UNIMAXTM Pedicle & Screw System

CAPABILITY • SIMPLICITY • STABILITY • RELIABILITY



Sanal[™] Cervical Plate









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MISSION STATEMENT

We at Paramount Surgicals, Inc are committed to designing, manufacturing and distributing the finest spinal implants and instruments.

Since its beginning, Paramount Surgicals, Inc has stood for one capability above all others – the ability to Innovate.

We strive without reserve for the greatest possible reliability and quality of our products and to be recognized in the market for our dedication, honesty and services.



UNIMAX[™]· Important Features

- Easy Maneuverability
- High Pullout Resistance
- Easy and definite correction of spinal deformities, like spondylolisthesis

Additional room for posterolateral fusion (PLF)

UNIMAX[™] is the first multiaxial pedicle screw and plate system in the market. It combines several desirable features, such as versatility, surgical maneuverability, stability and reliability.

Its interlocking construct closely follows the biomechanical principles of the normal spine, like the force transmission and load sharing at multiple fixation points.

UNIMAX offers both transverse and vertical load sharing of the spine, thereby providing maximum stability.



••••UNIMAX FEATURES & BENEFITS

FEATURES **BENEFITS**

Rectangular construct, stabilizing the spine at both the hori- zontal and vertical planes, treating each vertebra as one	Easy and multiple manipulations without compromising stability
Hemispherical bone screw-head and horizontal plate hole with a concave underside form a ball socket joint	Accommodates any pedicle angle
Unimax™ offers a two dimensional triangulation	Increases the pull-out resistance of the pedicle screws
Top loading system	Efficiently saves surgery time\
Vertical plates are placed more medially	Larger area for bone grafting
Simple, accurate set of instruments	Allows accurate reach and cuts surgery time by 30%

DEFORMITIES

UNIMAX[™] corrects low grade spondylolisthesis. Distraction or compression on either side allows scoliosis correction.

UNIMAX[™] PARTS & SURGICAL TOOLS



FLANGE NUT 9/32" Small Nut 7/16" Large Nut





IN THIS IMAGE: SELF DRILLING LUMBAR SCREWS 5.5 • 6.0 • 6.5 • 7.0 • 7.5 • 8.0 mm







Caution:

Federal law (USA) restricts the system for sale by or on the order of a physician.

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PEDICLE SCREW APPLICATION



HORIZONTAL PLATE APPLICATION

 Horizontal plates (with the square bolts pre-loaded) are applied over the pedicle screw heads and washers are placed over the end-holes of the horizontal plates.





INSTALLATION OF NUTS AND SCREWS

- The large flange nuts are applied onto the bone screws with the help of the nut wrench.
- The nuts are tightened halfway at this time.

VERTICAL PLATE INSTALLATION

- The vertical plates are applied over the horizontal plates after aligning the square bolts into a straight line.
- The small flange nuts are applied onto the square bolts and tightened.
- Large nuts are completely tightened.







 The Saral[™] Cervical Fixation System has a Unique Locking Mechanism. This ensures a stable locking of the cervical screws in the plate and a low profile that helps preserve the tissues. Its components are made from Titanium Alloy (Ti-6AI-4V) confirming to ASTM standard F-1717.

The ability to angle the screws up to 15° in all the directions allows for easy application and accomodation for settlement of the bony elements.



The Cervical Plates are available in a variety of sizes for 1 to 4 levels of cervical fusion.

The purpose of the SARAL[™] Cervical Fixation System is to provide stabilization during the development of a solid spinal fusion, improve initial stability in the post-operative period and result in a faster return to normal activities.



Sanal[™] Cervical Plate

> 1, 2, 3 & 4 LEVEL CERVICAL PLATES 18 - 34 mm, 38 - 52 mm, 55—70 mm, 75—91 mm

SCREWS

PLATES







SELF DRILLING SCREWS 10 - 18 mm SELF TAPPING SCREWS 10 - 18 mm RESCUE SCREWS

10 - 18 mm



Sanal M Surgical Echnique

- 1. The initial exposure and diskectomy are done as in any other classical anterior diskectomy on the right or left side, depending on the surgeon's preference.
- The incision made for a one or two level diskectomy can be from 1 to 2 inches. The dissection continues medially to the sternocleidomastoid muscle between the carotid vessels laterally and the trachea and esophagus medially.
- **3.** After reaching the anterior border of the vertebral bodies, the levels

are confirmed radiographically and radical diskectomy is carried out as usual.



- **4.** The disk space is then distracted using the disk spacer or any other system. The osteophytes and part of the cortical end-plates are removed to create the bed for bone grafting.
- **5.** A bone plug or spacer of either Allograft or Autograft is inserted into the disk space thus cleared.

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Sanal Cervical Plate



- **6.** The SARAL Cervical Plate of appropriate length is selected and it is laid over the vertebral bodies.
- **7.** After stabilizing the plate with a pin or an awl, a drill or a second awl is used to make the holes at the desired level.
- **8.** Screws of appropriate length are then locked into the plate. There is no additional procedure needed to lock the screw.

FDA Statement

This Device is approved for screw attachment or fixation to the pedicles of the Cervical spine. This Device system has labeling limitations. See package insert for further information.

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