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. Estimates indicate that the cost of treatment for a septic revision can exceed $125,000. Oftentimes, the diagnosis is difficult with only 25 percent 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. 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 O.R., 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*
- Improves quality of life between procedures
- Provides predictable, consistent local antibiotic release over time to prevent bacterial adhesion
- Reduces hospitalization and allows for a seamless transition to physical therapy
- Facilitates implant placement during second-stage revision with greater ease for the surgeon
- Offers functional success rates equivalent to non-infected revisions

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

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. Both components are to be fixed with Cemex® Genta Bone Cement.

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 should be confirmed through trial reduction, achieving a compromise between stability and joint mobility. Size selection for the InterSpace Knee is based upon:

- Dimensions of the removed implants
- **InterSpace Knee Trials and Templates**
- Remaining bone stock
- State of ligamentous apparatus
- Flexion and extension spaces

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

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

FEMORAL SIZING AND TRIAL PLACEMENT
Position the Trials into the joint space and reduce the knee (Figure 2). The knee should not be too tight 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.

**Figure 1** Flat, Narrow Flexible Osteotomes and/or a Sawblade can be Used to Transect the Tibial Plateau Portion of the Prosthesis

**Figure 2** Position the Trials Into the Joint Space and Reduce the Knee
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. 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. Apply a layer of highly viscous, very thick (doughy) bone cement to the non-articulating surface of the femoral component (Figure 3). Next, manually place the femoral component onto the distal femur (Figure 4). Due to the incongruency 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 of the procedure.

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

Prepare a fresh batch of Cemex Genta Bone Cement. Once it reaches a doughy state, apply a generous amount to the proximal surface of the tibia as well as the non-articulating surface of the tibial component (Figure 5). Some surgeons may choose to increase the stability of the tibial component by creating a short cement stem. Manually position the InterSpace tibial component on the proximal tibia, taking care to remove all extruding bone cement (Figure 6). 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 femoral component to “self-center” the tibial component, ensuring proper tracking of the InterSpace Knee. Final curing of the bone cement should be accomplished with the knee in extension.
DETAILED OPERATIVE TECHNIQUE

FINAL REDUCTION OF THE KNEE / POSTOPERATIVE CARE

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 should be stable with joint extension to 90 degrees.

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

POSTOPERATIVE CARE

Partial weight bearing must be assessed on an individual basis with relation to the anatomic condition of the femur and tibia, 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 Knee is to be used with mobility-assisting devices throughout the period of implantation.
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)**

Size appropriateness should be confirmed through trial reduction, achieving a compromise between stability and joint mobility. 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. Size selection for the InterSpace Hip can be determined with the following:

- Dimensions of the removed implants
- InterSpace Hip Trials and Templates
- Remaining bone stock
- State of ligamentous apparatus
- Flexion and extension spaces

* Parts indicated for use with the AcuDriver Automated Osteotome System.*
Removal of all Proximal Cement and Bone Allows the Prosthesis to be Removed Without Incidence

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.
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 10 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

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

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 wipe or 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.
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

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 16

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

GLENOID PREPARATION / TRIAL PLACEMENT AND REDUCTION / SHOULDER IMPLANT PLACEMENT

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).

Figure 17
Apply Cemex Genta Bone Cement to Underside of Head
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.
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.
### INTERSPACE KNEE SPECIFICATIONS

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![Interspace Knee Diagram](image)

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INTERSPACE HIP SPECIFICATIONS

INTERSPACE HIP TAPERED WEDGE STEM - SHORT STEM

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- 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 HIP TAPERED WEDGE STEM - LONG STEM

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

TRIALS
- SPC91Z3  Long Stem Trials, Tapered Wedge (S, M, L)
### INTERSPACE HIP CYLINDRICAL STEM - SHORT STEM

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**IMPLANTS**

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- SPC0122 54mm Short Stem (M)
- SPC0222 60mm Short Stem (L)*

**TRIALS**

- SPC90Z1 Short Stem Trials, Classic (S, M, L)

### INTERSPACE HIP CYLINDRICAL STEM - LONG STEM

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<tbody>
<tr>
<td>Small (S)</td>
<td>SPC0322</td>
<td>46</td>
<td>54.5</td>
<td>211</td>
<td>10</td>
<td>17</td>
<td>265</td>
<td>1.3g</td>
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<tr>
<td>Medium (M)</td>
<td>SPC0422</td>
<td>54</td>
<td>60</td>
<td>209</td>
<td>10.5</td>
<td>21.9</td>
<td>271</td>
<td>2.1g</td>
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<tr>
<td>Large (L)</td>
<td>SPC0522</td>
<td>60</td>
<td>73</td>
<td>211</td>
<td>11</td>
<td>24</td>
<td>283.5</td>
<td>3.2g</td>
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</tbody>
</table>

### CATALOG NUMBER

**IMPLANTS**

- SPC0322 46mm Long Stem (S)
- SPC0422 54mm Long Stem (M)
- SPC0522 60mm Long Stem (L)

**TRIALS**

- SPC91Z1 Long Stem Trials, Classic (S, M, L)

*No longer available for order
INTERSPACE SHOULDER SPECIFICATIONS

<table>
<thead>
<tr>
<th>Size</th>
<th>REF</th>
<th>A (mm)</th>
<th>B (mm)</th>
<th>C (mm)</th>
<th>D (mm)</th>
<th>Gentamicin Base</th>
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</thead>
<tbody>
<tr>
<td>Small (S)</td>
<td>SPS0121K</td>
<td>41</td>
<td>16</td>
<td>99</td>
<td>7</td>
<td>0.4g</td>
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<tr>
<td>Large (L)</td>
<td>SPS0021K</td>
<td>46</td>
<td>22</td>
<td>125</td>
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<td>0.8g</td>
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</tbody>
</table>

CATALOG NUMBER  PART DESCRIPTION

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

TRIALS
- SPS90Z1  InterSpace Shoulder Trials (S, L)
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. 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
REFERENCES

12. Data on file at Exactech Inc.

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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