced to endure ongoing pain and immobilization.

In recent years, the two-stage process has become the gold standard for treating an infected joint.² InterSpace® Knee, Hip and Shoulder are the first preformed temporary spacers for use in a two-stage septic revision arthroplasty. InterSpace offers more than just speed and time saved in the OR,³ it provides standardized geometries with reliable and reproducible mechanical and pharmacological properties.

InterSpace provides surgeons and patients the following advantages:

- Maintains joint space and allows limited mobility with partial weight-bearing^{2,4*}
- Improves quality of life between procedures²
- Yields predictable and consistent local antimicrobial activity compared to other treatment options^{3,5,6}
- Reduces hospitalization and allows for a seamless transition to physical therapy^{7,9}
- Stabilizes or tensions the soft tissues and reduces bone loss between stages, potentially facilitating easier re-implantation during a second-stage procedure^{2,7,9}
- Offers functional success rates equivalent to non-infected revisions¹⁰

The InterSpace Knee and Hip should be used with mobility-assisting devices throughout the period of implantation. The duration of implantation should not exceed six months, at which time it must be explanted and replaced with a permanent device.

** Partial weight-bearing must be assessed on an individual basis with relation to the anatomic condition of the local bone, bone quality and clinical conditions of the patient during rehabilitation stages. Care must be taken to minimize the risk of damaging bone tissue and the implant through excessive weight-bearing or forced mobilization.*

INTERSPACE KNEE

PREOPERATIVE PLANNING



InterSpace Knee is a preformed, articulating, partial load-bearing structure comprised of gentamicin-impregnated PMMA bone cement. InterSpace Knee is indicated as a temporary solution for skeletally mature patients undergoing the first stage of a two-stage revision arthroplasty undertaken as a result of joint sepsis. InterSpace Knee is not intended for use over 180 days, meaning the second stage of the revision arthroplasty, or another appropriate procedure, must take place within 180 days of InterSpace Knee implantation and the InterSpace Knee must be removed.

InterSpace Knee resembles an ultra-congruent condylar knee prosthesis. It consists of two articulating independent elements. The tibial component has a flat base upon which the femoral component articulates. InterSpace Knee is applied on the femoral condyles and on the tibial plate following removal of the previous implant. InterSpace Knee ATS is optional when a large tibial defect is present. Both components are to be fixed with Cemex® Genta Bone Cement. Because of the inherent mechanical limitations of the device material (gentamicin/polymethylmethacrylate), the InterSpace Knee is only indicated for patients who will consistently use traditional mobility assistance devices (e.g. crutches, walkers, canes) throughout the implantation period.

PREOPERATIVE PLANNING

No specific instrumentation is required to successfully implant InterSpace Knee; however, it is recommended that the following instruments and accessories be available for the procedure:

- **InterSpace Knee Trial** and **InterSpace Knee Templates**
- **Cemex® Genta Bone Cement**
- **AcuDriver® Automated Osteotome System**
 - Flat, Narrow Flexible Osteotome* and/or Sawblade
 - Notched Osteotome*
 - Impactor Osteotome*
- **Finishing Reamer**

Size appropriateness of the implant for the patient is based on the judgement of the surgeon with knowledge of the needs of the patient. The surgeon can become thoroughly familiar with the technique for implanting the device by reviewing relevant literature, revision knee surgery operative skills and techniques, and the instrumentation for sizing and implanting the InterSpace device. Additionally, transparent radiograph overlays and InterSpace Trial devices are available for this process. The selected implant should be that which is nearest to the size of the removed implant and achieves the best compromise between stability and joint mobility during the operation. Size selection for InterSpace Knee is based upon:

- Dimensions of the removed implants
- InterSpace Knee Trials and Templates
- The type of bone defect and remaining bone stock
- Ligamentous apparatus state
- Flexion and extension gaps

* Parts indicated for use with the AcuDriver Automated Osteotome System.

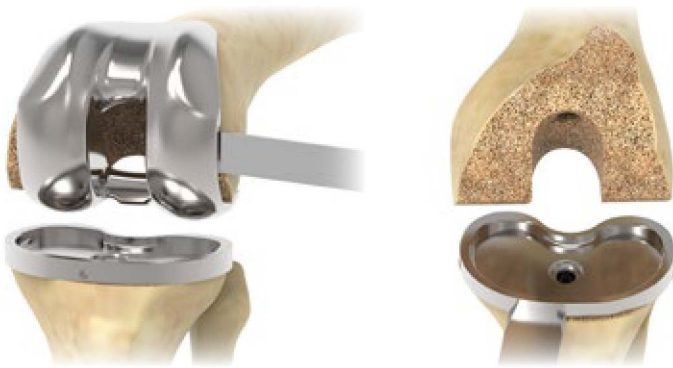


Figure 1

Flat, Narrow Flexible Osteotomes and/or a Sawblade can be Used to Transect the Prosthetic Components



Figure 2

Position the Trials into the Joint Space and Reduce the Knee

REMOVAL OF PROSTHETIC COMPONENTS

Infected components and residual bone cement must be removed from the femur, tibia and patella (*Figure 1*). Complete debridement of necrotic tissue should also be performed prior to implantation. This step is the most important process for successfully eradicating the infection.

FEMORAL SIZING AND TRIAL PLACEMENT

Select the correct implant size according to the guidelines referenced in "Preoperative Planning." The size to be implanted should be the nearest to the size of the removed implant and achieves the best compromise between stability and joint mobility during the operation. The use of the Augmented Tibial Stem (ATS) is recommended when there is tibial bone loss. Position the selected InterSpace Knee Trials into the joint space and reduce the knee (*Figure 2*).

Select the most suitable size on the basis of:

- Ligamentous apparatus state
- Flexion and extension gaps
- Dimensions of the removed implant
- Type of bone defect and when a significant amount of tibial bone loss has occurred (the use of InterSpace Knee ATS is recommended)

Position the selected InterSpace Knee and ATSTrials into the joint space and reduce the knee (*Figure 2*).

The knee should not be too tight during trialing as it will tighten further upon cement fixation of the femoral component. Tightness may be relieved through downsizing and/or recontouring the femoral bone to achieve a satisfactory fit. The optimal implant placement achieves the best compromise between stability and joint mobility during the operation and is stable in full extension and 90° flexion.

Note: The InterSpace Knee Trial must not be implanted. The thickness generated by the cement is not reflected in the trial.

DETAILED OPERATIVE TECHNIQUE

PLACEMENT OF THE FEMORAL COMPONENT



Figure 3

A Layer of Cement Should be Placed on the Bone-Mating Surface of the Femoral Component. The Femoral Component Should Then be Guided Onto the Distal Femur by Hand and Held in Place Until the Cement is Cured

PLACEMENT OF THE FEMORAL COMPONENT

Maintaining strict aseptic surgical techniques is important to the success of InterSpace Knee implantation. Thoroughly irrigate the joint with pulsatile lavage prior to implanting the femoral component. Take time to ensure the bone is dried and use clean, dry gloves for handling and implementing the InterSpace Knee. Avoid washing the spacer with aqueous solutions before or after implantation to maintain optimum levels of antibiotic release.

Fixation of the InterSpace Knee is indicated for Cemex Genta Bone Cement and is undertaken in two steps to minimize the possibility of inadvertently fusing the femoral and tibial components.

Ensure that the entire contact surface of the components is cemented to create continuity between spacer and bone. Missing or insufficient cement, especially in the posterior portion of the condyles, may weaken the structure of the device.

Apply a layer of highly viscous, very thick (doughy) bone cement to the non-articulating surface of the selected femoral

component. Next, manually place the femoral component onto the distal femur (*Figure 3*).

Due to the incongruity between the remaining femoral bone and the interior geometry of the InterSpace Knee, the femoral component may not rest “flush” on the distal femur. Take care not to force the component into position as this could result in fracturing the prosthesis itself.

DO NOT use an impactor and mallet to seat the prosthesis as this can fracture the implant. Remove all extruded bone cement, maintaining femoral component position until the cement fully cures.

A very doughy bone cement helps to prevent a strong fixation and minimizes interdigitation of the trabecular bone. The goal of the cementation is to provide a satisfactory fixation while allowing for an easy removal during the second-stage procedure.

Note: *The InterSpace Knee is a temporary device designed to accommodate various geometries. Additional bone cement can help compensate for incongruity that might exist between the distal femur and the femoral component.*

DETAILED OPERATIVE TECHNIQUE

PLACEMENT OF THE TIBIAL COMPONENT

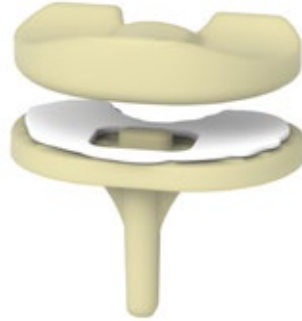


Figure 4

Apply Bone Cement to the Proximal Surface of the ATS and Affix to the Distal Surface of the Articular Tibial Insert



Figure 5

Apply Bone Cement to the Non-Articulating Surface of the Tibial Component and Guide onto the Proximal Tibia by Hand



Figure 6a

Remove All Excess Bone Cement

PLACEMENT OF THE TIBIAL AND ATS COMPONENTS

The use of InterSpace Knee ATS is highly recommended when a large tibial defect is present. If no large tibial defect is present, placement of the tibial component without the InterSpace Knee ATS may be most suitable.

Prepare a fresh batch of Cemex Genta Bone Cement.

Connect the selected sizes of the tibial and ATS components by applying a layer of highly viscous, very thick (doughy) bone cement between the two components (*Figure 4*). Then, manually position them on the proximal tibia, taking care to remove all excess bone cement (*Figure 5*). Reduce the knee, move into extension and flex-extend the knee several times,

all prior to the final setting of the cement. This allows the tibial component to “self-center” with the femoral component, ensuring proper tracking of the InterSpace Knee.

Make sure that the entire contact surfaces of the components are cemented to create continuity between them. Missing or insufficient cement may weaken the structure of the device. Final curing of the bone cement should be accomplished with the knee in extension (*Figure 6a*).

DETAILED OPERATIVE TECHNIQUE

PLACEMENT OF THE TIBIAL COMPONENT



Figure 6b

Remove All Excess Bone Cement

PLACEMENT OF THE TIBIAL COMPONENT (WITHOUT ATS)

Prepare a fresh batch of Cemex Genta Bone Cement.

Apply a layer of highly viscous, very thick (doughy) bone cement to the proximal surface of the tibia as well as the non-articulating surface of the selected tibial component.

Manually position the InterSpace tibial component on the proximal tibia, taking care to remove all excess of bone cement (*Figure 6b*). Make sure that the entire contact surfaces of the components are cemented to create continuity between them. Missing or insufficient cement may weaken the structure of the device.

Reduce the knee, move into extension and flex-extend the knee several times, all prior to the final setting of the cement. This allows the tibial component to “self-center” with the femoral component, ensuring proper tracking of the InterSpace Knee. Final curing of the bone cement should be accomplished with the knee in extension.



Figure 7

Excess Bone Cement Should be Cleared From all Edges of the Prosthesis and Articulating Surfaces Prior to Final Reduction

FINAL REDUCTION OF THE KNEE

Care must be taken to ensure that no unpolymerized bone cement remains on the articulating surfaces that could fuse the joint and/or accelerate the wear process (Figure 7).

Reduce the knee and close in standard fashion. The knee must be stable, not too tight, and should have a joint extension ranging from 0 to 90 degrees.

Note: Care should be taken to keep the wound dry once the final spacer implant has been placed. Any attempt to lavage the joint can result in a loss of antibiotic at the surface of the implant.

POSTOPERATIVE CARE

Generally, the postoperative treatment is similar to a primary knee prosthesis, but weight-bearing shall be limited (e.g. use of crutches). Partial weight-bearing must be assessed on an individual basis in relation to the anatomic conditions of the femur and tibia, bone trophism and the clinical conditions of the patient during rehabilitation stages.

Excessive weight-bearing and forced mobilization should be avoided to minimize the risk of InterSpace damaging the biological structure. Temporary use of an articulated

postoperative orthosis may be prescribed if the surgeon deems it necessary based on the stability achieved and the condition of the extensor apparatus.

Ultimately, the degree of weight-bearing and mobility must be evaluated by the surgeon on a patient-by-patient basis and moderated as appropriate.

Note: *InterSpace Knee is to be used with mobility-assisting devices throughout the period of implantation.*

EXPLANATION

The InterSpace device is not intended for use as a permanent prosthesis and must be removed within 180 days of implantation. Osteotomes, mallets and other revision instruments may be used to aid in the explanation procedure. Care should be taken to ensure that the wound site is thoroughly cleaned of all bone cement debris prior to implantation of a definitive prosthesis or performing an alternative surgical procedure (e.g. resection arthroplasty, fusion, etc.). Failure to remove cement and/or bone debris may shorten the survival of the revision implant.

DISPOSAL

Disposal of the device should be in accordance with local waste regulations.

INTERSPACE HIP

PREOPERATIVE PLANNING



InterSpace Hip resembles a femoral prosthesis. It is made of a load-bearing structure in stainless steel, which is coated with gentamicin-impregnated PMMA bone cement. InterSpace Hip is indicated for skeletally-mature patients undergoing the first stage of a two-stage revision arthroplasty undertaken as a result of joint sepsis.

InterSpace Hip is inserted into the femoral medullary canal and the acetabular cavity following removal of the existing femoral and acetabular implants and a complete debridement. When distal anchorage is required, the InterSpace Hip Extra-Long (XL) is indicated. Also, the InterSpace Hip XL is recommended in the absence of proximal support, in the presence of large metaphyseal defects or after a transfemoral approach.

PREOPERATIVE PLANNING

No specific instrumentation is required to successfully implant InterSpace Hip; however, it is recommended that the following instruments and accessories be available for the procedure:

- **InterSpace Hip Trial** and **InterSpace Hip Templates**
- Cemex Genta Bone Cement
- AcuDriver Automated Osteotome System
 - Notched or **Vee Osteotomes*** (cemented femoral stem removal)
 - **Long Straight Gouge** and **Long Notched Osteotome*** (cement removal from distal stem level)
 - Flat, Narrow Flexible Osteotome* (cementless femoral stem removal)
 - **Small and/or Medium Cup Osteotome*** (cemented or cementless cup removal)
- **Rat Tail Rasp** or **Lateralizing Broach**
- **Femoral Canal Reamers (Conical, Flexible, Primary, etc.)**
- **Acetabular Reamer**
- Finishing Reamers (Straight, Tapered, etc.)
- **Head Impactor (poly-tipped only)**

Transparent radiograph overlays and InterSpace Trial devices are available for this process. The appropriate size for the InterSpace Hip is based on the fit of the head into the acetabular cavity and the condition of the femur. Additionally, the selected implant should be that which is nearest to the size of the removed implant and achieves the best compromise between stability and joint mobility during the operation. Size selection for the InterSpace Hip is based upon:

- Dimensions of the removed implants
- InterSpace Hip Trials and Templates
- The type of bone defect and remaining bone stock
- Ligamentous apparatus state
- Flexion and extension spaces

** Parts indicated for use with the AcuDriver Automated Osteotome System.*



Figure 8

Removal of all Proximal Cement and Bone Allows the Prosthesis to be Removed Without Incidence



Figure 9

Extract the Femoral Component

REMOVAL OF PROSTHETIC COMPONENTS

Infected components and residual bone cement must be removed from the femoral canal and acetabular cavity. Break up the cement mantle directing force inward toward the prosthesis. Remove all cement or bone proximally and laterally so that the prosthesis can be removed without fracturing the metaphyseal region of the bone (*Figure 8*).

Once the cement-implant interface is adequately disrupted, the femoral component can be extracted using an extraction instrument (*Figure 9*). A complete debridement of necrotic tissue should also be performed prior to implantation. This step is the most important process for successfully eradicating the infection.

DETAILED OPERATIVE TECHNIQUE

CANAL PREPARATION



Figure 10

Longer Osteotomes can be Used to Remove Bone Cement at the Distal Stem Level



Figure 11

Prepare the Femoral Canal to Ensure Removal of any Infected Components and/or Bone Cement

CANAL PREPARATION

The technique for removing a cemented or press fit prosthesis is similar. A Notched or Vee Osteotome may be used for cemented femoral stem removal, and a Long Straight Gouge and Long Notched Osteotome can be used for bone cement removal from the distal stem level (*Figure 10*). A Flat, Narrow Flexible Osteotome may be used for a cementless femoral stem removal.

It may be necessary to prepare the femoral canal in order to obtain optimal fit of the InterSpace Hip stem (*see page 12 for Trial Placement and Reduction*). Prepare the bone proximally with Straight or Tapered Reamers. The use of a Rat Tail Rasp or Lateralizing Broach may also be used for proximal bone preparation utilizing a direct anterior approach. Flexible Reamers may be used for distal reaming during final preparation of the femoral canal (*Figure 11*).

DETAILED OPERATIVE TECHNIQUE

ACETABULUM PREPARATION / TRIAL PLACEMENT AND REDUCTION



Figure 12

Cup Osteotomes are Used to Separate the Acetabular Cup From the Prosthesis-Cement or Prosthesis-Bone Interface



Figure 13

If Necessary, Ream the Acetabulum to Obtain Optimal Fit

ACETABULUM PREPARATION

The head of the InterSpace Hip must articulate directly with the acetabular cavity. A Small and/or Medium Cup Osteotome can be used for a cemented or cementless cup removal (*Figure 12*). It may be necessary to ream the acetabulum in order to obtain optimal fit of the InterSpace Hip head (*Figure 13*). However, appropriate care must be considered to maintain as much healthy bone stock as possible. Any standard Acetabular Reamers may be used in this instance.

TRIAL PLACEMENT AND REDUCTION

InterSpace Hip Trials are available to determine appropriate implant sizing. Insert the Trial into the femoral canal to verify stem fit (*Figure 14*). Once properly seated, reduce the hip joint to determine correct fit in the acetabular cavity. An adequate fit of the InterSpace Hip head into the acetabular cavity will assist in reducing the incidence of dislocation.

Note: *The InterSpace Hip Trial must not be implanted.*

DETAILED OPERATIVE TECHNIQUE

HIP IMPLANT PLACEMENT/POSTOPERATIVE CARE



Figure 14

Place Hip Trial Into Femoral Canal to Test the Stem Fit



Figure 15

Properly Seat Prosthesis With a Poly-Tipped Head Impactor. Cement Prosthesis Around Proximal Neck to Avoid Dislocation.

HIP IMPLANT PLACEMENT

Prior to inserting the InterSpace Hip, the femoral canal and acetabulum should be thoroughly irrigated with pulsatile lavage to ensure all debris is removed. Care should be taken to keep the wound dry before the spacer is inserted to avoid loss of antibiotic at the surface of the implant, as the spacer antibiotic is activated in an aqueous environment. A poly-tipped Head Impactor can be used to properly seat the InterSpace Hip (*Figure 15*). Final placement of the InterSpace Hip stem is recommended with Cemex Genta Bone Cement to provide proximal fixation and rotational stability. When inserting an InterSpace Hip Tapered Wedge, it is mandatory to fix the spacer with Cemex Genta Bone Cement. Only utilize a highly viscous bone cement in order to reduce the incidence of interdigitation of the trabecular bone and allow for easier clean up. Once InterSpace Hip has been correctly positioned and the bone cement cured, the hip joint may be reduced.

Note: A metal head impactor may fracture the Spacer. Do not subject the device to excessive forces.

Additional Note: Any attempt to lavage the joint can result in a loss of antibiotic at the surface of the implant.

POSTOPERATIVE CARE

Physical therapy can be administered at the discretion of the surgeon during the time the InterSpace Hip is implanted. Partial weight-bearing must be assessed on an individual

basis with relation to the anatomic condition of the femur and acetabulum, bone quality and clinical conditions of the patient during rehabilitation stages. Care must be taken to minimize the risk of damaging bone tissue and the implant through excessive weight-bearing or forced mobilization.

Ultimately, the degree of weight-bearing and mobility must be evaluated by the surgeon on a patient-by-patient basis and moderated as appropriate.

Note: *InterSpace Hip is to be used with mobility-assisting devices throughout the period of implantation.*

EXPLANATION

The InterSpace device is not intended for use as a permanent prosthesis and must be removed within 180 days of implantation. Osteotomes, mallets and other revision instruments may be used to aid in the explantation procedure. Care should be taken to ensure that the wound site is thoroughly cleaned of all bone cement debris prior to implantation of a definitive prosthesis or performing an alternative surgical procedure (e.g. resection arthroplasty, fusion, etc.). Failure to remove cement and/or bone debris may shorten the survival of the revision implant.

DISPOSAL

Disposal of the device should be in accordance with local waste regulations.

INTERSPACE SHOULDER

PREOPERATIVE PLANNING



InterSpace Shoulder is a preformed, partial load-bearing structure coated with gentamicin-impregnated PMMA bone cement. InterSpace Shoulder is indicated for skeletally-mature patients undergoing the first stage of a two-stage revision arthroplasty undertaken as a result of joint sepsis.

InterSpace Shoulder is similar in construct to the InterSpace Hip. It is a unipolar hemiarthroplasty reinforced with a stainless steel core. The InterSpace Shoulder is inserted into the humeral canal following removal of primary components and complete debridement.

PREOPERATIVE PLANNING

No specific instrumentation is required to successfully implant InterSpace Shoulder; however, it is recommended that the following instruments and accessories be available for the procedure:

- **InterSpace Shoulder Trial** and **InterSpace Shoulder Templates**
- Cemex Genta Bone Cement
- AcuDriver Automated Osteotome System
 - Notched or Vee Osteotomes* (cemented humeral stem removal)
 - Straight Gouge and Notched Osteotomes* (cement removal from distal stem level)
 - Flat, Narrow Flexible Osteotome* (cementless humeral stem removal)
- **Humeral Canal Reamers (Conical, Flexible, Primary, etc.)**
- **Glenoid Reamers**
- Finishing Reamers (Straight, Tapered, etc.)
- Head Impactor (poly-tipped only)
- **Cement Curette**

Size appropriateness should be confirmed through trial reduction, achieving a compromise between stability and joint mobility. The appropriate size for the InterSpace Shoulder is based on the fit of the head into the glenoid and the condition of the humerus. Size selection for the InterSpace Shoulder can be determined with the following:

- Dimensions of the removed implants
- InterSpace Shoulder Trials and Templates
- Remaining bone stock
- Flexion and extension spaces

* Parts indicated for use with the AcuDriver Automated Osteotome System.

DETAILED OPERATIVE TECHNIQUE

REMOVAL OF PROSTHETIC COMPONENTS / CANAL PREPARATION



Figure 16

Remove Primary Components and Debride Completely.
Take Care to Remove all Residual Bone Cement.

REMOVAL OF PROSTHETIC COMPONENTS

Infected components and residual bone cement must be removed from the humeral canal and glenoid cavity. Break up the cement mantle directing force inward toward the prosthesis. Remove all cement or bone proximally and laterally so that the prosthesis can be removed without fracturing the metaphyseal region of the bone. Once the cement implant interface is adequately disrupted, the humeral component can be extracted using an extraction instrument (*Figure 16*). A complete debridement of necrotic tissue should also be performed prior to implantation. This step is the most important process for successfully eradicating the infection.

CANAL PREPARATION

The technique for removing a cemented or press fit prosthesis is similar. A Notched or Vee Osteotome may be used for cemented humeral stem removal, and a Straight Gouge and Notched Osteotome can be used for cement removal from the distal stem level. A Flat, Narrow Flexible Osteotome may be used for a cementless humeral stem removal. It may be necessary to ream the humeral canal in order to obtain optimal fit of the InterSpace Shoulder stem. Prepare the bone proximally with Straight or Tapered Reamers. Flexible Reamers may be used for distal reaming during final preparation of the humeral canal.



Figure 17

Apply Cemex Genta Bone Cement to Underside of Head

GLENOID PREPARATION

The head of the InterSpace Shoulder must articulate directly with the glenoid cavity. It may be necessary to ream the glenoid in order to obtain optimal fit of the InterSpace Shoulder head. However, appropriate care must be considered to maintain as much healthy bone stock as possible. Any standard Glenoid Reamer may be used in this instance.

TRIAL PLACEMENT AND REDUCTION

InterSpace Shoulder Trials are available to determine appropriate implant sizing. Insert the Trial into the humeral canal to verify stem fit. Once properly seated, reduce the shoulder joint to determine correct fit in the glenoid cavity. An adequate fit of the InterSpace Shoulder head into the

scapular glenoid cavity will assist in reducing the incidence of dislocation.

Note: *The InterSpace Shoulder Trial must not be implanted.*

SHOULDER IMPLANT PLACEMENT

Prior to inserting the InterSpace Shoulder, the humeral canal and glenoid should be thoroughly irrigated with pulsatile lavage to ensure that all debris is removed. Care should be taken to dry the wound before the spacer is inserted to avoid loss of antibiotic at the surface of the implant, as the spacer antibiotic is activated in an aqueous environment. Cemex Genta Bone Cement can be applied to the underside of the head to avoid spacer rotation in cases of lysis or fragmentation of the proximal humeral bone (*Figure 17*).

DETAILED OPERATIVE TECHNIQUE

SHOULDER IMPLANT PLACEMENT



Figure 18

Manually Insert the InterSpace Shoulder Into the Humeral Canal While Approximating Anatomical Version



Figure 19

When Further Seating is Desired, use a Head Pusher or Head Impactor for Leverage

Peripheral placement will minimize cement extrusion into the humeral canal. DO NOT place cement directly into the humeral canal as this may hinder removal and lead to additional bone loss. Only utilize a highly viscous bone cement in order to reduce the incidence of interdigitation of the trabecular bone and allow for easier clean up.

Manually insert the InterSpace Shoulder into the humeral canal while approximating anatomical version (*Figure 18*).

InterSpace Shoulder can be applied using an anterior deltopectoral approach or a trans-deltoid approach. When further seating is desired, use a Head Pusher or Head Impactor for leverage (*Figure 19*). DO NOT impact the InterSpace Shoulder with a mallet directly as this can result in fracture of the device. Remove all extruding bone cement with a Cement Curette (*Figure 20*). Upon curing of bone cement, evaluate joint motion and reduce the shoulder. Close in standard fashion.

Note: A metal Head Impactor may fracture the Spacer. Do not subject the device to excessive forces.



Figure 20

Remove all Extruding Bone Cement With a Curette

POSTOPERATIVE CARE

Physical therapy can be administered at the discretion of the surgeon during the time the InterSpace Shoulder is implanted. Activity must be assessed on an individual basis with relation to the anatomic condition of the humerus and glenoid, bone quality and clinical conditions of the patient during rehabilitation stages. Care must be taken to minimize the risk of damaging bone tissue and the implant through excessive activity or forced mobilization. Ultimately, the activity level and mobility must be evaluated by the surgeon on a patient-by-patient basis and moderated as appropriate.

EXPLANATION

The InterSpace device is not intended for use as a permanent prosthesis and must be removed within 180 days of implantation. Osteotomes, mallets and other revision instruments may be used to aid in the explantation procedure. Care should be taken to ensure that the wound site is thoroughly cleaned of all bone cement debris prior to implantation of a definitive prosthesis or performing an alternative surgical procedure (e.g. resection arthroplasty, fusion, etc.). Failure to remove cement and/or bone debris may shorten the survival of the revision implant.

DISPOSAL

Disposal of the device should be in accordance with local waste regulations.

INTERSPACE KNEE SPECIFICATIONS


INTERSPACE KNEE AND ATS (Augmented Tibial Stem)

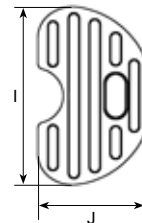
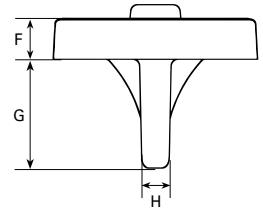
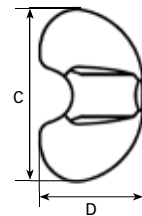
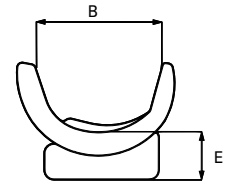
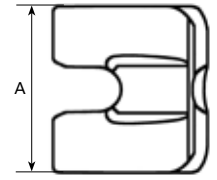
Size	REF	Trial Size	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	Gentamicin Base
Small (S)	SPK0022	6054	54	40	60	36	16	0.9g
Medium (M)	SPK0122	7064	64	47	70	42	17	1.3g
Large (L)	SPK0222	8074	74	54	80	48	18	1.8g
Extra Large (XL)	SPK0322	9084	84	61	90	54	19	2.7g

Trials SPK90Z1 InterSpace® Knee Trials (S, M, L) SPK03Z1 InterSpace® Knee Trials (XL)

Size	REF	InterSpace Knee Pairing	F (mm)	G (mm)	H (mm)	I (mm)	J (mm)	Gentamicin Base
InterSpace® ATS (60/07)	SPK0422	S or M	7	32	11	60	36	0.3g
InterSpace® ATS (60/12)	SPK0522	S or M	12	32	11	60	36	0.5g
InterSpace® ATS (80/07)	SPK0622	L or XL	7	40	11	80	48	0.5g
InterSpace® ATS (80/12)	SPK0722	L or XL	12	40	11	80	48	0.8g

Trials SPK90Z2 InterSpace® ATS Trials (All Sizes)

 Colors indicate ATS pairings



CATALOG NUMBER PART DESCRIPTION

IMPLANTS

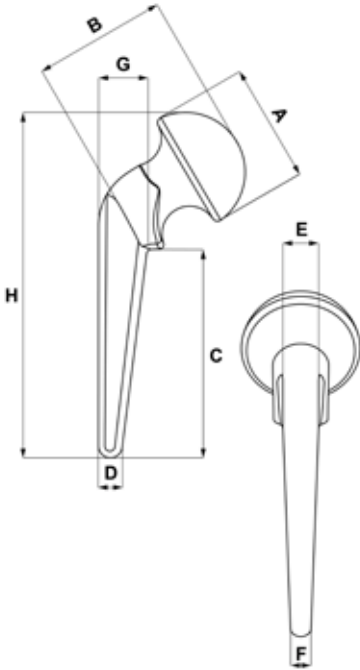
SPK0022	InterSpace Knee (S)
SPK0122	InterSpace Knee (M)
SPK0222	InterSpace Knee (L)
SPK0322	InterSpace Knee (XL)
SPK0422	InterSpace ATS (60/07)
SPK0522	InterSpace ATS (60/12)
SPK0622	InterSpace ATS (80/07)
SPK0722	InterSpace ATS (80/12)

TRIALS

SPK90Z1	InterSpace Knee Trials (S, M, L)
SPK03Z1	InterSpace Knee Trials (XL)
SPK90Z2	InterSpace ATS Trials (All Sizes)

INTERSPACE HIPTAPERED WEDGE STEM - SHORT STEM

Size	REF	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	F (mm)	G (mm)	H (mm)	Gentamicin Base
Small (S)	SPC0023	46	54.6	96	10	11	9	17	149	1.1g
Medium (M)	SPC0123	54	60	94.3	10.5	16	9	21.7	156	1.6g
Large (L)	SPC0223	60	73	95.8	11	16	9	24	168.5	2.6g



CATALOG NUMBER PART DESCRIPTION

IMPLANTS

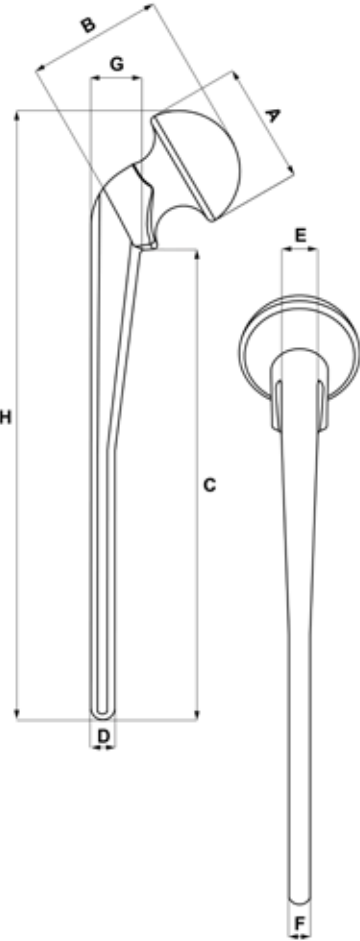
- SPC0023 46mm Short Stem (S)
- SPC0123 54mm Short Stem (M)
- SPC0223 60mm Short Stem (L)

TRIALS

- SPC90Z3 Short Stem Trials, Tapered Wedge (S, M, L)

INTERSPACE HIPTAPERED WEDGE STEM - LONG STEM

Size	REF	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	F (mm)	G (mm)	H (mm)	Gentamicin Base
Small (S)	SPC0323	46	54.6	211	10	11	9	17	265	1.2g
Medium (M)	SPC0423	54	60	209.2	10.5	16	9	21.7	271	1.8g
Large (L)	SPC0523	60	73	211	11	16	9	24	283.5	2.8g



CATALOG NUMBER PART DESCRIPTION

IMPLANTS

- SPC0323 46mm Long Stem (S)
- SPC0423 54mm Long Stem (M)
- SPC0523 60mm Long Stem (L)

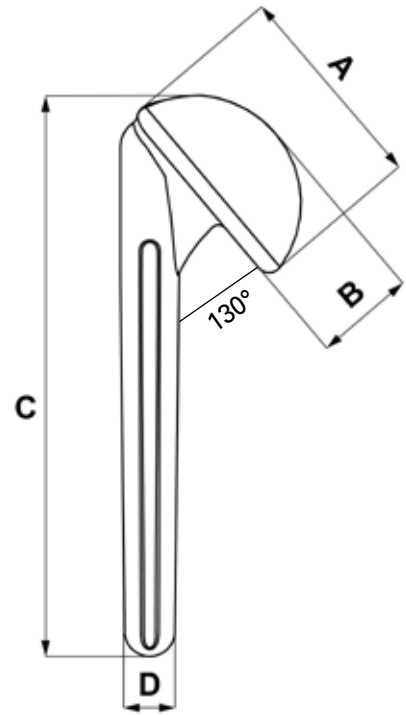
TRIALS

- SPC91Z3 Long Stem Trials, Tapered Wedge (S, M, L)

INTERSPACE SHOULDER SPECIFICATIONS

INTERSPACE SHOULDER STEM

Size	REF	A (mm)	B (mm)	C (mm)	D (mm)	Gentamicin Base
Small (S)	SPS0121K	41	16	99	7	0.4g
Large (L)	SPS0021K	46	22	125	11	0.8g



CATALOG NUMBER PART DESCRIPTION

IMPLANTS

SPS0121K	41mm (S)
SPS0021K	46mm (L)

TRIALS

SPS90Z1	InterSpace Shoulder Trials (S, L)
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INSTRUMENT LISTING

ADDITIONAL PRODUCTS

- 1400/AG US Cemex Genta Low Viscosity (40g)
- 1400/IG US Cemex Genta High Viscosity (40g)
- 13A2111 Cemex System Fast with Gentamicin (40g)
- 13A2101 Cemex System Fast with Gentamicin (70g)
- 1500/SG US Cemex Genta System (80g)



AUTOMATED OSTEOTOME SYSTEM

Use the AcuDriver® Automated Osteotome System for powered precision. This system is designed to aid the surgeon in increasing surgical efficiency while improving control in revision arthroplasty.¹² The system consists of an air-driven impact handpiece that is coupled with precision osteotomes of various shapes.

- 400-91-03 AcuDriver Handpiece
- 400-30-20 Straight Reamer
- 400-30-21 Tapered Reamer
- 400-40-01 Notched Osteotome
- 400-40-03 Straight Gouge
- 400-40-04 Vee Osteotome
- 400-40-07 Small Cup Osteotome
- 400-40-08 Medium Cup Osteotome
- 400-40-11 Round, Medium Flexible Osteotome
- 400-40-12 Round, Narrow Flexible Osteotome
- 400-40-14 Flat, Narrow Flexible Osteotome
- 400-40-15 Long Notched Osteotome
- 400-40-17 Long Straight Gouge
- 400-40-18 Long Vee Osteotome
- 400-40-19 Round, Long Flexible Osteotome
- 400-40-20 Flat, Long Flexible Osteotome
- 400-40-24 Impactor
- 400-40-25 Long Carbide Punch



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For additional device information, refer to the Exactech InterSpace®—Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information on InterSpace or AcuDriver, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, as the manufacturer of the AcuDriver device and the distributor of the InterSpace device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

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