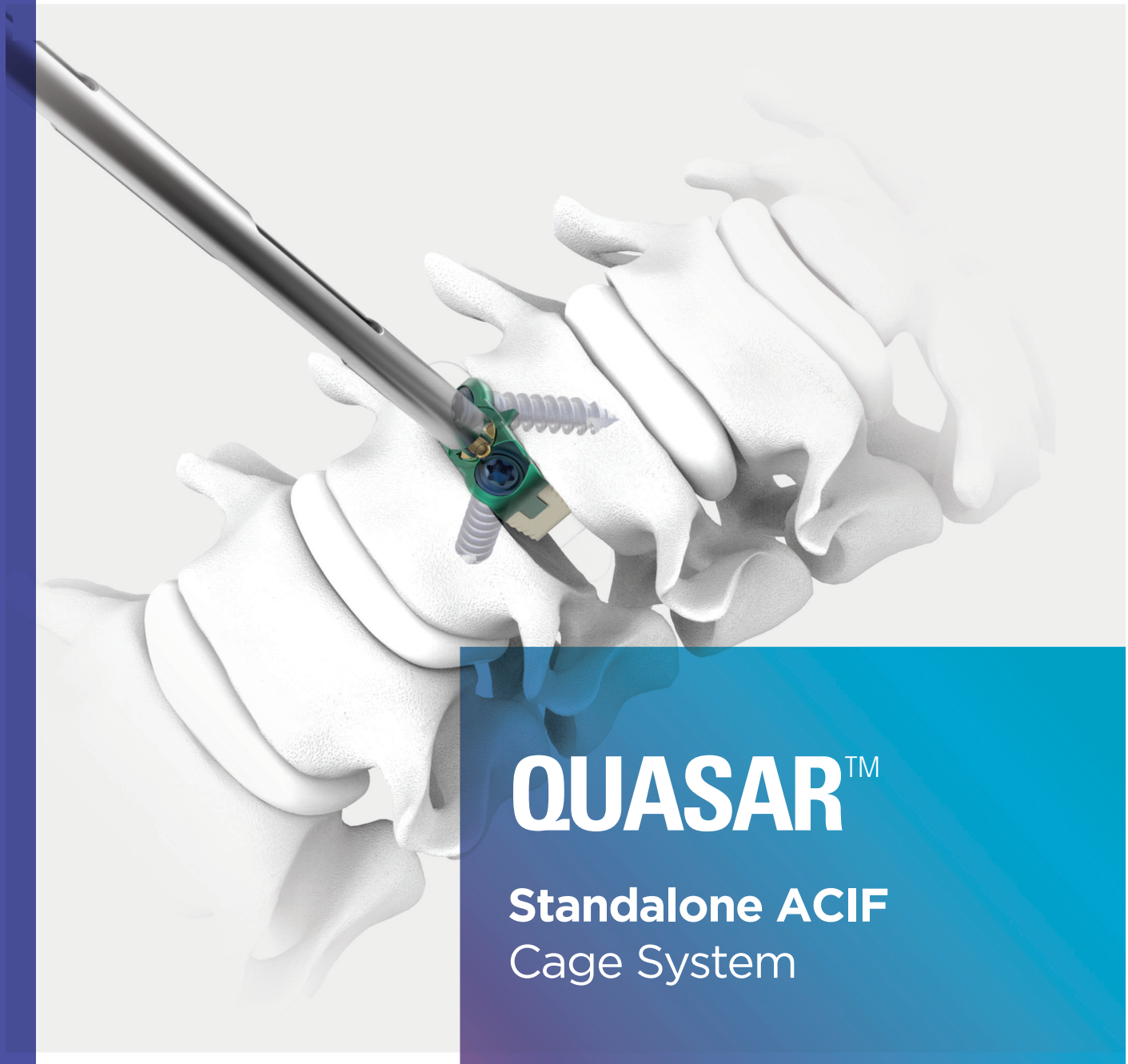
www.gsmedicalusa.com



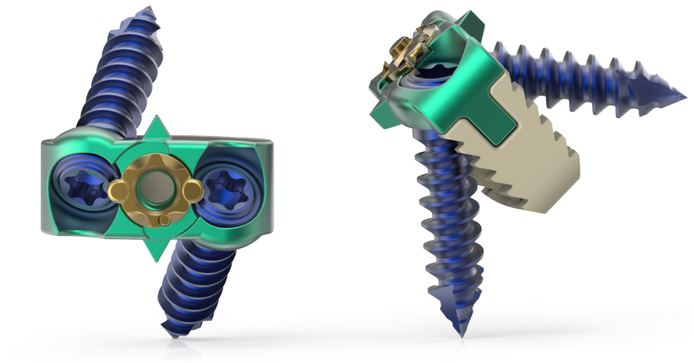
# QUASAR™

## Standalone ACIF
Cage System

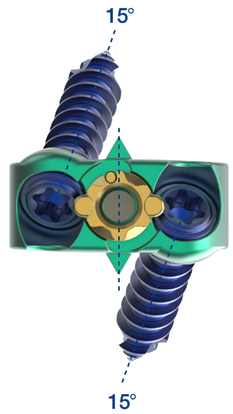
SURGICAL TECHNIQUE GUIDE

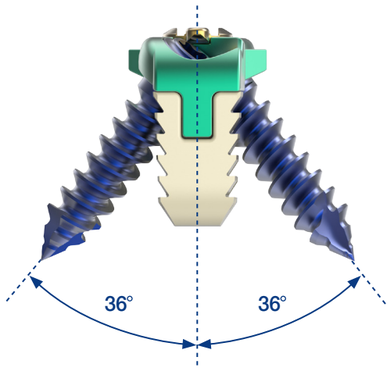
GS Medical

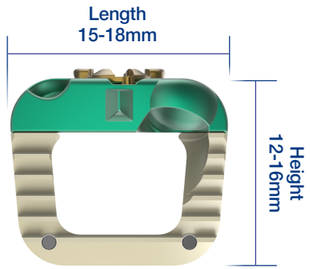
# QUASAR™ Standalone ACIF



| Footprints | Heights | Lordosis | Screws |
|---|---|---|---|
| 12X15mm | 5 -12mm | 0°, 8°, 12° | • 10–20mm Length<br>• Ø3.6mm, Ø4.1mm Diameter<br>• Variable and Fixed Angle<br>• Self-Tapping and Self-Drilling |
| 14X16mm | | | |
| 16X18mm | | | |



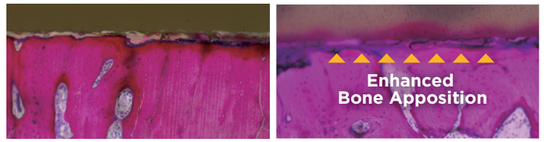

## Features and Benefits

### Less Invasive
Inserter located in the middle of the cage and plate construct that requires less working space during the insertion process.

### Intergrated Inserter and Locking Plate Rotator
Allows the insertion and locking steps intergrated for streamlined procedure.

### HA PEEK from Invibio™
- Earlier bone ongrowth with >75% direct bone contact after 4 weeks
- Enhanced bone apposition at 12 weeks

**4 WEEK HISTOLOGY**



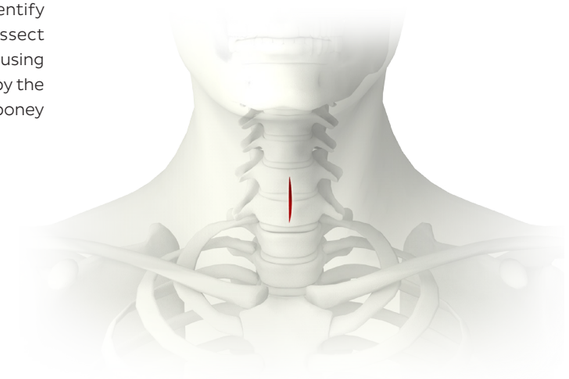

**PEEK-OPTIMA Natural** | **PEEK-OPTIMA HA Enhanced**

*More consistent and continuous degree of direct bone contact was observed.*

Step 1

# Surgical Approach

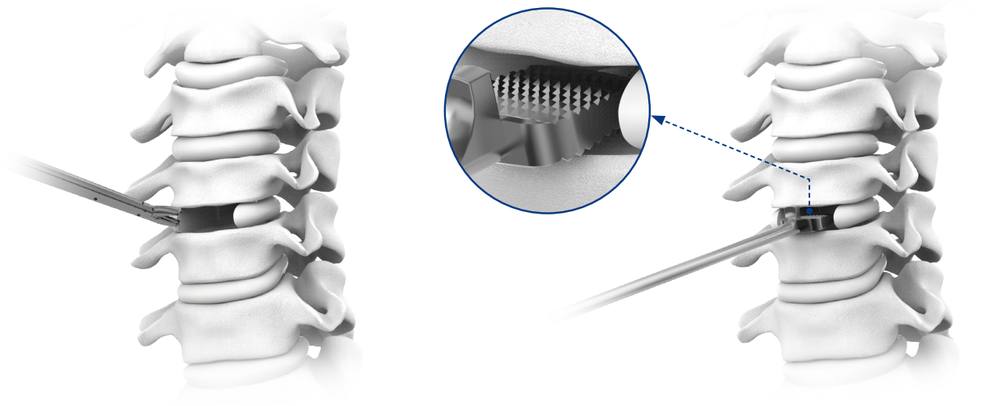
Expose the cervical spine via anterior approach. Identify level(s) of operation with radiographic imaging. Dissect down to the spine using traditional ACDF approach using necessary instruments and techniques determined by the surgeon to move through soft tissue and perform boney removal to gain access to the identified disc space.



Step 2

## Site Preparation

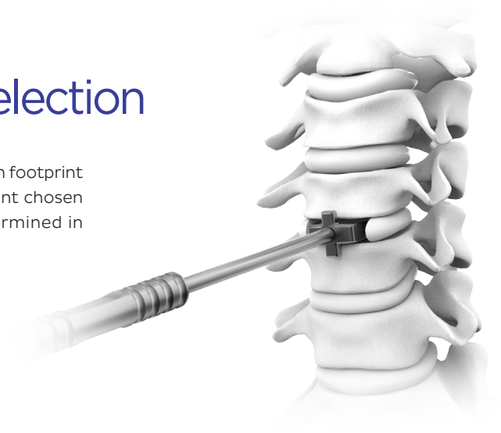
Once the operable level is exposed, prepare the space by excising the disc and performing spinal decompression using curettes or rasps or other instruments that the surgeon prefers. Rasps are included in the set and can be used at this time to help prepare vertebral endplates.



Step 3

## Trialing and Implant Selection

Insert various trials into the disc space to determine both footprint and implant size using radiographic imaging. The Implant chosen should have the footprint, height, and lordosis determined in trialing.



Step 4

## Implant Assembly

Assemble faceplate by attaching the inserter into the inserter hole in the middle of the faceplate Inside the caddy. Then bring the plate/inserter construct and press it onto the matching sized spacer in the caddy together until an audible click is heard. The QUASAR™ Standalone Cage is available in footprint 12x14mm, 14x16mm and 16x18mm, heights ranging from 5-12mm, and lordotic options of 0°, 8°. and 12° The implant trials are also available in a 12x14mm footprint, heights of 6mm, 8mm, 10mm, and 12mm, and a lordotic angle of 8°.



Step 5

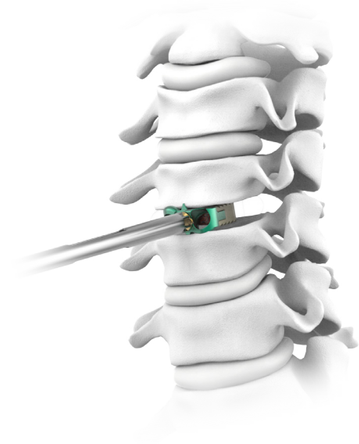
## Graft Packing

At this point, the surgeon may pack the implant with desired grafting material. All implants have an axial graft window that is able to be loaded with graft. Take the Bone Funnel from the implant set and pack with desired grafting material. Once the proper amount of graft is loaded, implant is ready to be inserted into the disc space.

Step 6

## Implant Insertion

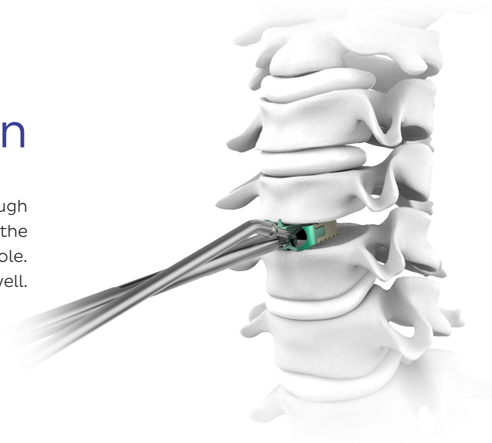
Insert implant into disc space using radiographic imaging. Maneuver implant until satisfied with the implant placement. The final position of the implant should be centered with the vertebral bodies and just flush with or slightly recessed from the vertebral bodies.



Step 7

## Screw Hole Preparation

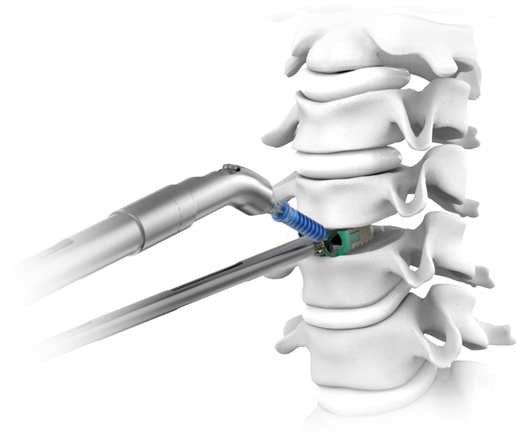
Start preparing the screw hole by inserting the Awl through the screw hole to break the cortex of the bone. Decide on the length of the drill and insert proper drill through screw hole. A Tap is also provided, and screw holes may be tapped as well.

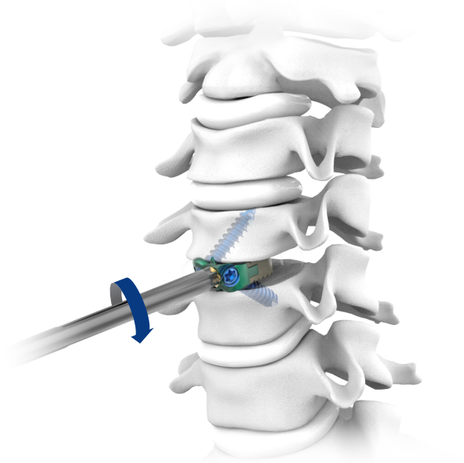


Step 8

## Screw Insertion

Attach desired screw to screwdriver. Straight and 35° curved screwdrivers are offered for streamlined screw insertion. Insert screw into the plate screw hole and drive screw until fully seated in the implant. Repeat steps with second screw.





Step 9

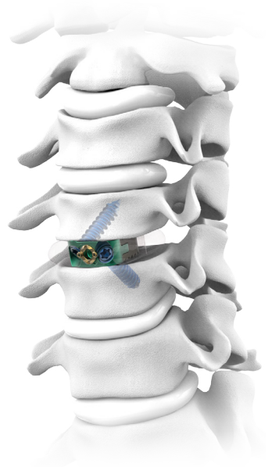
## Lock Blocking Plate

Screws are now inserted and ready to be locked in place. Screws are locked by the central locking plate. Secured location can be achieved by turning the Inserter Outer Shaft (GS136-1861) by counterclockwise rotation. Then the inserter can be detached by turning the Inserter Inner Shaft (GS136-1860) counterclockwise as well.

Step 10

## Closure

Properly irrigate the surgical site, then close the fascia, subcutaneous layers and skin, and seal with skin adhesive.



Step 11

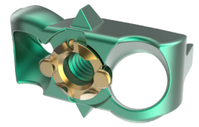
## Implant Removal

If implant removal becomes necessary, unlock the blocking plate by rotating clockwise using the inserter outer shaft and remove screws from the body. Once all screws are out, attach the center holes on the faceplate to the inserter and pull back to remove the implant from disc space. If the implant cannot be easily removed, other surgical instruments, like a cobb, may be used to loosen the implant from the endplate, then remove the implant.

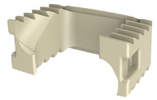


# Implants

**Faceplate**



**Interbody**



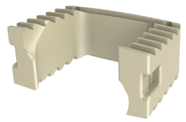
**Footprint**
**12X15mm**

| No | Part No. | Part Description |
|---|---|---|
| 1 | 6010-3005 | SA-ACIF Plate, Internally Fixated, 12x15x5mm |
| 2 | 6010-3006 | SA-ACIF Plate, Internally Fixated, 12x15x6mm |
| 3 | 6010-3007 | SA-ACIF Plate, Internally Fixated, 12x15x7mm |
| 4 | 6010-3008 | SA-ACIF Plate, Internally Fixated, 12x15x8mm |
| 5 | 6010-3009 | SA-ACIF Plate, Internally Fixated, 12x15x9mm |
| 6 | 6010-3010 | SA-ACIF Plate, Internally Fixated, 12x15x10mm |
| 7 | 6010-3011 | SA-ACIF Plate, Internally Fixated, 12x15x11mm |
| 8 | 6010-3012 | SA-ACIF Plate, Internally Fixated, 12x15x12mm |
| 9 | 6010-4005 | SA-ACIF Plate, Internally Fixated, 14x16x5mm |
| 10 | 6010-4006 | SA-ACIF Plate, Internally Fixated, 14x16x6mm |
| 11 | 6010-4007 | SA-ACIF Plate, Internally Fixated, 14x16x7mm |
| 12 | 6010-4008 | SA-ACIF Plate, Internally Fixated, 14x16x8mm |
| 13 | 6010-4009 | SA-ACIF Plate, Internally Fixated, 14x16x9mm |
| 14 | 6010-4010 | SA-ACIF Plate, Internally Fixated, 14x16x10mm |
| 15 | 6010-4011 | SA-ACIF Plate, Internally Fixated, 14x16x11mm |
| 16 | 6010-4012 | SA-ACIF Plate, Internally Fixated, 14x16x12mm |
| 17 | 6010-6005 | SA-ACIF Plate, Internally Fixated, 16x18x5mm |
| 18 | 6010-6006 | SA-ACIF Plate, Internally Fixated, 16x18x6mm |
| 19 | 6010-6007 | SA-ACIF Plate, Internally Fixated, 16x18x7mm |
| 20 | 6010-6008 | SA-ACIF Plate, Internally Fixated, 16x18x8mm |
| 21 | 6010-6009 | SA-ACIF Plate, Internally Fixated, 16x18x9mm |
| 22 | 6010-6010 | SA-ACIF Plate, Internally Fixated, 16x18x10mm |
| 23 | 6010-6011 | SA-ACIF Plate, Internally Fixated, 16x18x11mm |
| 24 | 6010-6012 | SA-ACIF Plate, Internally Fixated, 16x18x12mm |

| No | Part No. | Part Description | Comment |
|---|---|---|---|
| 1 | 6003-0005 | SA-ACIF Cage, 12x15x5mm 0° | Optional |
| 2 | 6003-0006 | SA-ACIF Cage, 12x15x6mm 0° | |
| 3 | 6003-0007 | SA-ACIF Cage, 12x15x7mm 0° | |
| 4 | 6003-0008 | SA-ACIF Cage, 12x15x8mm 0° | |
| 5 | 6003-0009 | SA-ACIF Cage, 12x15x9mm 0° | |
| 6 | 6003-0010 | SA-ACIF Cage, 12x15x10mm 0° | |
| 7 | 6003-0011 | SA-ACIF Cage, 12x15x11mm 0° | |
| 8 | 6003-0012 | SA-ACIF Cage, 12x15x12mm 0° | |
| 9 | 6003-0805 | SA-ACIF Cage, 12x15x5mm 8° | Standard |
| 10 | 6003-0806 | SA-ACIF Cage, 12x15x6mm 8° | |
| 11 | 6003-0807 | SA-ACIF Cage, 12x15x7mm 8° | |
| 12 | 6003-0808 | SA-ACIF Cage, 12x15x8mm 8° | |
| 13 | 6003-0809 | SA-ACIF Cage, 12x15x9mm 8° | |
| 14 | 6003-0810 | SA-ACIF Cage, 12x15x10mm 8° | |
| 15 | 6003-0811 | SA-ACIF Cage, 12x15x11mm 8° | |
| 16 | 6003-0812 | SA-ACIF Cage, 12x15x12mm 8° | |
| 17 | 6003-1205 | SA-ACIF Cage, 12x15x5mm 12° | Optional |
| 18 | 6003-1206 | SA-ACIF Cage, 12x15x6mm 12° | |
| 19 | 6003-1207 | SA-ACIF Cage, 12x15x7mm 12° | |
| 20 | 6003-1208 | SA-ACIF Cage, 12x15x8mm 12° | |
| 21 | 6003-1209 | SA-ACIF Cage, 12x15x9mm 12° | |
| 22 | 6003-1210 | SA-ACIF Cage, 12x15x10mm 12° | |
| 23 | 6003-1211 | SA-ACIF Cage, 12x15x11mm 12° | |
| 24 | 6003-1212 | SA-ACIF Cage, 12x15x12mm 12° | |

# Implants

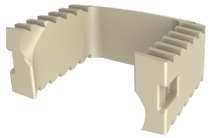
**Interbody**



**Footprint 14X16mm**

| No | Part No. | Part Description | Comment |
|---|---|---|---|
| 1 | 6004-0005 | SA-ACIF Cage, 14x16x5mm 0° | Optional |
| 2 | 6004-0006 | SA-ACIF Cage, 14x16x6mm 0° | |
| 3 | 6004-0007 | SA-ACIF Cage, 14x16x7mm 0° | |
| 4 | 6004-0008 | SA-ACIF Cage, 14x16x8mm 0° | |
| 5 | 6004-0009 | SA-ACIF Cage, 14x16x9mm 0° | |
| 6 | 6004-0010 | SA-ACIF Cage, 14x16x10mm 0° | |
| 7 | 6004-0011 | SA-ACIF Cage, 14x16x11mm 0° | |
| 8 | 6004-0012 | SA-ACIF Cage, 14x16x12mm 0° | |
| 9 | 6004-0805 | SA-ACIF Cage, 14x16x5mm 8° | Standard |
| 10 | 6004-0806 | SA-ACIF Cage, 14x16x6mm 8° | |
| 11 | 6004-0807 | SA-ACIF Cage, 14x16x7mm 8° | |
| 12 | 6004-0808 | SA-ACIF Cage, 14x16x8mm 8° | |
| 13 | 6004-0809 | SA-ACIF Cage, 14x16x9mm 8° | |
| 14 | 6004-0810 | SA-ACIF Cage, 14x16x10mm 8° | |
| 15 | 6004-0811 | SA-ACIF Cage, 14x16x11mm 8° | |
| 16 | 6004-0812 | SA-ACIF Cage, 14x16x12mm 8° | |
| 17 | 6004-1205 | SA-ACIF Cage, 14x16x5mm 12° | Optional |
| 18 | 6004-1206 | SA-ACIF Cage, 14x16x6mm 12° | |
| 19 | 6004-1207 | SA-ACIF Cage, 14x16x7mm 12° | |
| 20 | 6004-1208 | SA-ACIF Cage, 14x16x8mm 12° | |
| 21 | 6004-1209 | SA-ACIF Cage, 14x16x9mm 12° | |
| 22 | 6004-1210 | SA-ACIF Cage, 14x16x10mm 12° | |
| 23 | 6004-1211 | SA-ACIF Cage, 14x16x11mm 12° | |
| 24 | 6004-1212 | SA-ACIF Cage, 14x16x12mm 12° | |

**Interbody**



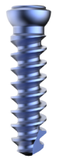
**Footprint 16X18mm**

| No | Part No. | Part Description | Comment |
|---|---|---|---|
| 1 | 6006-0005 | SA-ACIF Cage, 16x18x5mm 0° | Optional |
| 2 | 6006-0006 | SA-ACIF Cage, 16x18x6mm 0° | |
| 3 | 6006-0007 | SA-ACIF Cage, 16x18x7mm 0° | |
| 4 | 6006-0008 | SA-ACIF Cage, 16x18x8mm 0° | |
| 5 | 6006-0009 | SA-ACIF Cage, 16x18x9mm 0° | |
| 6 | 6006-0010 | SA-ACIF Cage, 16x18x10mm 0° | |
| 7 | 6006-0011 | SA-ACIF Cage, 16x18x11mm 0° | |
| 8 | 6006-0012 | SA-ACIF Cage, 16x18x12mm 0° | |
| 9 | 6006-0805 | SA-ACIF Cage, 16x18x5mm 8° | Standard |
| 10 | 6006-0806 | SA-ACIF Cage, 16x18x6mm 8° | |
| 11 | 6006-0807 | SA-ACIF Cage, 16x18x7mm 8° | |
| 12 | 6006-0808 | SA-ACIF Cage, 16x18x8mm 8° | |
| 13 | 6006-0809 | SA-ACIF Cage, 16x18x9mm 8° | |
| 14 | 6006-0810 | SA-ACIF Cage, 16x18x10mm 8° | |
| 15 | 6006-0811 | SA-ACIF Cage, 16x18x11mm 8° | |
| 16 | 6006-0812 | SA-ACIF Cage, 16x18x12mm 8° | |
| 17 | 6006-1205 | SA-ACIF Cage, 16x18x5mm 12° | Optional |
| 18 | 6006-1206 | SA-ACIF Cage, 16x18x6mm 12° | |
| 19 | 6006-1207 | SA-ACIF Cage, 16x18x7mm 12° | |
| 20 | 6006-1208 | SA-ACIF Cage, 16x18x8mm 12° | |
| 21 | 6006-1209 | SA-ACIF Cage, 16x18x9mm 12° | |
| 22 | 6006-1210 | SA-ACIF Cage, 16x18x10mm 12° | |
| 23 | 6006-1211 | SA-ACIF Cage, 16x18x11mm 12° | |
| 24 | 6006-1212 | SA-ACIF Cage, 16x18x12mm 12° | |

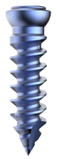


# Screws

## 3.6mm Variable



| No | Part No. | Part Description |
|---|---|---|
| 1 | 6080-1010 | Variable Angle, Self-Tapping, 10mm |
| 2 | 6080-1011 | Variable Angle, Self-Tapping, 11mm |
| 3 | 6080-1012 | Variable Angle, Self-Tapping, 12mm |
| 4 | 6080-1013 | Variable Angle, Self-Tapping, 13mm |
| 5 | 6080-1014 | Variable Angle, Self-Tapping, 14mm |
| 6 | 6080-1015 | Variable Angle, Self-Tapping, 15mm |
| 7 | 6080-1016 | Variable Angle, Self-Tapping, 16mm |
| 8 | 6080-1017 | Variable Angle, Self-Tapping, 17mm |
| 9 | 6080-1018 | Variable Angle, Self-Tapping, 18mm |
| 10 | 6080-1019 | Variable Angle, Self-Tapping, 19mm |
| 11 | 6080-1020 | Variable Angle, Self-Tapping, 20mm |



| No | Part No. | Part Description |
|---|---|---|
| 1 | 6080-0010 | Variable Angle, Self-Drilling, 10mm |
| 2 | 6080-0011 | Variable Angle, Self-Drilling, 11mm |
| 3 | 6080-0012 | Variable Angle, Self-Drilling, 12mm |
| 4 | 6080-0013 | Variable Angle, Self-Drilling, 13mm |
| 5 | 6080-0014 | Variable Angle, Self-Drilling, 14mm |
| 6 | 6080-0015 | Variable Angle, Self-Drilling, 15mm |
| 7 | 6080-0016 | Variable Angle, Self-Drilling, 16mm |
| 8 | 6080-0017 | Variable Angle, Self-Drilling, 17mm |
| 9 | 6080-0018 | Variable Angle, Self-Drilling, 18mm |
| 10 | 6080-0019 | Variable Angle, Self-Drilling, 19mm |
| 11 | 6080-0020 | Variable Angle, Self-Drilling, 20mm |

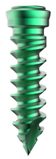
## 4.1mm Variable

| No | Part No. | Part Description |
|---|---|---|
| 1 | 6090-1010 | Variable Angle, Self-Tapping, 10mm |
| 2 | 6090-1011 | Variable Angle, Self-Tapping, 11mm |
| 3 | 6090-1012 | Variable Angle, Self-Tapping, 12mm |
| 4 | 6090-1013 | Variable Angle, Self-Tapping, 13mm |
| 5 | 6090-1014 | Variable Angle, Self-Tapping, 14mm |
| 6 | 6090-1015 | Variable Angle, Self-Tapping, 15mm |
| 7 | 6090-1016 | Variable Angle, Self-Tapping, 16mm |
| 8 | 6090-1017 | Variable Angle, Self-Tapping, 17mm |
| 9 | 6090-1018 | Variable Angle, Self-Tapping, 18mm |
| 10 | 6090-1019 | Variable Angle, Self-Tapping, 19mm |
| 11 | 6090-1020 | Variable Angle, Self-Tapping, 20mm |

| No | Part No. | Part Description |
|---|---|---|
| 1 | 6090-0010 | Variable Angle, Self-Drilling, 10mm |
| 2 | 6090-0011 | Variable Angle, Self-Drilling, 11mm |
| 3 | 6090-0012 | Variable Angle, Self-Drilling, 12mm |
| 4 | 6090-0013 | Variable Angle, Self-Drilling, 13mm |
| 5 | 6090-0014 | Variable Angle, Self-Drilling, 14mm |
| 6 | 6090-0015 | Variable Angle, Self-Drilling, 15mm |
| 7 | 6090-0016 | Variable Angle, Self-Drilling, 16mm |
| 8 | 6090-0017 | Variable Angle, Self-Drilling, 17mm |
| 9 | 6090-0018 | Variable Angle, Self-Drilling, 18mm |
| 10 | 6090-0019 | Variable Angle, Self-Drilling, 19mm |
| 11 | 6090-0020 | Variable Angle, Self-Drilling, 20mm |

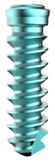
## 3.6mm Fixed

| No | Part No. | Part Description |
|---|---|---|
| 1 | 6081-1010 | Fixed Angle, Self-Tapping, 10mm |
| 2 | 6081-1011 | Fixed Angle, Self-Tapping, 11mm |
| 3 | 6081-1012 | Fixed Angle, Self-Tapping, 12mm |
| 4 | 6081-1013 | Fixed Angle, Self-Tapping, 13mm |
| 5 | 6081-1014 | Fixed Angle, Self-Tapping, 14mm |
| 6 | 6081-1015 | Fixed Angle, Self-Tapping, 15mm |
| 7 | 6081-1016 | Fixed Angle, Self-Tapping, 16mm |
| 8 | 6081-1017 | Fixed Angle, Self-Tapping, 17mm |
| 9 | 6081-1018 | Fixed Angle, Self-Tapping, 18mm |
| 10 | 6081-1019 | Fixed Angle, Self-Tapping, 19mm |
| 11 | 6081-1020 | Fixed Angle, Self-Tapping, 20mm |



| No | Part No. | Part Description |
|---|---|---|
| 1 | 6081-0010 | Fixed Angle, Self-Drilling, 10mm |
| 2 | 6081-0011 | Fixed Angle, Self-Drilling, 11mm |
| 3 | 6081-0012 | Fixed Angle, Self-Drilling, 12mm |
| 4 | 6081-0013 | Fixed Angle, Self-Drilling, 13mm |
| 5 | 6081-0014 | Fixed Angle, Self-Drilling, 14mm |
| 6 | 6081-0015 | Fixed Angle, Self-Drilling, 15mm |
| 7 | 6081-0016 | Fixed Angle, Self-Drilling, 16mm |
| 8 | 6081-0017 | Fixed Angle, Self-Drilling, 17mm |
| 9 | 6081-0018 | Fixed Angle, Self-Drilling, 18mm |
| 10 | 6081-0019 | Fixed Angle, Self-Drilling, 19mm |
| 11 | 6081-0020 | Fixed Angle, Self-Drilling, 20mm |

## 4.1mm Fixed



| No | Part No. | Part Description |
|---|---|---|
| 1 | 6091-1010 | Fixed Angle, Self-Tapping, 10mm |
| 2 | 6091-1011 | Fixed Angle, Self-Tapping, 11mm |
| 3 | 6091-1012 | Fixed Angle, Self-Tapping, 12mm |
| 4 | 6091-1013 | Fixed Angle, Self-Tapping, 13mm |
| 5 | 6091-1014 | Fixed Angle, Self-Tapping, 14mm |
| 6 | 6091-1015 | Fixed Angle, Self-Tapping, 15mm |
| 7 | 6091-1016 | Fixed Angle, Self-Tapping, 16mm |
| 8 | 6091-1017 | Fixed Angle, Self-Tapping, 17mm |
| 9 | 6091-1018 | Fixed Angle, Self-Tapping, 18mm |
| 10 | 6091-1019 | Fixed Angle, Self-Tapping, 19mm |
| 11 | 6091-1020 | Fixed Angle, Self-Tapping, 20mm |

| No | Part No. | Part Description |
|---|---|---|
| 1 | 6091-0010 | Fixed Angle, Self-Drilling, 10mm |
| 2 | 6091-0011 | Fixed Angle, Self-Drilling, 11mm |
| 3 | 6091-0012 | Fixed Angle, Self-Drilling, 12mm |
| 4 | 6091-0013 | Fixed Angle, Self-Drilling, 13mm |
| 5 | 6091-0014 | Fixed Angle, Self-Drilling, 14mm |
| 6 | 6091-0015 | Fixed Angle, Self-Drilling, 15mm |
| 7 | 6091-0016 | Fixed Angle, Self-Drilling, 16mm |
| 8 | 6091-0017 | Fixed Angle, Self-Drilling, 17mm |
| 9 | 6091-0018 | Fixed Angle, Self-Drilling, 18mm |
| 10 | 6091-0019 | Fixed Angle, Self-Drilling, 19mm |
| 11 | 6081-0020 | Fixed Angle, Self-Drilling, 20mm |

# Instruments

| | | |
|---|---|---|
| GS136-2200 | Caspar Retractor |  |
| GS136-2460 | Pin Driver |  |
| GS136-2310 | Pin, 12mm |  |
| GS136-2300 | Pin, 14mm |  |
| GS136-1351<br>GS136-1352<br>GS136-1353 | Graft Holder, 12x14mm Top<br>Graft Holder, 14x16mm Top<br>Graft Holder, 16x18mm Top |  |
| GS136-2110 | Bone Impactor |  |
| GS136-3310 | Tamp |  |
| GS136-1860 | Inserter Inner Shaft |  |
| GS136-1861 | Inserter Outer Shaft |  |

# Instruments

| | | |
|---|---|---|
| GS136-1910 | Quick Connect Handle, Small Axial, Cap |  |
| GS136-0110 | Straight Awl |  |
| GS136-0120 | Straight Awl, with Sleeve |  |
| GS136-0230<br>GS136-0231<br>GS136-0232<br>GS136-0233<br>GS136-0234<br>GS136-0235 | Straight Drill, 10mm<br>Straight Drill, 12mm<br>Straight Drill, 14mm<br>Straight Drill, 16mm<br>Straight Drill, 18mm<br>Straight Drill, 20mm |  |
| GS136-1200 | Straight Tap |  |
| GS136-7100 | Screwdriver, Self-Retaining |  |
| GS136-0100 | Angled Awl |  |
| GS136-7000 | Angled Screwdriver |  |
| GS136-3400 | Counter Torque |  |

# Instruments

| | |
|---|---|
| GS136-6005 | Trial, Universal, 12x14x5,6mm 0° |
| GS136-6007 | Trial, Universal, 12x14x7,8mm 0° |
| GS136-6009 | Trial, Universal, 12x14x9,10mm 0° |
| GS136-6011 | Trial, Universal, 12x14x11,12mm 0° |
| GS136-6105 | Trial, Universal, 12x14x5,6mm 8° |
| GS136-6107 | Trial, Universal, 12x14x7,8mm 8° |
| GS136-6109 | Trial, Universal, 12x14x9,10mm 8° |
| GS136-6111 | Trial, Universal, 12x14x11,12mm 8° |
| GS136-6205 | Trial, Universal, 12x14x5,6mm 12° |
| GS136-6207 | Trial, Universal, 12x14x7,8mm 12° |
| GS136-6209 | Trial, Universal, 12x14x9,10mm 12° |
| GS136-6211 | Trial, Universal, 12x14x11,12mm 12° |

| | |
|---|---|
| GS136-6305 | Trial, Universal, 14x16x5,6mm 0° |
| GS136-6307 | Trial, Universal, 14x16x7,8mm 0° |
| GS136-6309 | Trial, Universal, 14x16x9,10mm 0° |
| GS136-6311 | Trial, Universal, 14x16x11,12mm 0° |
| GS136-6405 | Trial, Universal, 14x16x5,6mm 8° |
| GS136-6407 | Trial, Universal, 14x16x7,8mm 8° |
| GS136-6409 | Trial, Universal, 14x16x9,10mm 8° |
| GS136-6411 | Trial, Universal, 14x16x11,12mm 8° |
| GS136-6505 | Trial, Universal, 14x16x5,6mm 12° |
| GS136-6507 | Trial, Universal, 14x16x7,8mm 12° |
| GS136-6509 | Trial, Universal, 14x16x9,10mm 12° |
| GS136-6511 | Trial, Universal, 14x16x11,12mm 12° |

| | |
|---|---|
| GS136-6605 | Trial, Universal, 16x18x5,6mm 0° |
| GS136-6607 | Trial, Universal, 16x18x7,8mm 0° |
| GS136-6609 | Trial, Universal, 16x18x9,10mm 0° |
| GS136-6611 | Trial, Universal, 16x18x11,12mm 0° |
| GS136-6705 | Trial, Universal, 16x18x5,6mm 8° |
| GS136-6707 | Trial, Universal, 16x18x7,8mm 8° |
| GS136-6709 | Trial, Universal, 16x18x9,10mm 8° |
| GS136-6711 | Trial, Universal, 16x18x11,12mm 8° |
| GS136-6805 | Trial, Universal, 16x18x5,6mm 12° |
| GS136-6807 | Trial, Universal, 16x18x7,8mm 12° |
| GS136-6809 | Trial, Universal, 16x18x9,10mm 12° |
| GS136-6811 | Trial, Universal, 16x18x11,12mm 12° |

| | |
|---|---|
| GS136-4005 | Rasp, 12x14x5mm 0° |
| GS136-4105 | Rasp, 12x14x5mm 8° |
| GS136-4205 | Rasp, 12x14x5mm 12° |



# Instructions for Use

## QUASAR™ Standalone ACIF System (Non-Sterile)

### General Information about QUASAR™ Standalone ACIF System

**NON STERILE PRODUCT**

**Caution**: Federal (USA) Law restricts this device for sale by or on the order of a physician (or properly licensed practitioner) that has appropriate training or experience.

### General Prerequisites for Use (In case of QUASAR™ Standalone ACIF System)

These products may only be implanted by surgeons with the necessary training and expertise in spinal surgery. Any decision on possible use has to consider the non-operative and surgical indications, possible risks and benefits of this type of surgery, indications, cautions and adverse events specified in these instructions for use, type of materials, and mechanical characteristics of the implants employed according to the surgical technique recommended by GS Medical.

Detailed instructions on the correct use of the QUASAR™ Standalone ACIF System by GS Medical are found in the manual on surgical technique. Precise preoperative planning of the implant position, based on plain radiographs, CT scans, etc., is absolutely mandatory. Normally, selection of the proper size device cannot be realized before the procedure but must be performed during surgery. All instruments are designed so as to help the surgeon determine the correct size of the implant. Implant size is clearly marked on each packaging.

### DEVICE DESCRIPTION

The QUASAR™ Standalone ACIF System cages are designed for restoring the height of the intervertebral space after resection of the disc while also providing biomechanical stability with the addition of an integrated plate. This integrated plate allows for the user to bypass using an additional plate as seen with traditional ACIF spacers. The QUASAR™ Standalone ACIF System devices consist of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The intervertebral body fusion devices are made of HA polyether-ether-ketone (PEEK OPTIMA LT1 with hydroxyapatite) body with a titanium alloy (Ti-6Al-4V) plate and X-Ray (radio-opaque) markers made of Tantalum.

The intervertebral QUASAR™ Standalone ACIF System by GS Medical is designed for implantation between the endplates of adjacent vertebral bodies. Their size and shape have been adapted to the intervertebral spaces and to the specified surgical techniques. They comprise a cavity for bone graft material. The ACIF Standalone Cage is available in symmetric or convex designs.

**QUASAR™ Standalone ACIF System**

- The QUASAR™ Standalone ACIF System is designed for segments C3 to C7

### MATERIALS

The implants are made of HA polyether ether ketone (PEEK OPTIMA LT1 with hydroxyapatite) body (manufacturer: INVIBIO), a titanium alloy (Ti-6Al-4V) plate conforming to ASTM F136, and the X-ray radio-opaque markers are made of Tantalum.

### CONTRAINDICATIONS

#### Absolute contraindications

Surgery should not be considered if any of the following contraindications are present:

- acute and chronic infections or major bone defects in the vertebral bodies,
- bone tumors close to the fixation sites of the implants,
- prior fusion at the level(s) to be treated,
- probable excessive stresses placed on implant and bone.

#### Relative contraindications

Surgery should not be considered if any of the following contraindications are present:

- osteoporosis or other bone loss,
- bone tumors near the implant,
- poor general health,
- drug abuse or alcoholism,
- psychosocial problems or noncompliance of the patient,
- pregnancy,
- infections or symptoms/signs of infection.

The surgeon must take these absolute and relative contraindications into account when making his/her decision. This list is by no means complete. Patients with previous spinal surgery at the level(s) to be treated may have different outcomes compared to those without a previous surgery.

#### Risks

Potential risks associated with this type of procedure are:

- nerve complications due to hyperdistension of or trauma to the nerve roots or the dura,
- disc diminution due to resection of normal bone.

Potential risks associated with spinal surgery are:

- pseudarthrosis,
- bone graft resorption,
- vertebral slippage,
- implant malposition,
- infections.

Possible adverse events

- delayed union of the fusion, no visible fusion, and pseudarthrosis,
- neurologic complications, paralysis, tissue lesions,
- pain as sequela to the procedure,
- implant migration,
- superficial and deep infection or signs/symptoms of infection,
- implant material sensitivity or allergic reaction,
- implant creep into the vertebral body,
- decrease in bone density due to stress shielding,
- neurologic and/or dural lesions during the procedure,
- wear/degradation
- microdebris around the implant

This list of adverse events is by no means complete. In case of adverse event(s), reoperation may become necessary.

### GENERAL CONDITIONS OF USE

The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indications, the potential risks, and limitations related to this type of surgery; the contraindications, side effects, and precautions defined.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

# Instructions for Use

## INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-ups.

The surgeon must warn the patient of the surgical risks and make aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability, or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting or muscle strain), the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.

## INSTRUMENTS

Specialized instruments are provided by GS Medical and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures and disposal attention. Instruments should be examined for wear or damage prior to surgery.

## REUSE

The QUASAR™ Standalone ACIF System implants are intended for SINGLE USE ONLY.
An implant should never be reused. Although the device may appear intact upon removal, internal modifications due to the stresses and strains placed on it or small defects may exist which may lead to failure of the implant.
It is recommended to verify that the instruments are in good condition and operating order prior to use.

## HANDLING

Correct handling of the implant is extremely important. To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable GS Medical Surgical Technique.

The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by GS Medical. For example, the force exerted when repositioning an instrument in-situ must not be excessive, as this is likely to cause injury to the patient.

## IMPLANT SELECTION AND USE

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.

In addition, every effort should be made to ensure that all implants needed are available.

## PACKAGING AND STORAGE

- The implants are delivered in packages; these must be intact at the time of receipt,
- The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.
- They must be stored in a clean, dry and temperate place

## CLEANING AND DECONTAMINATION

Unless just removed from an unopened GS Medical package, all instruments and implants must be disassembled and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or return of the product to GS Medical.

### Manual Cleaning:

Prepare Enzol® detergent[1] according to manufacturer's recommendations (1 oz/gal) using lukewarm tap water. Fully immerse the articles in the prepared detergent, actuating them through their full range of motion, flushing all hard-to-reach areas using an appropriately sized syringe with a minimum of 50 mL of the prepared detergent per article, and then allow the article to soak for a minimum of two (2) minutes.
After the minimum two minute soak, brush the articles thoroughly using a soft bristled brush (M16) beneath the surface of the prepared detergent until all visible soil has been removed. Pay special attention to hard-to-reach areas.
Remove the articles from the detergent solution and thoroughly rinse under running tap water until all detergent residues are removed. Actuate the articles through their full range of motion while rinsing. During rinsing, thoroughly brush the articles using a soft bristled brush (M16), paying special attention to hard-to-reach areas. Actuate the articles through their full range of motion while brushing. During rinsing, flush the articles thoroughly using an appropriately sized syringe with a minimum of 50 mL of tap water per article, paying special attention to hard-to-reach areas. Actuate the articles through their full range of motion while flushing.
Dry the articles using a clean, soft cloth and filtered pressurized air (≤40psi). Visually inspect the articles for cleanliness.

### Automated Cleaning:

Thoroughly rinse the articles under running tap water using a disposable paper towel to remove gross contamination.
Transfer the articles into the automatic washer/disinfector for processing. Orient the articles at an incline to facilitate drainage.
Select the cleaning cycle set to the following set of parameters, set to high:

| Phase | Recirculation Time (minutes) | Temperature | Detergent Type and Concentration |
|---|---|---|---|
| Pre-wash 1 | 2:00 | Cold tap water | N/A |
| Enzyme Wash | 2:00 | Hot tap water | Enzol®[1], 1oz/gal |
| Wash 1 | 2:00 | 66°C | Valsure® Neutral[2], 3/4 oz/gal |
| Rinse 1 | 2:00 | Hot tap water | N/A |
| Drying | 7:00 | 115°C | N/A |

Remove the articles from the automatic washer/disinfector. If moisture remains on the articles, dry the articles using a clean, soft cloth and filtered pressurized air (≤40 psi).

[1]Enzol® is a product of Advanced Sterilization Products (ASP), a division of Ethicon US, LLC (ASP). For information on Enzol®, contact ASP at 33 Technology Drive, Irvine, CA 92618 USA.
[2]Valsure® Neutral is a product of STERIS Corporation. For information on Valsure® Neutral Detergent, contact STERIS at P.O. Box 147, St. Louis, MO 63166 USA.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.
All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

### Sterilization Procedure Recommended for Non-Sterile Medical Devices Including Implants

These are non-sterile implants. All implants and instruments used in surgery must be sterilized by the hospital prior to use.
Medical Devices must be sterilized with water vapor in an autoclave in accordance with standard hospital procedure. The sterilization method suggested has been validated according to the AAMI TIR 12 in order to obtain a Sterility Assurance Level (SAL) of $10^{-6}$
Use the storage trays for sterilization and intraoperative storage. The following recommendations should be followed when autoclaving:

STERILIZATION CONDITIONS: 1 set of low parameters have been validated on wrapped items

| Method | Cycle Type | Sterilization Temperature | Exposure Time | Dry time |
|---|---|---|---|---|
| Steam | Pre-vacuum | 132°C (270°F) | 4 mins | 30 min |
| Steam | Gravity-displacement | 132°C (270°F) | 15 min | 15 min |
| Steam | Gravity-displacement | 121°C (250°F) | 30 min | 15 min |

Note: This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.
The autoclave must be validated by the hospital and regularly checked to guarantee proper usage.
If sterilization containers with paper filters are used, it is advised to use a new filter for each sterilization.
GS Medical recommends usage of an FDA-cleared wrap to ensure that the device is sterile prior to implantation.
If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated.

## FURTHER INFORMATION

A surgical technique brochure is available upon request through your GS agent or directly from GS Medical. Users with brochures over two years old at the time of surgery are advised to ask for an updated version.

## MAGNETIC RESONANCE ENVIRONMENT

The QUASAR™ Standalone ACIF System has not been evaluated for safety and compatibility in the MR environment. The QUASAR™ Standalone ACIF System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the QUASAR™ Standalone ACIF System in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

## PRE-OPERATIVE PRECAUTION

Anyone using GS Medical products can obtain a Surgical Technique brochure by requesting one from a distributor or from GS Medical directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version

GS Medical devices can only be used by doctors who are fully trained and familiar with the surgical technique required. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by GS Medical. For example, the force exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels. Unless otherwise specified on the label, the instrument can be reused after decontamination, cleaning and sterilization.

## CAUTION

Federal law restricts this device for sale by or on the order of a licensed physician.

## PRECAUTION

The implantation of intervertebral body fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this intervertebral body fusion system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

## COMPLAINTS

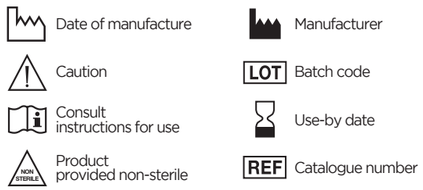
Any health professional having a complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or its performance, should notify GS Medical or its representative. Further, if a device has malfunctioned (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of having malfunctioned, GS Medical or its representative must be advised immediately.
If a GS Medical product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or GS Medical must be informed as soon as possible by telephone, fax or in writing.
For all complaints, please give the name and reference, along with the batch number of the component(s), your name and address and an exhaustive description of the event to help GS Medical understand the cause of the complaint.
Any report of such an event should include as many details as possible (product designation, order no., serial no., charge no., etc.), the type of claim or a precise description of the event, any consequences, as well as any technical element which could aid a future expert opinion (implant component. radiographs, etc.).

### For further information or complaints, please contact

Manufacturer
GS Medical Co., Ltd.
90, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
Tel : 82-43-237-7393 Fax : 82-43-237-7403
Home Page : www.gsmedi.com

US Distribution
GS Medical, LLC.
23263 Madero Suite C
Mission Viejo, CA 92691
Tel. 949-380-6385 FAX. 886-600-9712

## PRODUCT LABELING SYMBOLS



# QUASAR™

## STANDALONE ACIF CAGE SYSTEM

The surgical technique described hereafter in this surgical technique guide is considered standard use by the manufacturer, GS Medical, Co., Ltd. The guide is put forth as a recommendation and should be used in tandem with the surgical knowledge of the surgeon.

For additional information on the products listed in this guide, please contact the GS Medical Customer Service Department:

GS Solutions, Inc. DBA GS Medical
Attn: Customer Service
23263 Madero Suite C
Mission Viejo, CA 92691
Phone: 949.380.6385
www.gsmedicalusa.com

GS Medical, Co. Ltd.
Attn: Customer Service
90 Osongsaengmyeong 4-ro, Osong-Eup,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,
28161, Korea
+82-43-237-7393
www.gsmedi.com

GSST-2104-2302-US(1)