Trinica® and Trinica® Select Anterior Cervical Plate Systems

A New Twist to Anterior Cervical Plates

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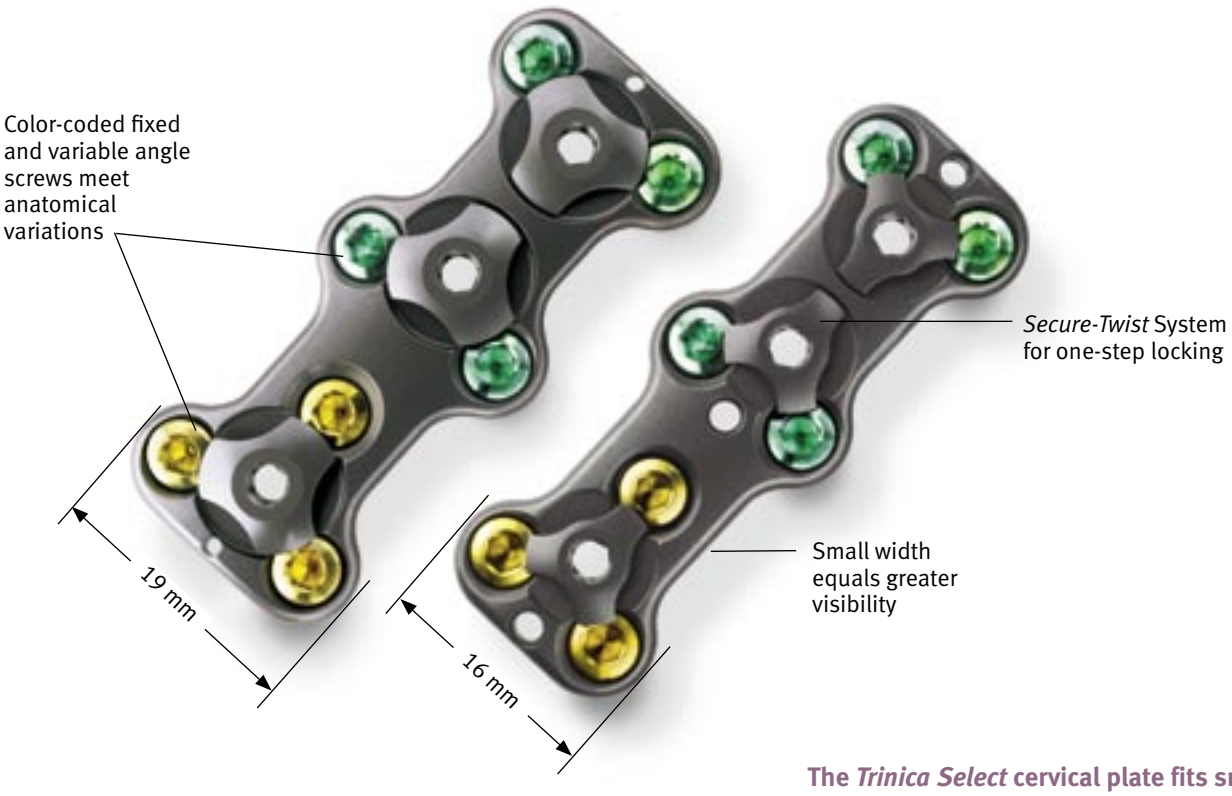
Trinica® and Trinica® Select Anterior Cervical plate systems

Trinica and *Trinica Select* offer a new twist to anterior cervical plates.

The *Trinica* and *Trinica Select* Anterior Cervical Plate Systems give surgeons the flexibility to easily customize them to each patient's unique anatomy. Flexibility is built-in to every aspect of the systems – from plate design and the innovative *Secure-Twist™* anti-migration system to the screw options and the instrumentation set. The result is a cervical plate system that is effective and easy to use.

One-step anti-migration system for fast securing

The unique *Secure-Twist* anti-migration system secures up to three screws at once with one simple twist. The anti-migration system is recessed into the plate, creating a smooth, low-profile fixation.



The *Trinica Select* cervical plate fits small anatomies

The slim, low-profile design and 16 mm lateral width provides the right fit for small anatomies.

All-Through-One Instrumentation

All-Through-One Placement Options

Single-barrel swivel guide
Maximized visibility during screw placement

Fixed guide
Facilitates placement of fixed screws and serves as a plate holder

Variable-angle guide
Angulation of the guide (cephalad and caudad) accommodates placement of variable angle screws

Multiple constructs for optimum flexibility and performance

Color-coded fixed and variable angle screws can be used alone or in combination to meet anatomical variations and achieve the surgeon's desired goal.

Screws

Screws for both the *Trinica* and *Trinica Select* Systems come in two configurations: self-drilling and self-tapping.

Self-drilling screws seek to provide surgeon's the option to reduce the number of instruments needed to implant a *Trinica* and *Trinica Select* anterior cervical plate.

Screws are easy to use and converge medially to create strong purchase.

Screw sizes easily accommodate individual anatomical situations.

A fitting profile creates better fit

The *Trinica* Anterior Cervical Plate Systems feature a rigid, pre-lordosed plate designed for better anatomical fit with little or no plate bending.

The *Trinica* plate's recessed anti-migration system and sleek design minimize esophageal irritation.

A full-range of plate sizes further ensures appropriate fit.

Instrumentation designed for ease-of-use

- A single hex driver is used to place the screws, and a quarter turn of the Secure-Twist anti-migration system locks down up to three screws at once.
- A power or manual drill, tap or awl can be used for hole preparation, depending on surgeon preference.
- Drilling, tapping and screw placement can be performed through the *Trinica Select* All-Through-One (ATO) guide to facilitate precise screw placement and protect soft tissues.

Trinica and *Trinica Select* Specifications

Plates	***Trinica***	***Trinica Select***
Levels	1,2,3,4	1,2,3
Material	Titanium Alloy (Ti-6Al-4V-Tiodized)	Titanium Alloy (Ti-6Al-4V-Tiodized)
Width	19 mm	16 mm
Thickness	2.5 mm	2.5 mm
Length	22 - 92 mm	20 - 72 mm
Screws	**Screws available in standard (4.2 mm) and large (4.6 mm) sizes**	
Fixed	10-18 mm in one mm increments	10-18 mm in one mm increments
Variable	10-18 mm in one mm increments	10-18 mm in one mm increments

All-Through-One (ATO) instrumentation for the Trinica® Select Anterior Cervical Plate System simplifies the surgical procedure while requiring less retraction and reduces risk of soft-tissue damage

Instrumentation designed for ease of use.

The right instruments can reduce procedure time and increase reliability of plate placement. *Trinica Select* System instrumentation has several benefits:

- Common guide for drill, tap and screw simplifies procedure
- Guided screw insertion increases placement accuracy
- Protected screw placement minimizes need for retraction
- Minimal gap between guide and plate provides soft-tissue protection
- Unique, shorter instruments facilitate ease of implementation

A close fit between the All-Through-One guide and plate reduces risk of soft-tissue damage, even with minimal retraction

DEVICE DESCRIPTION: The *Trinica*® and *Trinica*® *Select* Anterior Cervical Plate Systems consist of cervical plates, locking caps, bone screws, and the instruments necessary to implant this specific system. All implant components are made from a titanium alloy (Ti-6Al-4V). The *Trinica* and *Trinica Select* Anterior Cervical Plate Systems are intended to provide stabilization of the cervical vertebra for various indications (see below). The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and self-drilling bone screws using an anterior approach. Bone screws are available for fixed angle or variable angle implantation. The *Trinica* and *Trinica Select* Anterior Cervical Plate Systems are intended to be removed after solid fusion has occurred.

INDICATIONS: The *Trinica* and *Trinica Select* Anterior Cervical Plate Systems are intended for anterior interbody screw fixation of the cervical spine. The Systems are indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

CONTRAINDICATIONS: Contraindications for use of the *Trinica* and *Trinica Select* Anterior Cervical Plate Systems include: overt infection or distant foci of infections, local inflammation, with or without fever or leukocytosis, pregnancy, diseases or conditions other than those specifically described in the Indications section, use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae, where attempted correction exceeds the limits of physiological conditions, uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions, metabolic disorders that may impair bone formation, inadequate bone stock to support the device, inability to restrict high activity level, obesity, poor prognosis for good wound healing (e.g. decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition), failure to explant the device after bony fusion

WARNINGS: Some metals, polymers, chemicals, and other materials utilized with orthopedic implants have been known to cause cancer and other adverse body reactions, or reports in the literature have suggested such causation. Any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget's disease has been reported to progress to cancer; surgical candidates suffering from this disease should be warned accordingly. Implantation of foreign material in tissues can elicit an inflammatory reaction. Current literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.

PRECAUTIONS: The *Trinica* and *Trinica Select* Anterior Cervical Plate Systems instrumentation should only be used after the surgeon has had adequate training in this method of fixation and has become thoroughly knowledgeable about the spinal anatomy and biomechanics. A surgical technique for the *Trinica* and *Trinica Select* Anterior Cervical Plate Systems are available upon request. This technique is not a substitute for training and is for general informational purposes only. Components from other anterior cervical plating systems must not be intermixed with the *Trinica* and *Trinica Select* Anterior Cervical Plate Systems components since compatibility of the components is not known. Do not use implants made from dissimilar metals (such as cobalt chromium-molybdenum alloy or stainless steel) in contact with components of the *Trinica* and *Trinica Select* Anterior Cervical Plate Systems; otherwise, galvanic corrosion may occur. If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant(s) surface. The plates must not be repeatedly or excessively bent. Do notreverse bend the plate.

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