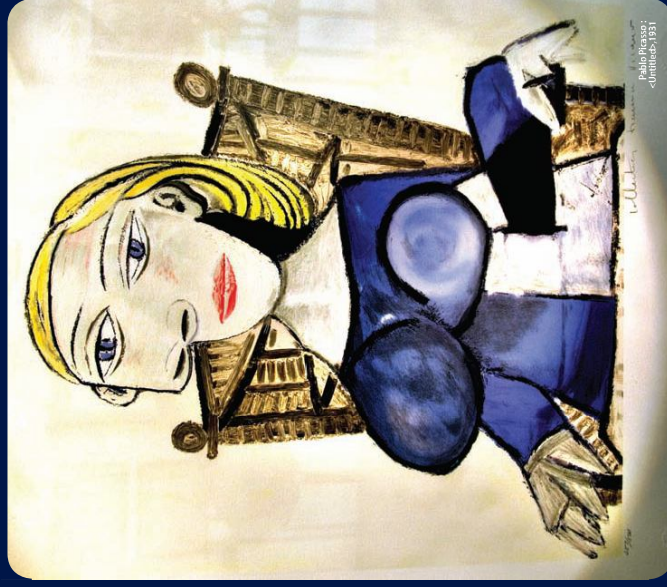



Occipito-Cervico-Thoracic Spinal Fixation System
Surgical Technique



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Introduction

SKY™ is an Occipito Cervico Thoracic Spinal Fixation System.

This implant system was designed to offer an appropriate method of posterior stabilisation and fusion of occipito-cervico-thoracic spine.

The design features of this system are directed towards making the procedure safe for the patient and simple for the operating surgeon.

SKY™ was developed with the help of some eminent spinal neurosurgeons in Yonsei Severance Hospital, Republic of Korea.

Do-heum Yoon
Yonsei University Severance Hospital, Republic of Korea.



Hyun-chul Shin
Kangbuk Samsung Hospital, Republic of Korea.



Keung-nyun Kim
Yonsei University Severance Hospital, Republic of Korea.



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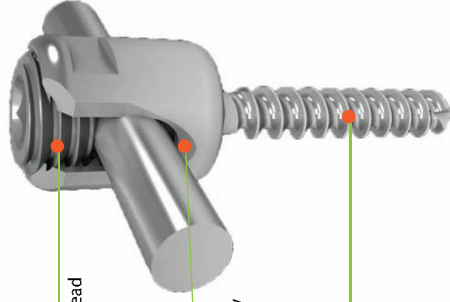
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Design Rationale

Poly Axial Screw
The poly axial screw head design allows up to 50 degree angulation. This high degree of angulation minimizes the need for rod contouring for nonlinear placement of screw heads.



Hexa & Butress Type
Set screw features a specially designed butress thread which reduces the potential for cross threading and gives strong fixation with screw head.



Double Locking System
The washer at the bottom of the screw head enhances the fixation power of the poly screw by pressing the top of the screw core.



Self-tapping Thread
Useful to penetrate the vertebral body

Indications

The SKY™ system is indicated for posterior instrumentation of the Occipital, posterior Cervical and upper Thoracic spine.

- Acute and chronic instability
- Instability due to posterior element fractures
 - Multilevel fractures
 - Posterior ligamentous injuries
 - Postlaminectomy instability
 - Tumor

Anterior cervical pseudarthrosis
Instability from tumor
Stabilization after multilevel anterior decompression and fusion

Application Levels

Occipital, C1 ~ C7, Upper Thoracic

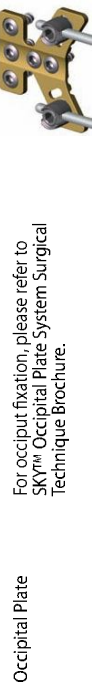
Contraindication

Severe osteoporosis

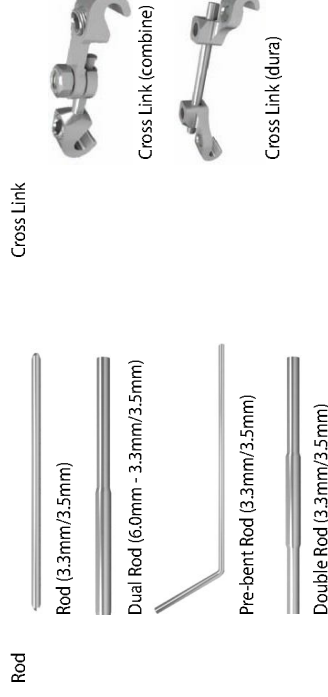
Approach

Posterior

SKY Implant Features

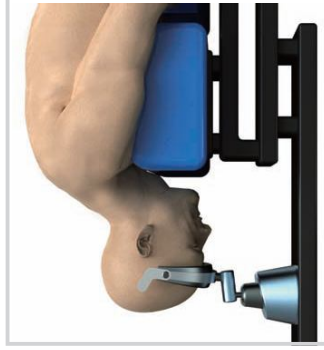


For occiput fixation, please refer to SKY™ Occipital Plate System Surgical Technique Brochure.



Positioning

The patient is positioned prone with rigid fixation by pins placed in the calvarium. Generally, pionion headrest or MAYFIELD™ headrest is attached on the operating table to secure the skull to the table.



Preoperative radiographic workup includes static plain radiographs, lateral flexion and extension views

Exposure

A standard midline posterior approach is used to expose the posterior spinal elements. Posterior dissection is performed subperiosteally along the lamina out to the lateral margin of the lateral masses. The exposure is extended one to two levels below the lower end of planned arthrodesis to allow for optimal screw placement.



Screw Channel Preparation

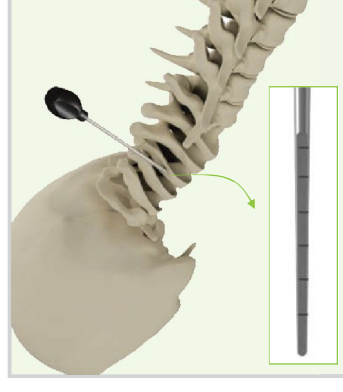
GS112-0200 AWL

Create a pilot hole for the screw with the AWL to preserve the normal anatomical landmark for the screw trajectory and to prevent displacement of drill bit during initial insertion.



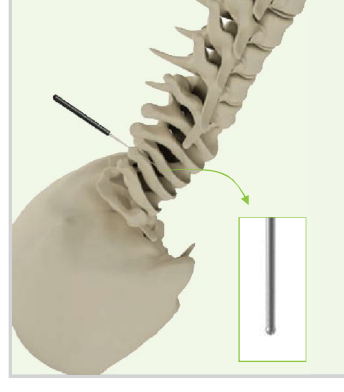
GS112-0300 Pedicle Probe (Straight)
GS112-0310 Pedicle Probe (Curved)

After creating the entry point, a path for the screw is prepared with the Pedicle probe (Straight /Curved) The Pedicle probe which has markings at every 5 mm, helps in not only dilating the track for the screw but also in accurately measuring the length of the screw.



GS112-0400 Tester

Use the Tester to palpate the screw channel walls.



Drilling

- GS112-1020 Drill Bit 2.0mm (for Tap 3.5mm)
- GS112-1025 Drill Bit 2.5mm (for Tap 4.0mm)
- GS112-1030 Drill Bit 3.0mm (for Tap 4.5mm)
- GS112-0600 Handle
- GS112-1010 Drill Guide

Though the entry point and screw trajectory for lateral mass screws are dependant on the anatomy, usually the entry is 1mm medial to the center of the lateral mass, and the drill is directed 20° cephalad and 20° to 30° lateral.



Tapping

- GS112-0535 Tap 3.5mm
- GS112-0540 Tap 4.0mm
- GS112-0545 Tap 4.5mm
- GS112-0600 Handle
- GS112-1010 Drill Guide

Insert the Tap into the barrel of the Drill guide and rotate the Tap clockwise to advance it, till resistance is met.

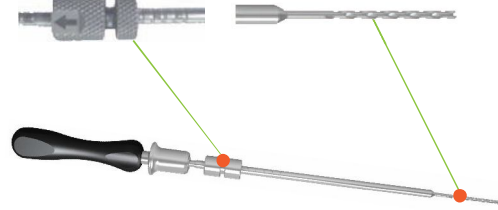
SKY™ Polyaxial screws are self tapping and manual tapping may not be necessary.

Stopper system on the Tap limits the depth of penetration and it is available in intervals of 2mm up to a length of 40mm. (Diameters : 3.5/4.0/4.5mm)



Drill Manual

Drill Bit
The Drill bit (Diameters : 2.0/2.5/3.0mm) is available in 2mm intervals up to a length of 40mm . The stopper on the drill bit limits the depth of penetration.



Handle
The universal handle can be coupled with the shaft of the Drill bit, Tap and Poly screw driver.

Drill Guide
Drill bit and Tap are used with the Drill guide to prevent over penetration and to protect the surrounding tissues.



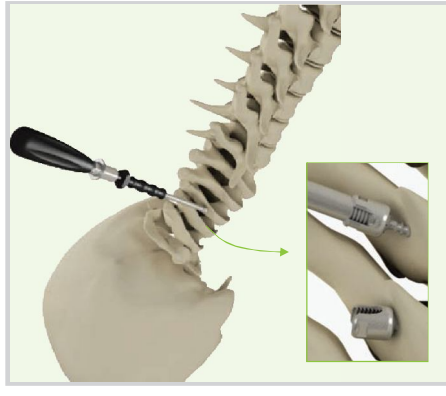
Polyaxial Screw Insertion

- GS112-0940 Poly Screw Driver
- GS112-1100 Poly Quick Screw Driver

Insert the cruciate tip of the Poly screw driver into the head of polyaxial screw. Make sure that the screw is straight and firmly connected to the Poly screw driver, and then insert the screw into the prepared hole. Stop advancing the screw when the polyaxial head comes in contact with bone. For more accurate placement, fluoroscopic control is recommended.

If you need to advance the screw further, or withdraw it, after the Poly Screw Driver is disconnected, the Poly quick screw driver can be used.

Repeat the above steps for all screw placements.



Preparation for Rod Insertion

GS112-1510 Rod Bender
GS112-1400 Rod Cutter



Once the screw have been inserted and aligned, the length of the required rod is measured.

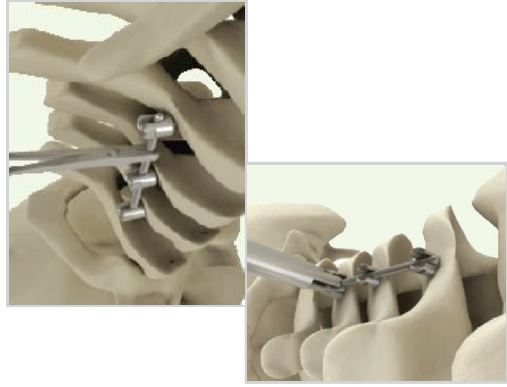
Cut the rod to the appropriate length using the Rod cutter.

Contour the rod to the appropriate shape using the Rod bender.

Do not straighten the rod after bending.

Rod Insertion

GS112-2000 Alignment T-Driver
GS112-1200 Rod Holder
GS112-1710 Rod Pusher
GS112-1900 Persuader
GS112-1520 In-situ Bender (Left)
GS112-1530 In-situ Bender (Right)



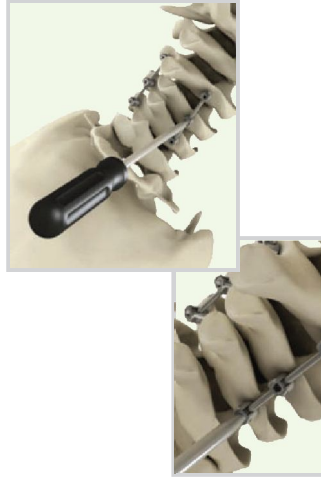
Insert the rod into the head of screw using the Rod holder. The Alignment T-Driver may be used to help in orienting the Screw heads in the correct position.

The Rod pusher or the Persuader may also be used to facilitate rod placement and locking the screw insertion.

In-situ benders are available for additional contouring of the rods after the rods are seated in the screw.

Locking with Set Screw

GS112-2300 Set Screw Driver(Start)



Insert the set screw into the screw head using the Set screw driver and provisionally tighten the set screw.

Compression or Distraction

GS112-2700 Compressor
GS112-2800 Distracter



If needed, the Compressor and the Distracter may be used to compress or distract to achieve the desired alignment of the spine.

Final Tightening

GS112-2400 Set Screw Driver
GS112-0610 Torque Limiting Handle
GS112-2900 Anti-torque Device



After compression or distraction has been achieved, tighten the set screws using the Set screw driver, combined with the Torque limiting handle which is preset to a limit of 5Nm.

Transverse Link Connection Optional

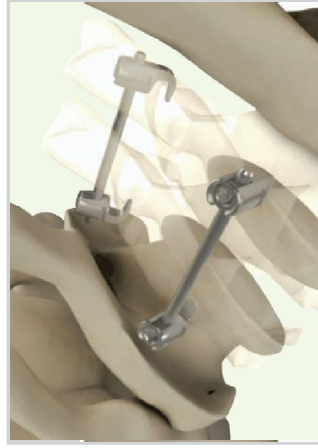
- GS112-3400 Transverse Link Driver
- GS112-3300 Transverse Link Wrench

It is recommended that the transverse links be used to increase the rotational stability of the construct. Removal of the spinous process is advisable if the transverse link are to be used.

Choose a transverse link of appropriate length and apply it to the rod.
The rods are first secured to the transverse link by tightening the set screws on the transverse link with the Transverse link driver. Finally, the hexagonal nut in the middle of the transverse link connector is tightened by using the Transverse link wrench, to complete the assembly.



Laminar Hook Placement Optional



GS112-6110 Hook Elevator
GS112-6010 Hook Holder

In some cases, in the upper thoracic and cervical spine, instead of the polyaxial screws, laminar hooks may be used. The Hook elevator may be used to prepare the lamina and dissect the ligamentum flavum. The correct size of hook to be used, depends upon the thickness of the lamina.

IMPLANTS

1. SKY™ Cervical Polyaxial Screw

Standard Range
Optional Range

Cervical Screw



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2. SKY™ Partially Cervical Polyaxial Screw

Partial Screw



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3. SKY™ Set Screw



Cat. No.	Description
0850-0001	3.7 X 7mm

4. SKY™ Rod



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5. SKY™ Dual Rod

Dual Rod ø3.3mm - ø6.0mm



Cat.No.	Length
1452-0100	100mm
1452-0200	200mm
1452-0300	300mm
1452-0400	400mm
1452-0500	500mm
1452-0600	600mm
1452-0800	800mm
1452-1000	1000mm

Dual Rod ø3.5mm - ø6.0mm



Cat.No.	Length
1462-0100	100mm
1462-0200	200mm
1462-0300	300mm
1462-0400	400mm
1462-0500	500mm
1462-0600	600mm
1462-0700	700mm
1462-0800	800mm
1462-0900	900mm
1462-1000	1000mm

IMPLANTS

6. SKY™ Cross Link
Cross Link (combine)

Cat. No.	Length
1300-3330	30mm
1300-3335	35mm
1300-3340	40mm
1300-3345	45mm
1300-3350	50mm
1300-3360	60mm
1300-3365	65mm
1300-3370	70mm



Cross Link (dura)

Cat. No.	Length
1305-0001	63mm (63mm Ready)



7. SKY™ Axial Connector
Axial Connector

Cat. No.	Diameter
1300-3333	3.5-5.0mm
1300-3350	3.5-5.0mm
1300-3353	3.5-5.0mm
1300-3360	3.5-6.0mm
1300-3363	3.5-6.3mm



9. SKY™ Domino
Domino (closed)

Cat. No.	Length
1360-3633	3.5-5.0mm
1360-3636	3.5-5.0mm
1360-3639	3.5-5.0mm
1360-3642	3.5-6.0mm
1360-3645	3.5-6.3mm



Domino (Triangle_closed)

Cat. No.	Length
1362-3650	3.5-5.0mm
1362-3653	3.5-5.0mm
1362-3656	3.5-6.0mm
1362-3659	3.5-6.3mm



Domino (open)

Cat. No.	Length
1370-3633	3.5-5.0mm
1370-3650	3.5-5.0mm
1370-3653	3.5-5.0mm
1370-3660	3.5-6.0mm
1370-3663	3.5-6.3mm



Domino (Triangle_open)

Cat. No.	Length
1372-3650	3.5-5.0mm
1372-3653	3.5-5.0mm
1372-3656	3.5-6.0mm
1372-3659	3.5-6.3mm



10. SKY™ Laminar Hook System
Laminar Hook

Cat. No.	Height
1400-0404	4mm
1400-0405	5mm
1400-0406	6mm
1400-0407	7mm
1400-0408	8mm
1400-0409	9mm
1400-0410	10mm



Angled Hook (Left)

Cat. No.	Height
1430-0404	4mm
1430-0405	5mm
1430-0406	6mm
1430-0407	7mm
1430-0408	8mm
1430-0409	9mm
1430-0410	10mm



Angled Hook (Right)

Cat. No.	Height
1432-0404	4mm
1432-0405	5mm
1432-0406	6mm
1432-0407	7mm
1432-0408	8mm
1432-0409	9mm
1432-0410	10mm



INSTRUMENTS

GS112-0200



GS112-0300
GS112-0310



GS112-0400



GS112-1020
GS112-1025
GS112-1030



GS112-0535
GS112-0540
GS112-0545



GS112-0600
Handle



GS112-2000



GS112-0940



GS112-1100



GS112-1200



GS112-1710
















GS112-1510



GS112-1510

INSTRUMENTS

GS112-1400	Rod Cutter	
GS112-2700	Compressor	
GS112-2800	Distracter	
GS112-1900	Persuader	
GS112-1520 GS112-1530	In-situ bender (Left) In-situ bender (Right)	
GS112-2900	Anti torque Device	
GS112-2300	Set Screw Driver(Start)	
GS112-2400	Set Screw Driver(Final)	
GS112-0610	Torque Limiting Handle	
GS112-3400	Transverse Link Driver	
GS112-3300	Transverse Link Wrench	
Option		
GS112-6110	Hook Elevator	
GS112-6010	Hook Holder	

Instruction For Use

(SKY™ Reconstruction System)

1.General Prerequisites for Use

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 the type of surgery, indications, cautions and contraindications are specified in the instructions for use. Medical devices and instruments are used in accordance with the instructions for use provided by GS Medical. Details on the use of the SKY Reconstruction System by GS Medical are found in the manual on surgical technique. Precise preoperative planning of the implant position, based on plain radiographs, MRI, CT scans, etc., is absolutely mandatory. Normal 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.

2.Application

The SKY Reconstruction System is intended to help provide correction, immobilization and stabilization of spinal segments as an adjunct to fusion of occipitocervical and cervical.

3.Description

The Non-sterile Occipitocervical & Cervical Fixation System is used exclusively for the mono-segmental and multi-segmental spine stabilization of occipitocervical and cervical.

- Materials
 - Ti6Al4V ELI according to ISO 5832-3 and ASTM F-136
- System Components
 - Occipitocervical components: OCT Plates, OCT Plate Screws, Rods, Hooks are intended to provide stabilization to promote fusion in the occipitocervical junction and the cervical spine. The OCT plate screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.
 - Cervical Screws, Hooks, Rods, and Connectors: The Cervical Screws are limited to placement in C3-T3. The screws are not intended to be placed in Occiput - C2.

4.Indications

Surgically installed implants serve to support normal healing process. They are not intended to replace normal body structures or as permanent support for fusions occurring in cases where healing does not take place or is delayed. During the implantation of the SKY Reconstruction System additional support may be required, with bone graft or cage etc. The following and any other indications are to be established by the operating surgeon, taking into account the specific clinical, biological and biomechanical situation.

Use for the following indications:

- Degenerative Disc Disease
- Trauma
- Fractures
- Dislocations
- Tumors
- Stenosis
- Deformity
- Kyphosis
- Lordosis
- Scoliosis
- Pseudarthrosis
- Failed previous fusions

5.Contraindication

Do not apply in the presence of:

- Fever
- Leukocytosis
- Infection
 - Systemic
 - Local
 - In the spine
- Pregnancy
- Acute osteopenia
- Medical or surgical conditions that could negatively affect the success of the implantation
- Foreign body sensitivity to the implant materials
- Inadequate patient compliance
- Severe osteoporosis or similar loss of bone density
- Severe damage to bone structures that would prevent the stable implantation of implant components
- Bone tumor in the region of implant fixation
- Anticipated excessive load on the implant
- Dependency on pharmaceutical drugs, drug abuse, Or alcoholism
- Systemic or metabolic diseases
- Morbid obesity (adiposity)
- Generally poor condition of the patient
- Wound healing disorders
- Mental illness
- Use in the mid and lower thoracic or lumbar spine
- Cases not listed under indications

6. Side Effects or adverse interactions

- Nonunion, delayed union
- Infection of the hardware or implant
- Metal sensitivity, or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress-shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage
- Paralysis
- Screw back-out
- Possibly leading to implant loosening
- Spinal cord impingement or damage
- Death

7. Safety information

- Warning
 - It is the operating surgeon's responsibility to ensure that the operative procedure is performed properly
 - It is the operating surgeon's responsibility to ensure that the patient is adequately monitored during the procedure
 - The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
 - The operating surgeon must be thoroughly familiar with bone anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- GS Medical is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- The instructions for use of Non-sterile Occipitocervical & Cervical Fixation System components must be observed.
- Only combine GS Medical modular implant components with each other.
- Components by other manufacturers must not be used with components of the Non-sterile Occipitocervical & Cervical Fixation System.
- Implants that have already been used must not be reused.
- Implants that have already been in contact with body tissue or body fluids must not be re-sterilized.
- It is the operating surgeon's responsibility to ensure the correct combination of implant components and their implantation.
- Delayed healing can cause implant components to fracture as a result of metal fatigue.
- The implant components applied, along with their article number, the name of the implant, as well as the batch number and serial number (if available) must be documented in all patient records.
- Damage to load-transferring bone structures can result in loosening of the components, bone or implant fractures or other severe complications.
- To ensure the earliest possible detection of such causes of dysfunction, the implant must be checked periodically, using appropriate techniques.
- A precise diagnosis requires x-rays taken.
 - The implant components are supplied in an unsterile condition.
 - The implant components are delivered in an individual packaging.
- For implant components in original packaging:
 - Store the implant components in their original packaging and only remove them from their original and protective packaging immediately prior to application.
 - Use implant system storage trays for reprocessing, sterilization and sterile setup.
- Make certain that the implant components in their implant system storage trays will not get into contact with each other or with instruments.
- Make certain that the implant components will not be damaged under any circumstances.

8. Sterilization method and parameters

- Sterilize with steam, taking note of the following:
 - These are non-sterile implants. They must be sterilized before use.
 - Use the storage trays for sterilization and intra-operative storage.
 - The following recommendations should be followed when autoclaving:
 - Only Sterile products should be placed in the operative field. For a 10-6 Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the two sets of process parameters below:

No.	Method	Cycle	Temperature	Exposure Time
1	Steam	Gravity	250F(127C)	20 minutes
2	Steam	Gravity	275F(130C)	15 minutes

9. Cautions

- In case of sterilization boxes with paper filters the integrity of the filters must be checked before autoclaving.
- The user assumes responsibility for any other type of sterilization and relieves GS Medical of any liability. The user should contact GS Medical for full details.

10. Storage

- Store the product in a dry place (< 25°C).

11. Warranty

- The warranty is only valid if the product has been used and implanted according to the specified surgical technique and the normal conditions set down in these instructions.

12. Additional information

- For a brochure and manual of the surgical technique, please inquire at your GS Medical representative or at GS Medical directly.

13. Complaints and claims

- Any professional (customer or user) with complaints or claims regarding the services and/or quality, identification, resistance, reliability, safety, effectiveness and/or performance of products by GS Medical must inform his/her GS Medical representative or authorized supplier. The supplier will inform GS Medical about this complaint or claim in a written report as quickly as possible. Should a malfunction or impairment of the device or any error in the instructions for use have or could have resulted in death or a severely impaired state of health of a patient or user, this adverse event must be reported immediately by phone or fax. 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 additional information and claim reports, please contact us

GS INFORMATION

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