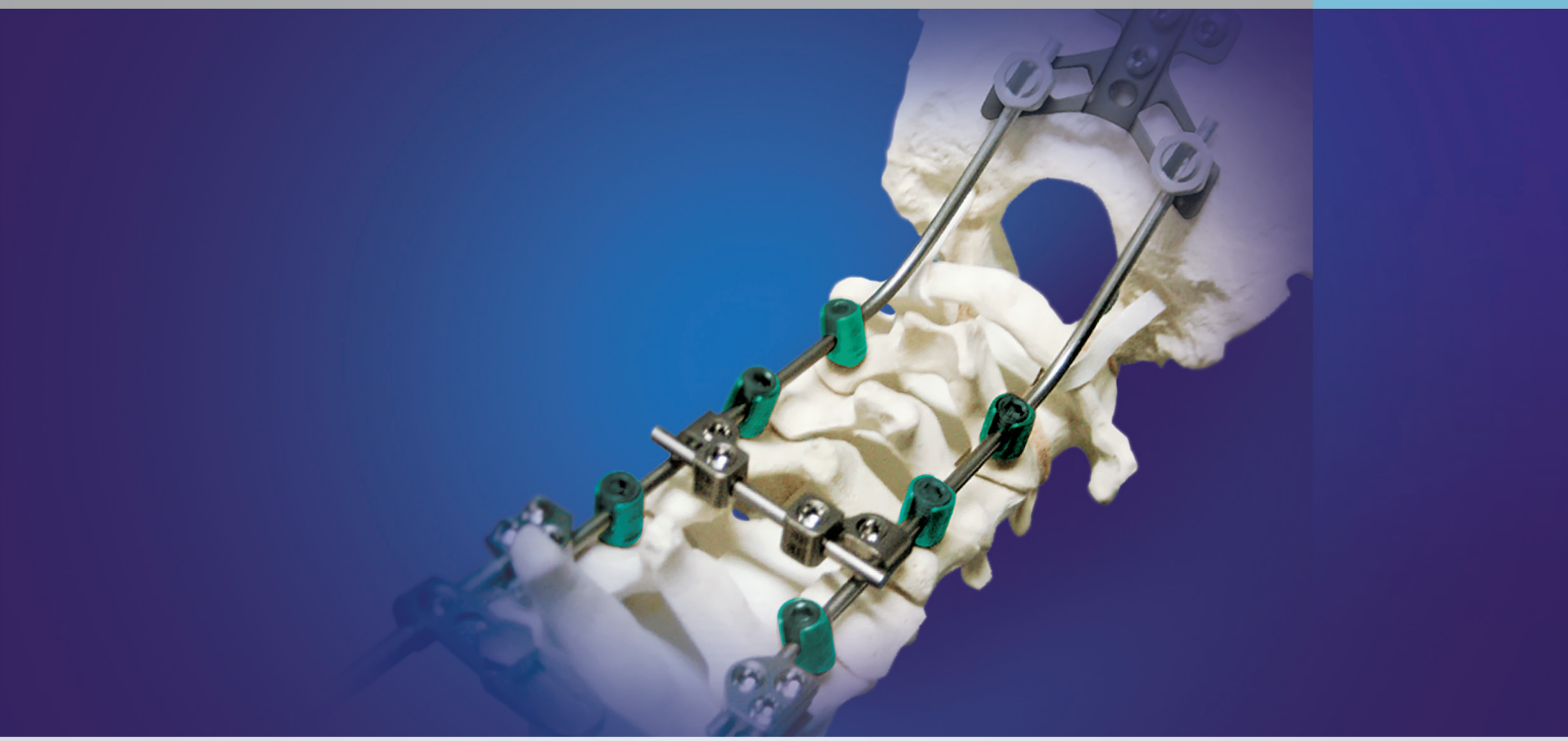
GS Medical

SKY™ OCT Spinal Fixation System



SKY™ is Occipito Cervico Thoracic Spinal Fixation System

This implant system was made to offer an appropriate posterior fixation of occipito cervico thoracic vertebra for patients. This instrument system was made to offer simpler procedure and to prevent the risk factorin operation for surgeons.

1 P.D. 1 techninių reikalavimų punktas

OCT Spinal Fixation System

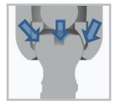
Poly Axial Screw

1 P.D. 3.1 techninių reikalavimų punktas

The polyaxiel 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 & Buttress Type

Set screw features a specially designed buttress thread which reduces the potential for cross threading and gives strong fixation with screw head.

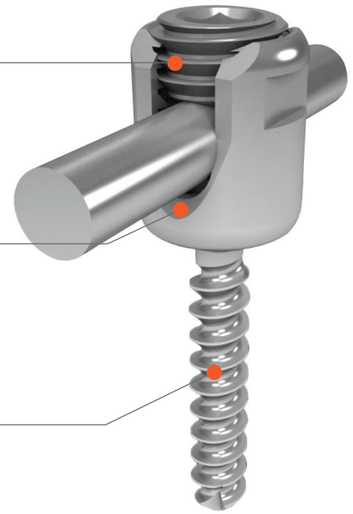


Double Locking System

The washer in the bottom of the screw head enhances fixation power of the poly screw by pressing the top of screw core.

Self-tapping Thread

Useful to penetrate the vertebral body



Indications

1 P.D. 1 techninių reikalavimų punktas

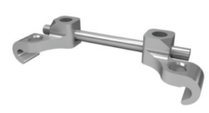
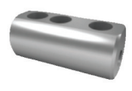
The SKY™ system is indicated for posterior instrumentation of the Occipital, posterior Cervical and upper Thoracic spine.

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 multisegment anterior decompression and fusion

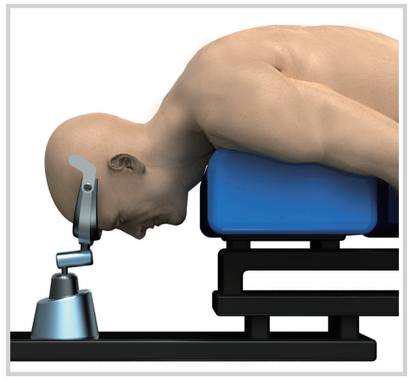
- **Application Levels**
  Occipital, C1-C7, Upper Thoracic
- **Contraindication**
  Severe osteoporosis
- **Approach**
  Posterior

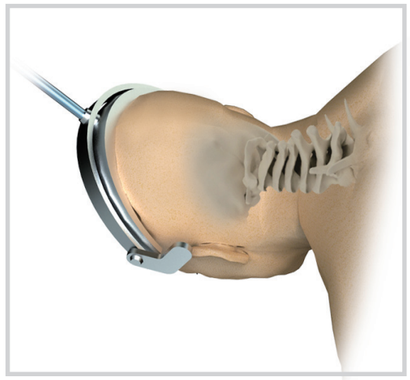
SKY™ Implant Features

Screw	Cortical Polyaxial Screw		Partial Polyaxial Screw	
Hook	Laminar Hook		Angled Laminar Hook (Left, Right)	
Occipital Plate	For occiput fixation, please refer to SKY™ Occipital Plate System Surgical Technique Brochure.			
Rod	Rod (3.3mm/3.5mm)			
	Dual Rod (6.0mm - 3.3mm/3.5mm)			
	Pre-bent Rod (3.3mm/3.5mm)			
	Double Rod (3.3mm/3.5mm)			
Cross Link	Cross Link (combine)		Cross Link (dura)	
Connector	Axial Connector		Lateral Connector (Anterior Open)	
Domino	Closed		Open	
	Triangle - Closed		Triangle - Open	

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.

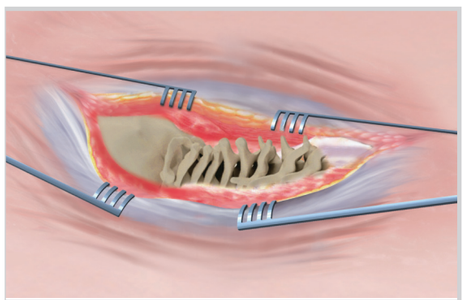




Preoperative radiographic workup includes static plain radiographs, lateral flexion and extension views

Exposure

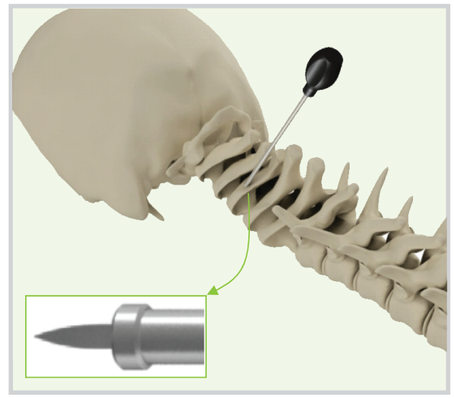
A standard midline posterior approach is used to reveal the posterior spinal elements.
The exposure was extended for one to two levels below the inferior end of planned arthrodesis to allow for optimal screw placement.



Screw Channel Preparation

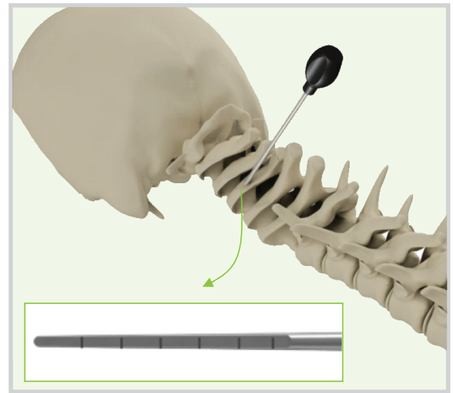
GS112-0200 AWL

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.



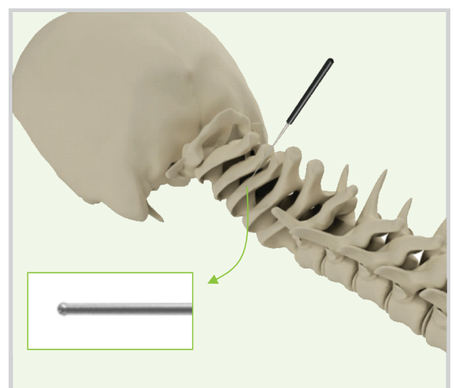
GS112-0300 Pedicle Probe (Straight)
GS112-0310 Pedicle Probe (Curved)

After creating the entry point, a pathway is prepared with the Pedicle Probe (Straight/Curved) to dilation and confirm the accurate depth of screw placement within bone. Pedicle Probe is available in 5mm intervals.



GS112-0400 Tester
GS112-0410 Tester

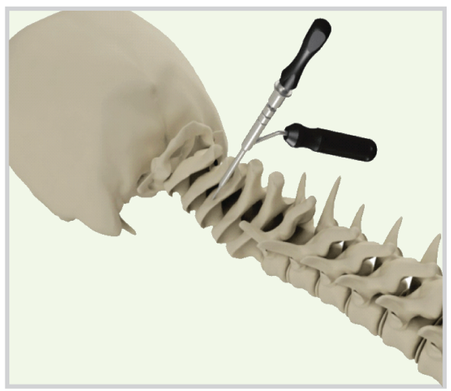
Use the Tester to palpate the screwchannel walls.



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 I-Handle
GS112-1010 Drill Guide

The entry point and screw trajectory at each lateral mass are depending on the anatomy of patient's vertebral body. In the general case, entry points are 1mm medial to the center of the lateral mass, and trajectories are 20 cephalad and 20 to 30 lateral.

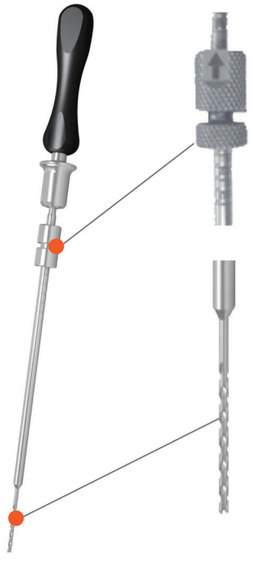


Drill Manual

- Drill Bit

GS112-1040 Adjustable Drill Stop

Stopper system on the Drill Bit limits the depth of penetration and it is available in 2mm intervals up to 40mm. (Diameters : 2.0/2.5/3.0mm)



- Handle

This handle is assembled all of shaft instruments such as Drill Bit, Tap, Poly Screw Driver.

- Drill Guide

Drill Bit and Tap have to be used with Drill Guide to prevent a mis-penetrating and to protect around tissues.

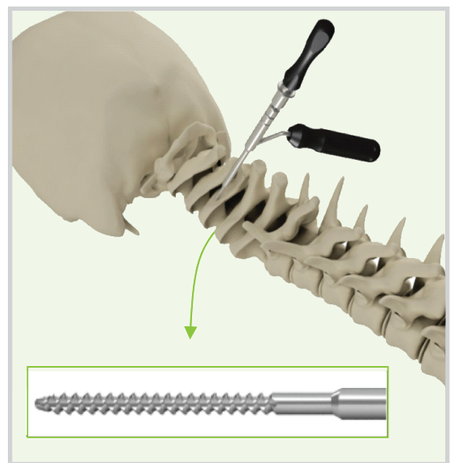
Tapping

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

Insert the Tap into the barrel of the Drill Guide and rotate clockwise manner while advancing the penetration until resistance is met.

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

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



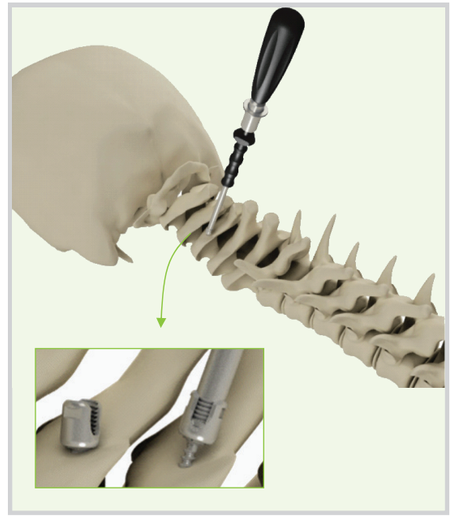
Polyaxial Screw Insertion

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

Assemble the cruciate tip of the Poly Screw Driver into the head of Polyaxial Screw until besure the screw is straight and rigidly connected and then, Insert the screw into the prepared threaded hole. Stop advancing the screw when the polyaxial head contacts the bone. For more clear fixation, checking the fluoroscope is recommended.

If you need more screw inserting and loosening after disconnecting the Poly Screw Driver, Poly Quick Screw Driver is recommended.

Repeat for all Screw placements.



Preparation for Rod Insertion

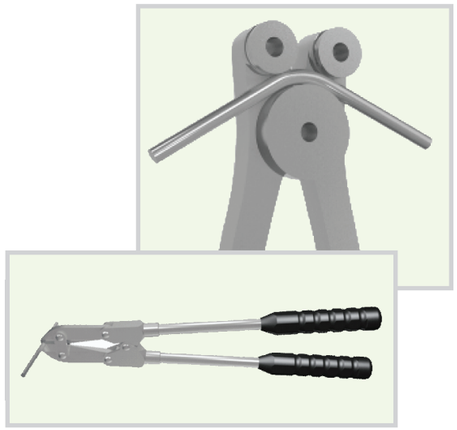
GS112-1510 Rod Bender
GS112-1400 Rod Cutter

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

Cut the rod to the appropriate length using Rod Cutter.

Contour the Rod to the appropriate shape using Rod Bender.

Do not straighten the Rod after bending.



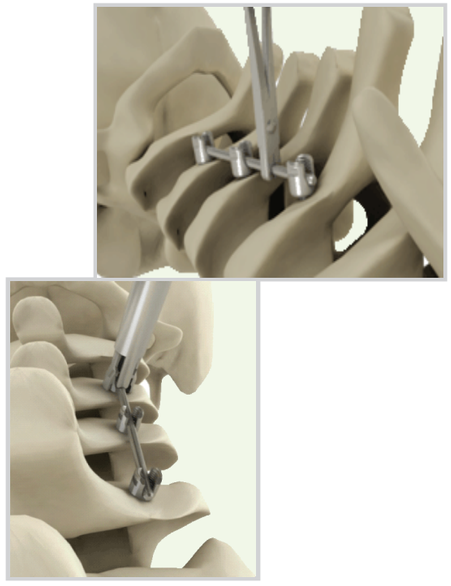
Rod Insertion

GS112-2000 Alignment T-Driver
GS112-1200 Rod Holder
GS112-1710 Rod Pusher
GS112-1900 Persuader
GS112-1520 Bending Iron

Insert the Rod into the head of screw using the Rod Holder, The Alignment T-Driver may be used to help to orient the Screw heads for the correct position.

Use the Rod Pusher or Persuader to facilitate rod placement and locking screw insertion.

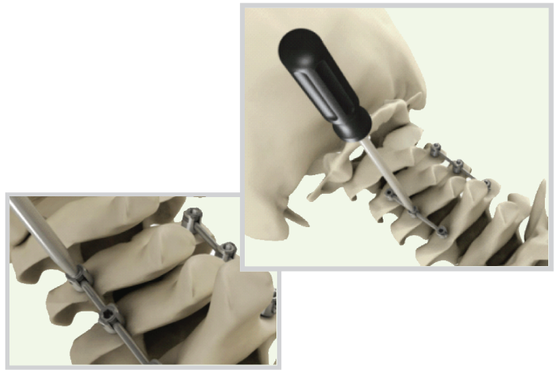
Bending Irons are available for additional contour adjustments after seating the screw.



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.



Compression or Distraction

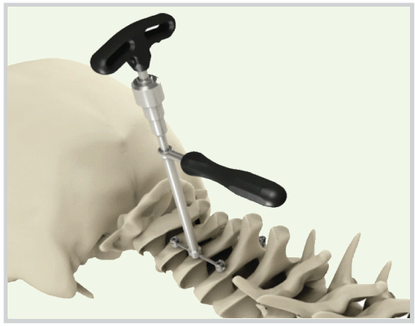
GS112-2700 Compressor
GS112-2800 Distracter

If needed, using the Compressor and Distractor to control the interval of disc is useful for proper operation.

Final Tightening

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

After compression or distraction is achieved, tighten the set screws using the Set Screw Driver combined with Torque Limiting Handle to the preset of 5Nm.

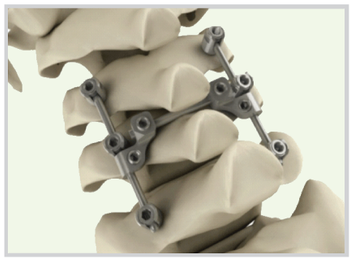


Transverse Link Connection (Optional)

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

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

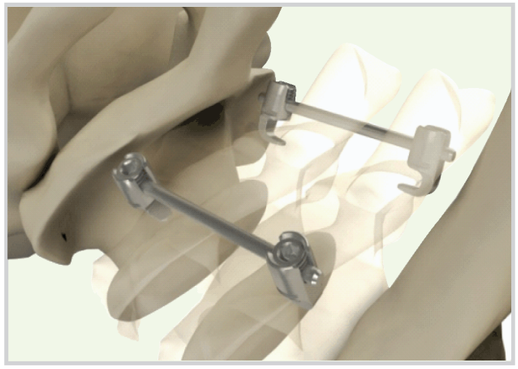
Choose a transverse link of appropriate length and apply the transverse link to the rod. And use the Transverse Link Driver, then secure the transverse link to rods by tightening the set screws by using Transverse Link Driver. Finally, transverse link connection is completed by tightening the hexagonal screw in the middle of transverse link by using Transverse Link Wrench.



Laminar Hook Placement (Optional)

GS112-6110 Hook Elevator
GS112-6010 Hook Holder

In some case, laminar hook is used in the cervical and upper thoracic spine instead of polyaxial screw. The lamina preparation and ligamentum flavum dissection is performed by using the Hook Elevator. The proper size of hook is used based on the thickness of the lamina.



Implants

Standard Range
Optional Range

1. SKY™ Cervical Poly Screw

Cortical Screw

1 P.D. 3.2 techninių reikalavimų punktas

1 P.D. 3.4 techninių reikalavimų punktas

ø3.5mm		ø4.0mm		ø4.5mm	
Cat. No.	Length	Cat. No.	Length	Cat. No.	Length
0821-3508	8mm	0821-4008	8mm	0821-4508	8mm
0821-3510	10mm	0821-4010	10mm	0821-4510	10mm
✓ 0821-3512	12mm	✓ 0821-4012	12mm	✓ 0821-4512	12mm
✓ 0821-3514	14mm	✓ 0821-4014	14mm	✓ 0821-4514	14mm
✓ 0821-3516	16mm	✓ 0821-4016	16mm	✓ 0821-4516	16mm
✓ 0821-3518	18mm	✓ 0821-4018	18mm	✓ 0821-4518	18mm
✓ 0821-3520	20mm	✓ 0821-4020	20mm	✓ 0821-4520	20mm
✓ 0821-3522	22mm	✓ 0821-4022	22mm	✓ 0821-4522	22mm
✓ 0821-3524	24mm	✓ 0821-4024	24mm	✓ 0821-4524	24mm
✓ 0821-3526	26mm	✓ 0821-4026	26mm	✓ 0821-4526	26mm
✓ 0821-3528	28mm	✓ 0821-4028	28mm	✓ 0821-4528	28mm
✓ 0821-3530	30mm	✓ 0821-4030	30mm	✓ 0821-4530	30mm
✓ 0821-3532	32mm	✓ 0821-4032	32mm	✓ 0821-4532	32mm
0821-3534	34mm	0821-4034	34mm	0821-4534	34mm
0821-3536	36mm	0821-4036	36mm	0821-4536	36mm
0821-3538	38mm	0821-4038	38mm	0821-4538	38mm
0821-3540	40mm	0821-4040	40mm	0821-4540	40mm
		0821-4042	42mm	0821-4542	42mm
		0821-4044	44mm	0821-4544	44mm
		0821-4046	46mm	0821-4546	46mm
		0821-4048	48mm	0821-4548	48mm
		0821-4050	50mm	0821-4550	50mm
		0821-4052	52mm		

2. SKY™ Partially Cervical Poly Screw

Partial Screw

1 P.D. 3.5 techninių reikalavimų punktas

ø3.5mm		ø4.0mm	
Cat. No.	Length	Cat. No.	Length
✓ 0825-3526	26mm	✓ 0825-4026	26mm
✓ 0825-3528	28mm	✓ 0825-4028	28mm
✓ 0825-3530	30mm	✓ 0825-4030	30mm
✓ 0825-3532	32mm	✓ 0825-4032	32mm
✓ 0825-3534	34mm	✓ 0825-4034	34mm
✓ 0825-3536	36mm	✓ 0825-4036	36mm
✓ 0825-3538	38mm	✓ 0825-4038	38mm
✓ 0825-3540	40mm	✓ 0825-4040	40mm

3. SKY™ Set Screw

1.6 pirkimo punktas

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

4. SKY™ Rod

1 P.D. 4 techninių reikalavimų punktas

ø3.3mm		ø3.5mm	
Cat. No.	Length	Cat. No.	Length
0865-0040	40mm	0866-0040	40mm
0865-0050	50mm	0866-0050	50mm
0865-0060	60mm	0866-0060	60mm
0865-0070	70mm	0866-0070	70mm
0865-0080	80mm	0866-0080	80mm
0865-0090	90mm	0866-0090	90mm
0865-0100	100mm	0866-0100	100mm
0865-0110	110mm	0866-0110	110mm
0865-0120	120mm	0866-0120	120mm
0865-0130	130mm	0866-0130	130mm
0865-0140	140mm	0866-0140	140mm
0865-0150	150mm	0866-0150	150mm
0865-0160	160mm	0866-0160	160mm
0865-0170	170mm	0866-0170	170mm
0865-0180	180mm	0866-0180	180mm
✓ 0865-0190	190mm	0866-0190	190mm
✓ 0865-0200	200mm	✓ 0866-0200	200mm
0865-0210	210mm	0866-0210	210mm
0865-0220	220mm	0866-0220	220mm
0865-0230	230mm	0866-0230	230mm
0865-0240	240mm	0866-0240	240mm
0865-0250	250mm	0866-0250	250mm

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

ø3.5mm - ø6.0mm	
Cat. No.	Length
1462-0100	100mm
1462-0200	200mm
1462-0300	300mm
1462-0400	400mm

Implants

1 P.D. 5.3 techninių reikalavimų punktas

6. SKY™ Cross Link

Cross Link (combine)

Cat. No.	Length
1300-3530	30mm
1300-3535	35mm
1300-3540	40mm
1300-3545	45mm
1300-3550	50mm
1300-3555	55mm
1300-3560	60mm
1300-3565	65mm
1300-3570	70mm

Cross Link (dura)

Cat. No.	Length
1305-0001	Free (3.3mm Rod)

1 P.D. 5.1 techninių reikalavimų punktas

9. SKY™ Domino

Domino (closed)

Cat. No.	Length
1360-3535	3.5-3.5mm
1360-3550	3.5-5.0mm
1360-3555	3.5-5.5mm
1360-3560	3.5-6.0mm
1360-3563	3.5-6.3mm

Domino (Triangle_closed)

Cat. No.	Length
1360-3535	3.5-3.5mm
1360-3550	3.5-5.0mm
1360-3555	3.5-5.5mm
1360-3560	3.5-6.0mm
1360-3563	3.5-6.3mm

Domino (open)

Cat. No.	Length
1370-3535	3.5-3.5mm
1370-3550	3.5-5.0mm
1370-3555	3.5-5.5mm
1370-3560	3.5-6.0mm
1370-3563	3.5-6.3mm

1 P.D. 5.1 techninių reikalavimų punktas

7. SKY™ Axial Connector

Axial Connector

Cat. No.	Diameter
1350-3535	3.5-3.5mm
1350-3550	3.5-5.0mm
1350-3555	3.5-5.5mm
1350-3560	3.5-6.0mm
1350-3563	3.5-6.3mm

10. SKY™ Laminar Hook System

Laminar Hook

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

1 P.D. 5.2 techninių reikalavimų punktas

8. SKY™ Lateral Connector

Lateral Connector (Anterior Open)

Cat. No.	Diameter
1323-3510	10mm
1323-3512	12mm
1323-3514	14mm
1323-3516	16mm

Angled Hook (Left)

Cat. No.	Height
1431-0404	4mm
1431-0405	5mm
1431-0406	6mm
1431-0407	7mm
1431-0408	8mm
1431-0409	9mm
1431-0410	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	AWL	
GS112-0300 GS112-0310	Probe (Straight) Probe (Curved)	
GS112-0400 GS112-0410	Tester	
GS112-1020 GS112-1025 GS112-1030 GS112-1040	Drill Bit 2.0mm (for Tap 3.5mm) Drill Bit 2.5mm (for Tap 4.0mm) Drill Bit 3.0mm (for Tap 4.5mm) Adjustable Drill&Tap Stop	
GS112-0535 GS112-0540 GS112-0545	Tap 3.5mm Tap 4.0mm Tap 4.5mm	
GS112-0600	Handle	
GS112-1010 GS112-1040	Drill Guide	
GS112-2000	Alignment T-Driver	
GS112-0940	Poly Screw Driver	
GS112-1200	Rod Holder	
GS112-1710	Rod Pusher	
GS112-1510	Rod Bender	
GS112-1400	Rod Cutter	

Instruments

GS112-2700	Compressor	
GS112-2800	Distracter	
GS112-1900	Persuader	
GS112-1520	In-situ Bender	
GS112-2900	Anti Torque Wrench	
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	
GS112-1220	Rod Connector Holder	

Option

GS112-6110	Hook Elevator	
GS112-6010	Hook Holder	
GS112-1100	Poly Quick Screw Driver	
GS112-9020 GS112-9010	Instruments Tray (SKY) Implants Tray (SKY)	

Instruments Tray

GS112-9020	SKY Instruments Tray	
GS112-9010	Implant Tray	

Instruction for Use

(SKY™ Reconstruction System)

1 P.D. 2 techninių reikalavimų punktas

• DEVICE DESCRIPTION

GS Medical Spinal Fixation Systems are made of devices for the posterior fixation of the non cervical spine. They include screws, hooks, set screws, connectors and rods (details are as below). The components are manufactured from titanium alloy (Ti6Al4V ELI) according to ISO 5832-3 and ASTM F-136.

• COMPONENTS

SKY Reconstruction System
: Screws , Hooks, Set Screw, Axial connectors, Cross Links and Rods (ø3.5, ø4.0 ø 4.5)., OCT Plate

• INDICATION FOR THE GS MEDICAL SPINAL FIXATION SYSTEMS

GS Medical Spinal Fixation Systems are indicated for temporary or permanent correction or stabilization of the vertebral column from the Occipital to the Cervical and with the aim of helping consolidation or bone fusion.
Use for the following indications;

- **Degenerative Disc Disease**
- **Degenerative Spondylolisthesis**
  - √ **Trauma**
  - √ **Fractures**
  - √ **Dislocations**
- **Tumors**
- **Stenosis**
- **Deformity**
  - √ **Kyphosis**
  - √ **Lordosis**
  - √ **Scoliosis**
- **Pseudarthrosis**
- **Revision of failed previous fusions**

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Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cell count (WBC), or marked shift in the WBC differential count.

• GENERAL CONDITIONS OF USE

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
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

• 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-up.
The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and dose 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 advice 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, disposal attention. Instruments should be examined for wear or damage prior to surgery.

• REUSE

An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.
It is recommended to verify that the instruments are in good condition and operating order prior to use during surgery.

• HANDLING

Correct handling of the implant is extremely important. The operating surgeon should avoid notching or scratching the device.

• 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.
Patient's overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.
The size and shape of the bone structures determine the size, shape and type of the implants.
Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.
Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates only is recommended if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon has to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the GS Medical surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

• SYSTEM COMPATIBILITY

While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer's spinal system. Any such use will negate the responsibility of GS Medical for the performance of the resulting mixing component implant.

• 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.

• STERILIZATION PROCEDURE RECOMMENDED FOR NON-STERILE MEDICAL DEVICES INCLUDING IMPLANTS

These are non-sterile implants. They must be sterilized before use. Use the storage trays for sterilization (except 600mm rods) 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.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	250 ℉(121 ℃)	20 Minutes
Steam	Gravity	273 ℉(134 ℃)	15 Minutes

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.

• 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 familiar with the surgical technique required and who have been trained to this end. 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 forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.
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.
Extreme care must be taken when the instruments are used near vital organs, nerves or vessels. Particular precautions must be taken when using the instruments in pediatrics.
Unless otherwise specified on the label, the instrument can be reused after decontamination, cleaning and sterilization.

• COMPLAINTS

Any health professional, having a complaint or grounds for dissatisfaction relating to the quality of the product its identity, its durability, its reliability, safety, effectiveness and/or its performance, should notify **GS Medical** or its representative. Moreover, if a device has malfunctioned, 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.

For further information or complaints, please contact:

Notes

Notes

SKY™

OCT Spinal Fixation System

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