S^4 Cervical System

Aesculap Spine

AESCULAP®
Implant Systems

S4 Cervical System

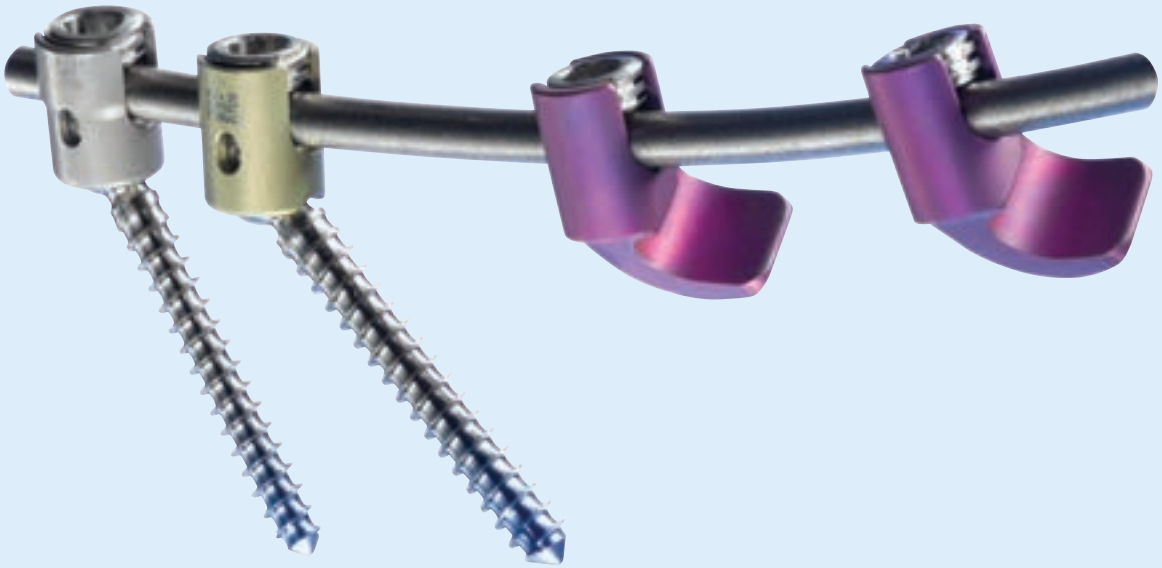
By combining the exceptionally small, yet stable design of the screw construct with simple instrumentation, the S4 Cervical System is a remarkably safe system for posterior column fixation.

The S4 Cervical System fulfills these aims with its four key features:

S4

- **Small size**
- **Stable screw rod connection**
- **Simple insertion**
- **Safe procedure**

The S4 Cervical System efficiently transfers these features to its implant and instrument versatility to meet the special needs of the cervical and thoracic spine.



Small

- Revolutionary undercut thread for miniature size of the screw head
- Wide screw angle and low profile for adaptation of the construct to patient anatomy
- Minimal access instruments for percutaneous approach

Stable

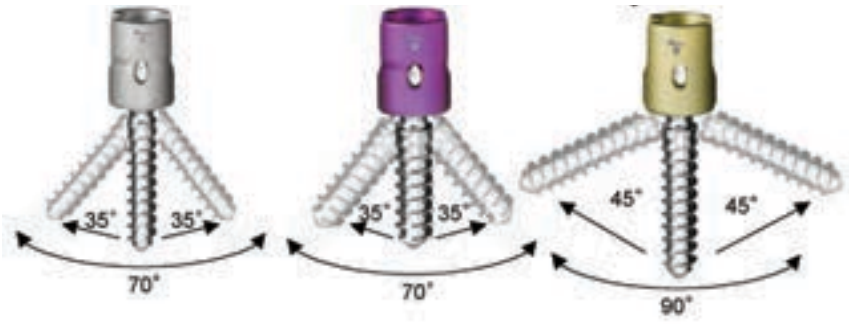
- Unique S⁴ closure mechanism with undercut thread stabilizes polyaxial construct
- Special shaped seat inside the screw body creates pressure vessel effect
- Provides high overall biomechanical stability

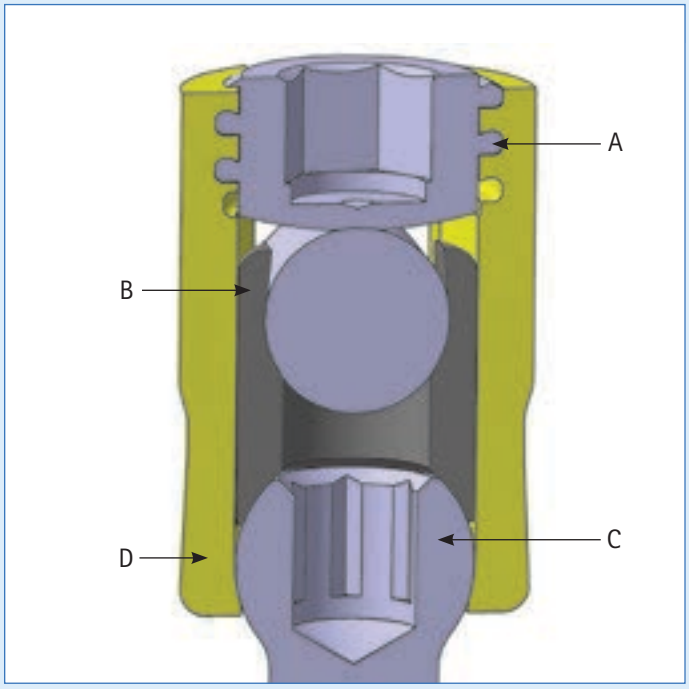
S⁴C Polyaxial and Favored Angle Screws

Diameter: 3.5 mm
Length: 10-30 mm

Diameter: 4.0 mm
Length: 10-30 mm

Favored Angle
Diameter: 4.0 mm
Length: 10-56 mm





A. Small screw head allowed by inward directed force of innovative thread design.

B. Superior axial rod grip from commercially pure titanium inserts.

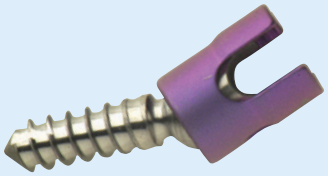
C. High interconnection strength developed at the interface of the screw body attached to the rough-ridged bone screw.

D. Unmatched locking power with less input torque as a result of pushing the bone screw into the screw body and forcing the screw body into its elastic range.

S4 Cervical System

Simple

- Specialized instruments for easy screw and hook placement in various anatomical situations
- Color-coded implants and instruments for ease-of-use
- Guiding instruments for minimal access and soft tissue and nerve root protection



Safe

Small implant volume, overall biomechanical strength, and easy access instruments help to achieve a fast and efficient surgical procedure and an optimal patient outcome

S⁴ Cervical provides several screw choices for challenging anatomy:

3.5 mm and 4.0 mm Polyaxial Screws:

- Lengths beginning at 10 mm and extending to 30 mm in 2 mm increments
- +/- 35° conical angulation
- Silver screw head for 3.5 mm
- Purple screw head for 4.0 mm

Favored Angle Screws:

- Lengths beginning at 10 mm and extending to 56 mm in 2 mm increments
- +/- 35° angulation with an additional 10° biased angulation in the cephalad and caudal directions for an angulation of 45° in either direction
- Gold screw head

Smooth Shank Screws:

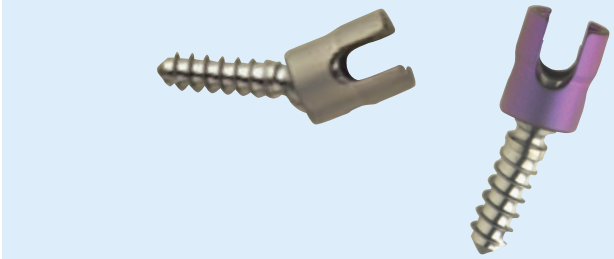
- Threaded portion lengths at 16 mm, 18 mm, 20 mm, 22 mm, 24 mm, and 26 mm with a variable smooth shank portion
- +/- 35° conical angulation
- Light blue screw head

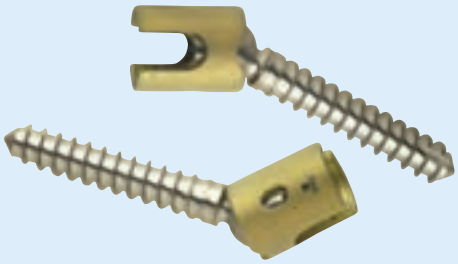
S⁴ Cervical offers an occiput plate in 4 sizes:

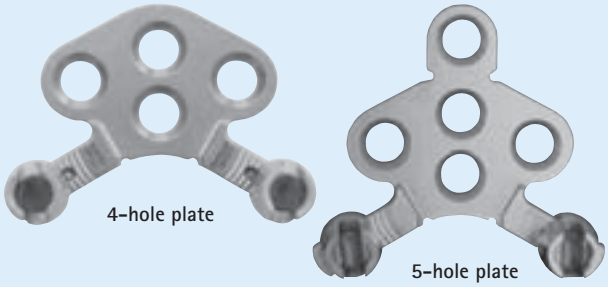
- Small, 4 hole: 28 – 38 mm medial-lateral
- Small, 5 hole: 28 – 38 mm medial-lateral
- Large, 4 hole: 38 – 48 mm medial-lateral
- Large, 5 hole: 38 – 48 mm medial-lateral

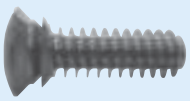
S⁴ Cervical offers occiput screws:

- 4.5 mm diameter occiput bone screws of lengths between 6-16 mm (1 mm increments)
- 5.5 mm diameter occiput bone screws of lengths between 6-16 mm (1 mm increments)

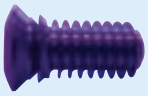








4.5 mm screw



5.5 mm screw

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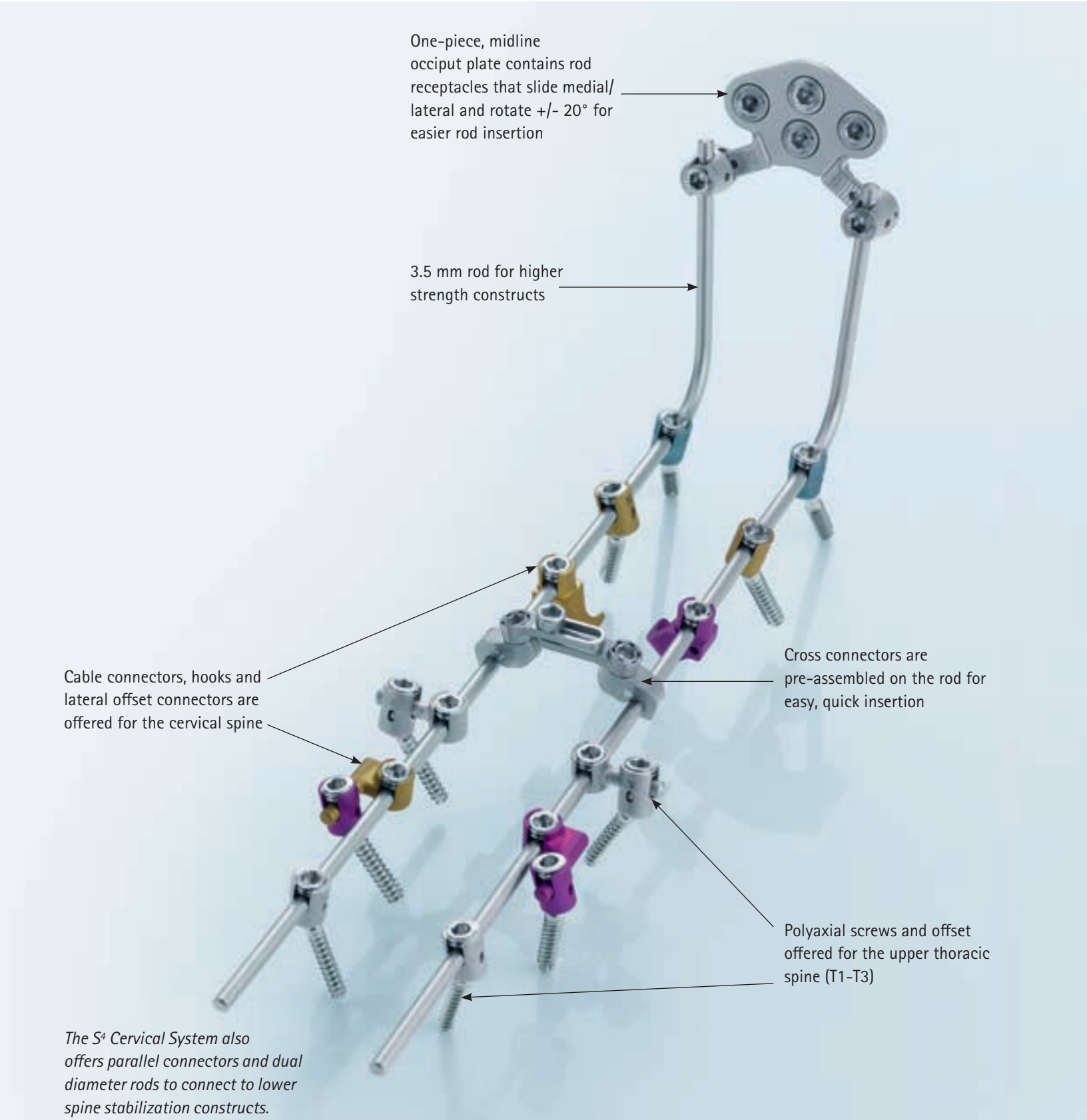

The S4 Cervical System also offers parallel connectors and dual diameter rods to connect to lower spine stabilization constructs.

Instructions for Use

The S4 Cervical System is used for posterior occipital, cervical, and thoracic fusion. The instruments listed in the technique form part of this system. They are used for adapting the S4 Cervical implants to the individual patient and to position and insert the implants.

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

When intended to promote fusion of the cervical spine and the thoracic spine (C1 – T3), the S4 Cervical Spinal System is intended for the following;

- DDD (Neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 – T3) spine.
The use of the polyaxial screws is limited to placement in T1 – T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

WARNING

The safety and effectiveness of pedicle screw spinal systems in general have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant; mechanical instability of the thoracic, lumbar, and sacral spine due to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

DEVICE Description

The S4 Cervical Spinal System consists of 3.5 mm rods in various lengths, thin and thick lamina hooks, 3.5 and 4.0 mm polyaxial screws of various lengths, occiput plates and screws, and various connectors.

CUSTOMER SERVICE

For further information regarding the S4 Cervical Spinal System or a copy of the S4 Cervical Surgical Technique Manual, please contact Aesculap Implant Systems, Inc. at 866-229-3002 or your local Aesculap Implant Systems Spine Distributor.

Aesculap Implant Systems, LLC | 3773 Corporate Parkway | Center Valley, PA | 18034
Phone 866-229-3002 | Fax 610-984-9096 | www.aesculapimplantsystems.com

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