uNion®

cervical plate system

Surgical Technique

100 Years

Over A Century Of Innovation

ulrich medical USA

Surgical Technique

uNion

Contents

Introduction

1.

This surgical technique describes the implant, the instruments, and the steps necessary to implant the uNion cervical plate system. This technique is not sufficient as the sole basis for a successful procedure with the system. It is recommended to master the surgical technique with an experienced surgeon or company trainer.

uNion is a cervical plate system used to provide mechanical support of the cervical spine. The system provides standard plate designs as well as midline plates. The plating system offers a variety of screw options including self-drilling, self-drilling/self-tapping and rescue self-tapping screws, all available in either fixed or variable designs.

The same screws and instruments are used for all cervical plates. Screw sizes include 4mm and 4.5mm diameters and 12mm to 18mm lengths.

The plates are designed with a blocking mechanism to restrict screw backout. The blocking mechanism is engaged by the same driver used to insert the screws. Visual and tactile blocking of each screw allows for easy implantation.

Indications for Use

The uNion cervical plate system is intended for anterior fixation of the cervical spine (C2 to T1). The system is to be used to provide stabilization of the anterior cervical spine as an adjunct to fusion for the treatment of degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), pseudarthrosis or failed previous fusion.

Contraindications

- Patients with acute infection, whether superficial or deep
- Observed bone defects of the anterior spine without additional anterior bridging
- Patients with fever or leukocytosis
- Patients with spine associated infections (e.g., spondylodiscitis)
- Patients with documented material allergy or tendency for reactions to foreign bodies
- Patients with a poor general medical or psychological condition which could be further exacerbated by the intervention; in these patients the attending surgeon must carefully weigh the risks and benefits
- Patients with insufficient bone mass or bone quality (e.g., severe osteoporosis, osteopenia, osteomyelitis)
- Patients who are pregnant
- Any condition not described in the indications for use

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

Warnings and Precautions

The following warnings and precautions should be understood by the surgeon and explained to the patient. These warnings are important considerations particular to metallic internal fixation devices. General surgical risks should also be explained to the patient prior to surgery.

- This product is only to be used by a surgeon experienced in spinal surgery. Use of the uNion cervical plate system should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics. The latest revisions of the package insert and surgical technique are available from ulrich medical USA, at 18221 Edison Ave., Chesterfield, MO 63005 (Phone: 636.519.0268, Fax: 636.519.0271, Web: www.ulrichmedicalusa.com).
- Responsibility for the proper selection of patients, adequate training and experience in the choice and placement of implants rests with the surgeon.
- The patient is to be instructed carefully as to the risks involved in the implantation of the uNion system. The surgeon should discuss the expectations of the surgery inherent in the use of the product with the patient, also with respect to the physical limitations of the product.
- Postoperative activities influence the duration of the implant and its durability in the bone. The patient must therefore be advised regarding the risk involved in everyday activities and regarding the appropriate behavior. The physician's instructions are to be strictly obeyed.
- Particular attention should be given to a discussion postoperatively and to the necessity for periodic medical follow-up.
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
- The plate should only be contoured in the bend zones using the supplied plate bender. Contouring the plate should be gradual and great care should be used to avoid damaging the surface of the device. Do not reverse bend as this can weaken the plate.
- Selection of the correct implant and its placement is to be observed carefully, applying the appropriate radiological technique, before, during and after surgery. Errors in implant selection and position could result in premature clinical implant failure.
- Failure to use the appropriate product for the application may result in a clinical failure. The product should be used in the correct anatomic location, consistent with the standards of internal fixation. The features and quality of human bone limit the size and resistance of the implant. Without successful fusion, no implant can resist long term biomechanical forces. Implant failure is possible even after successful fusion.
- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Careful handling and storage of the product is required. Scratching or damage to the component can significantly reduce the strength and fatigue resistance of the product. If bending is needed, bending should be done in the middle of the plate. The implant should not be bent repeatedly or excessively or re-bent. Such damage can lead to failure of the implant.
- Delayed healing, non-union or subsequent bone resorption or trauma may lead to excessive stress on the implant(s) and result in loosening, bending, cracking or fracturing.
- A successful result is not always achieved in every surgical procedure. In spine surgery, there are many extenuating circumstances which may compromise results. The device system is not intended to be the sole means of spinal support. Implants can break when subjected to the increased loading associated with delayed healing or non-union.
- Careful preoperative, intraoperative and postoperative planning is important in the successful utilization of the system by a surgeon. In addition, the proper selection and compliance of the patient will greatly affect the results.
- At no time should titanium implants be used together with components made of other materials such as stainless steel. Mixing of dissimilar metals can accelerate the corrosion process.
- Use uNion CPS components only with other uNion components. Do not use with components from any other spinal system or manufacturer.
- Implants are single use only. Once the implant has been used, it must not be used again. Even if the implant appears undamaged, previous strain may have resulted in irregularities that could shorten the implant life. Only new, undamaged implants may be used. Used or potentially damaged implants must be discarded.
- A prolonged healing phase, unsuccessful bone fusion or subsequent bone resorption or trauma can place undue stress on the implant, which, in turn, could lead to loosening, deformation, cracking or breakage of the implant.
- uNion has not been evaluated for safety and compatibility in the MR environment. uNion has not been tested for heating or migration in the magnetic resonance imaging (MRI) environment.

uNion Implants

Cervical Plates

Plate features:

- Plate length measures from center of hole to center of hole
- Standard plates: 2.0mm thickness at waist, 16.5mm width

UM102-01-xx

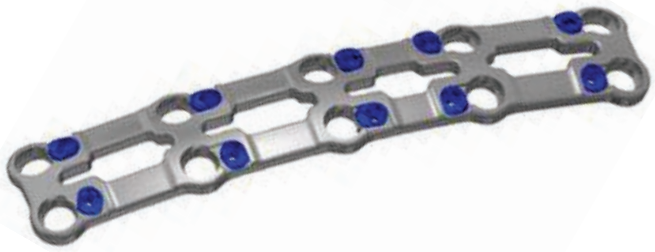
standard cervical plate, one-level, lengths 12mm - 26mm

UM102-02-xx

standard cervical plate, two-level, lengths 24mm - 46mm

UM102-03-xx

standard cervical plate, three-level, lengths 39mm - 69mm



UM102-04-xx

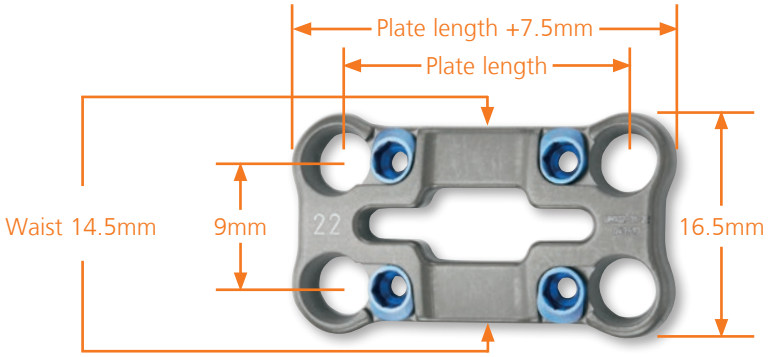
standard cervical plate, four-level, lengths 60mm - 84mm

UM101-01-xx

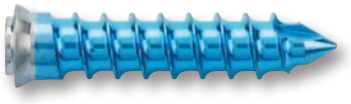
midline cervical plate, one-level, lengths 12mm - 26mm

UM101-02-xx

midline cervical plate, two-level, lengths 24mm - 46mm

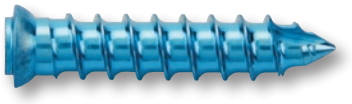


uNion Implants



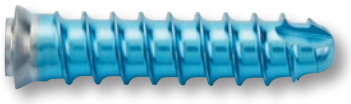
UM144-40-xx

screw, self-drilling/self-tapping fixed
Ø 4mm, length 12mm - 18mm



UM154-40-xx

screw, self-drilling/self-tapping variable
Ø 4mm, length 12mm - 18mm

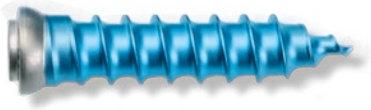


UM142-45-xx

screw, rescue self-tapping fixed
Ø 4.5mm, length 12mm - 18mm

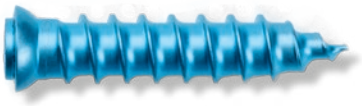
UM152-45-xx

screw, rescue self-tapping variable
Ø 4.5mm, length 12mm - 18mm



UM140-40-xx

screw, self-drilling fixed
Ø 4.0mm, length 12mm - 18mm

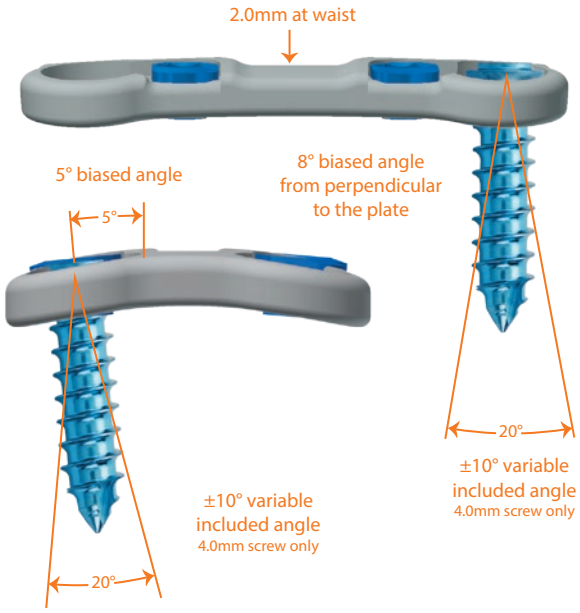


UM150-40-xx

screw, self-drilling variable
Ø 4.0mm, length 12mm - 18mm

Screw Color (Anodizing) Chart

	Fixed Screw		Variable Screw
Screw Length	**Shaft**	**Head**	**Shaft & Head**
12mm	**Dark Blue**	Gray	**Dark Blue**
14mm	**Magenta**	Gray	**Magenta**
16mm	**Gold**	Gray	**Gold**
18mm	**Light Blue**	Gray	**Light Blue**



uNion Instruments

UM170-00-01

2.5mm Ø awl (10mm depth in drill guide, 4mm depth in sleeve)

UM170-00-12

awl sleeve

UM170-00-02, 03, 04

drill guides: (from top to bottom) fixed angle guide, variable angle guide, dual drill guide - variable converging design allows drill only to pass through sleeves

UM170-00-05

plate bender

UM170-00-06 or CS-1871

plate holder
outer connection

UM170-00-09

jeweler handle: A/O connect

UM170-00-10, 11

2.5mm hex screwdrivers
option 1: split tip - 10
option 2: tapered tip (black laser etching) - 11

UM170-00-07, 08

2 handles: A/O connect
option 1: ratcheting - 07
option 2: static - 08

UM180-00-10, 12, 14, 16, 18

2.5mm Ø drills
(lengths: 10mm, 12mm, 14mm, 16mm, 18mm)

UM180-00-25

cervical plate temporary fixation screw
(2.5mm thread diameter)

■ Implant Selection and Placement

Midline Plates

The application for the midline plate is identical to the procedure for implanting a standard plate which is described below.

Implant selection

Choose the appropriate length plate and type of screws.

The length indicated on plates corresponds to the hole center to hole center spacing. The screw length is the depth the screw extends below the plate. Ensure that the plate length provides sufficient area for cephalad and caudal screw angulation without end plate penetration.

Plate bending (UM170-00-05)

Plates are precontoured with an 8° lordotic curve. If bending is required to provide a better match to the anatomy, the plate bender may be used for contouring.

Caution: Midline plates should not be bent.

Caution: Do not bend the plate in the proximity of the screw holes or blocking mechanism. Once bent, do not reverse bend as this can weaken the plate.

Caution: Bending the plate may cause a loss of function to the blocking mechanism.

Plate placement

Place the plate into position using the provided plate holder(s) (UM170-00-06 or CS 1871).

Temporary fixation screws (UM180-00-25) may be placed in any of the screw holes. Use the 2.5mm hex screwdrivers (UM170-00-10, -11) for insertion. Ensure temporary fixation screws are removed before completing the case.

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■ Implantation

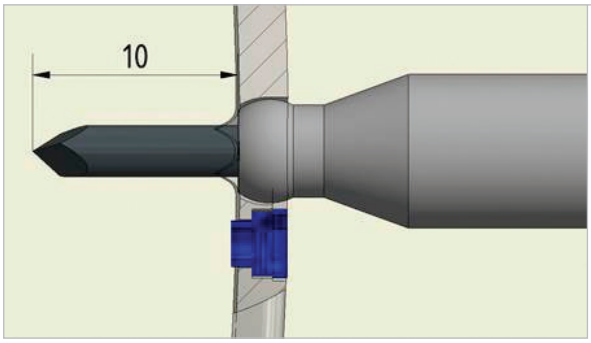
Drill guides

Fixed angle | Variable angle

Guide options for hole preparation

Option 1: Fixed angle drill guide (UM170-00-03) is aligned to the screw hole with the small pilot diameter on the tip of the drill guide.

Option 2: Variable angle drill guide (UM170-00-02) allows for free hand angle selection. Ensure that the angle of the guide relative to the biased angle of the hole does not exceed 10 degrees.



Fixed angle | Variable angle

Use corresponding drill based on screw length (10mm - 18mm)

Hole preparation

The hole can be created with the Ø 2.5mm awl (UM170-00-01), which creates a 10mm deep hole when used with the drill guide or 4mm hole with the awl sleeve (UM170-00-12), or with the Ø 2.5mm drill.

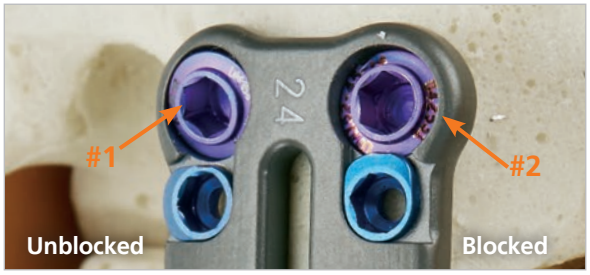
If using the Ø 2.5mm drill (UM180-00-10, 12, -14, -16, -18), select the drill length that corresponds to the chosen screw length and attach it to an A/O handle (UM170-00-07, -08, -09). Both the drill and the awl should be advanced until they stop on the drill guide to achieve the depth specified.

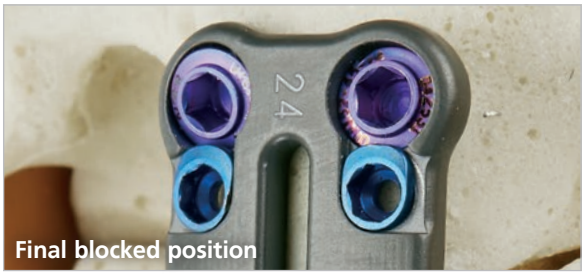
Screw insertion

Screw insertion

The 2.5mm hex screwdriver (UM170-00-10, -11) is offered in two self-retaining tips (split & tapered) to hold the screw during insertion. Load the desired 4.0mm primary screw length onto the screwdriver. Advance the screw until it seats firmly inside the screw hole in the plate. Screws must be seated completely for the blocking mechanism to engage.

Note: Variable screws cannot be angulated more than plus or minus 10 degrees. Ø 4.5mm variable screws may be angulated but will need to be threaded into the screw hole.





Screw #1: 4.0mm variable screw at 10 degree angulation
Screw #2: 4.5mm variable screw at 0 degree angulation

Engage blocking mechanism

Each screw is secured by rotating the blocking mechanism ¼ turn with the same driver used for screw insertion.

Caution: Depending on the screw hole location, blocking mechanisms will need to be turned either clockwise or counter-clockwise (See picture). Do not turn the blocking mechanism in the wrong direction. The blocking mechanism only requires ¼ turn to properly position it over the screw head. Turning the blocking mechanism requires limited force.

If excessive force is required, STOP and evaluate. Issues that may increase the required force to be applied to the blocking mechanism may include:

- Screw head is not properly seated into the screw hole
- Blocking mechanism is turned past the ¼ turn position
- Blocking mechanism is turned in the wrong direction

Note: To familiarize yourself with the behavior of the blocking mechanism, it is recommended to turn it to the locked position and then back to the unlocked position prior to implantation.

■ Removal

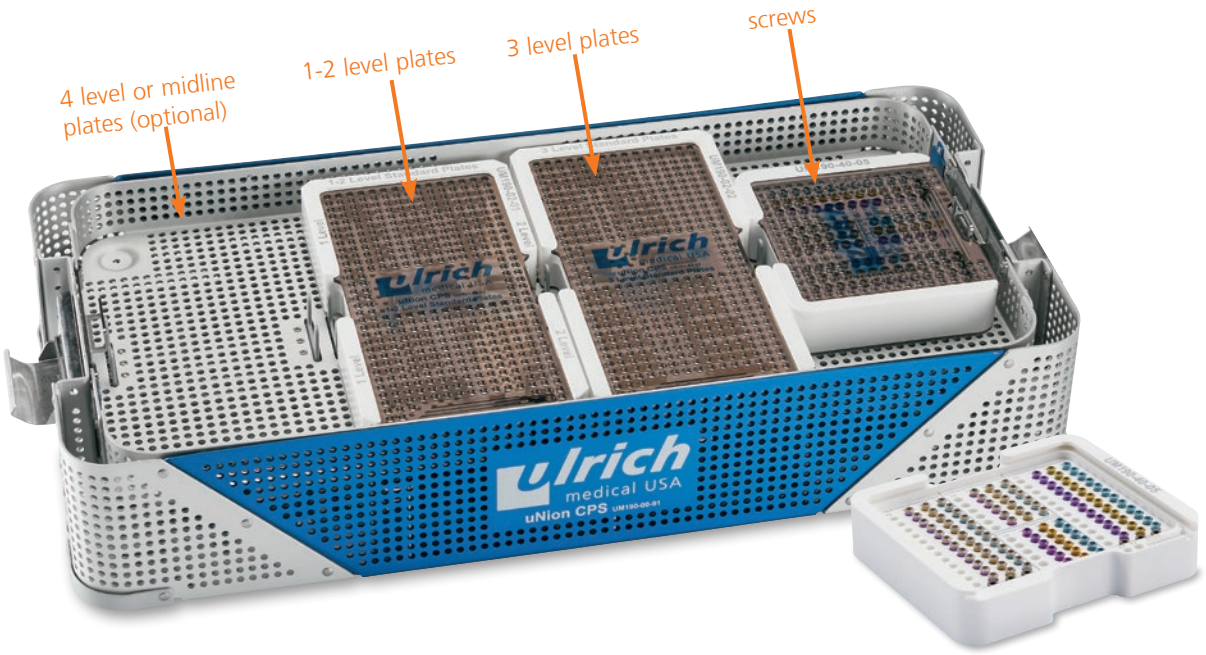
Remove screws

Using the 2.5mm screwdriver, rotate the blocking mechanism ¼ turn to uncover the screw head. The mechanism is now in the unblocked position.

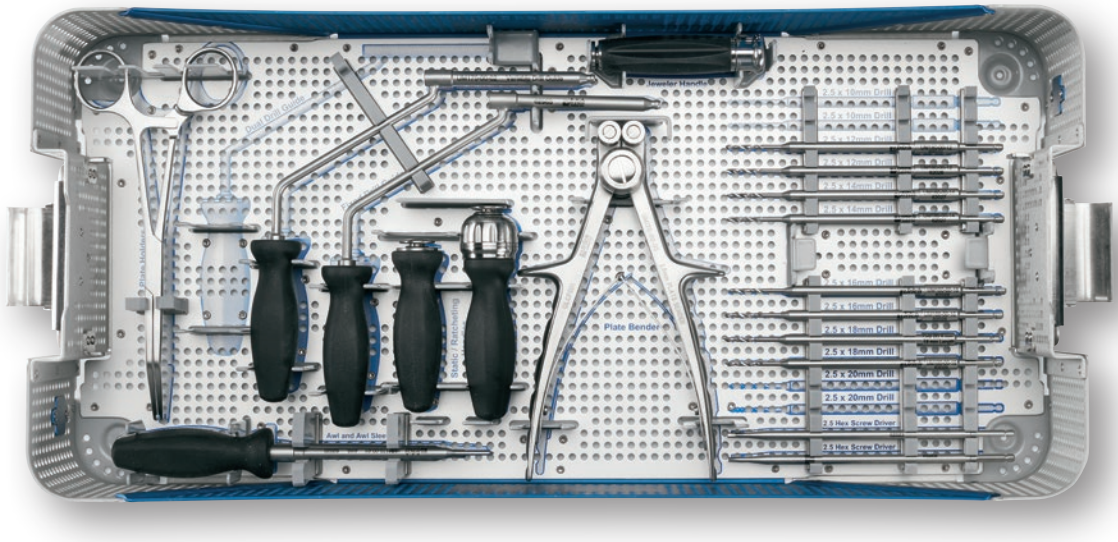
After the blocking mechanisms have been rotated, each screw can be removed by using the 2.5mm screwdriver.

Note: Do not over rotate the blocking mechanism, apply ¼ turn only.

Trays



Implant Tray (modular)



Instrument Tray

Components

Implants	Product Number
Midline Cervical Plate, 1-Level, 12mm	UM101-01-12
Midline Cervical Plate, 1-Level, 14mm	UM101-01-14
Midline Cervical Plate, 1-Level, 16mm	UM101-01-16
Midline Cervical Plate, 1-Level, 18mm	UM101-01-18
Midline Cervical Plate, 1-Level, 20mm	UM101-01-20
Midline Cervical Plate, 1-Level, 22mm	UM101-01-22
Midline Cervical Plate, 1-Level, 24mm	UM101-01-24
Midline Cervical Plate, 1-Level, 26mm	UM101-01-26
Midline Cervical Plate, 2-Level, 24mm	UM101-02-24
Midline Cervical Plate, 2-Level, 26mm	UM101-02-26
Midline Cervical Plate, 2-Level, 28mm	UM101-02-28
Midline Cervical Plate, 2-Level, 30mm	UM101-02-30
Midline Cervical Plate, 2-Level, 32mm	UM101-02-32
Midline Cervical Plate, 2-Level, 34mm	UM101-02-34
Midline Cervical Plate, 2-Level, 37mm	UM101-02-37
Midline Cervical Plate, 2-Level, 40mm	UM101-02-40
Midline Cervical Plate, 2-Level, 43mm	UM101-02-43
Midline Cervical Plate, 2-Level, 46mm	UM101-02-46
Standard Cervical Plate, 1-Level, 12mm	UM102-01-12
Standard Cervical Plate, 1-Level, 14mm	UM102-01-14
Standard Cervical Plate, 1-Level, 16mm	UM102-01-16
Standard Cervical Plate, 1-Level, 18mm	UM102-01-18
Standard Cervical Plate, 1-Level, 20mm	UM102-01-20
Standard Cervical Plate, 1-Level, 22mm	UM102-01-22
Standard Cervical Plate, 1-Level, 24mm	UM102-01-24
Standard Cervical Plate, 1-Level, 26mm	UM102-01-26
Standard Cervical Plate, 2-Level, 24mm	UM102-02-24
Standard Cervical Plate, 2-Level, 26mm	UM102-02-26
Standard Cervical Plate, 2-Level, 28mm	UM102-02-28
Standard Cervical Plate, 2-Level, 30mm	UM102-02-30
Standard Cervical Plate, 2-Level, 32mm	UM102-02-32
Standard Cervical Plate, 2-Level, 34mm	UM102-02-34
Standard Cervical Plate, 2-Level, 37mm	UM102-02-37
Standard Cervical Plate, 2-Level, 40mm	UM102-02-40
Standard Cervical Plate, 2-Level, 43mm	UM102-02-43
Standard Cervical Plate, 2-Level, 46mm	UM102-02-46
Standard Cervical Plate, 3-Level, 39mm	UM102-03-39
Standard Cervical Plate, 3-Level, 42mm	UM102-03-42
Standard Cervical Plate, 3-Level, 45mm	UM102-03-45
Standard Cervical Plate, 3-Level, 48mm	UM102-03-48
Standard Cervical Plate, 3-Level, 51mm	UM102-03-51
Standard Cervical Plate, 3-Level, 54mm	UM102-03-54
Standard Cervical Plate, 3-Level, 57mm	UM102-03-57
Standard Cervical Plate, 3-Level, 60mm	UM102-03-60
Standard Cervical Plate, 3-Level, 63mm	UM102-03-63
Standard Cervical Plate, 3-Level, 66mm	UM102-03-66
Standard Cervical Plate, 3-Level, 69mm	UM102-03-69
Standard Cervical Plate, 4-Level, 60mm (optional)	UM102-04-60
Standard Cervical Plate, 4-Level, 64mm (optional)	UM102-04-64
Standard Cervical Plate, 4-Level, 68mm (optional)	UM102-04-68
Standard Cervical Plate, 4-Level, 72mm (optional)	UM102-04-72
Standard Cervical Plate, 4-Level, 76mm (optional)	UM102-04-76

Components

Implants	Product Number
Standard Cervical Plate, 4-Level, 80mm (optional)	UM102-04-80
Standard Cervical Plate, 4-Level, 84mm (optional)	UM102-04-84
Self Drilling Fixed Screw, Ø 4.0x12mm	UM140-40-12
Self Drilling Fixed Screw, Ø 4.0x14mm	UM140-40-14
Self Drilling Fixed Screw, Ø 4.0x16mm	UM140-40-16
Self Drilling Fixed Screw, Ø 4.0x18mm	UM140-40-18
Rescue Self-Tapping Fixed Screw, Ø 4.5mm, length 12mm	UM142-45-12
Rescue Self-Tapping Fixed Screw, Ø 4.5mm, length 14mm	UM142-45-14
Rescue Self-Tapping Fixed Screw, Ø 4.5mm, length 16mm	UM142-45-16
Rescue Self-Tapping Fixed Screw, Ø 4.5mm, length 18mm	UM142-45-18
Self-Drilling/Self-Tapping Fixed Screw, Ø 4mm, length 12mm	UM144-40-12
Self-Drilling/Self-Tapping Fixed Screw, Ø 4mm, length 14mm	UM144-40-14
Self-Drilling/Self-Tapping Fixed Screw, Ø 4mm, length 16mm	UM144-40-16
Self-Drilling/Self-Tapping Fixed Screw, Ø 4mm, length 18mm	UM144-40-18
Self Drilling Variable Screw, Ø 4.0x12mm	UM150-40-12
Self Drilling Variable Screw, Ø 4.0x14mm	UM150-40-14
Self Drilling Variable Screw, Ø 4.0x16mm	UM150-40-16
Self Drilling Variable Screw, Ø 4.0x18mm	UM150-40-18
Rescue Self-Tapping Variable Screw, Ø 4.5mm, length 12mm	UM152-45-12
Rescue Self-Tapping Variable Screw, Ø 4.5mm, length 14mm	UM152-45-14
Rescue Self-Tapping Variable Screw, Ø 4.5mm, length 16mm	UM152-45-16
Rescue Self-Tapping Variable Screw, Ø 4.5mm, length 18mm	UM152-45-18
Self-Drilling/Self-Tapping Variable Screw, Ø 4mm, length 12mm	UM154-40-12
Self-Drilling/Self-Tapping Variable Screw, Ø 4mm, length 14mm	UM154-40-14
Self-Drilling/Self-Tapping Variable Screw, Ø 4mm, length 16mm	UM154-40-16
Self-Drilling/Self-Tapping Variable Screw, Ø 4mm, length 18mm	UM154-40-18

Components

Instruments	Product Number
Awl (2.5mm)	UM170-00-01
Variable Drill Guide	UM170-00-02
Fixed Drill Guide	UM170-00-03
Dual Drill Guide	UM170-00-04
Plate Bender	UM170-00-05
Plate Holder - Outer Connection	UM170-00-06 or CS 1871
Ratcheting Handle (optional)	UM170-00-07
Static Handle	UM170-00-08
Jeweler Handle	UM170-00-09
2.5 Hex Screwdriver Shaft Split Tip	UM170-00-10
2.5 Hex Screwdriver Shaft Tapered Tip	UM170-00-11
Awl Sleeve	UM170-00-12
Drill, 2.5 x 10mm (optional)	UM180-00-10
Drill, 2.5 x 12mm	UM180-00-12
Drill, 2.5 x 14mm	UM180-00-14
Drill, 2.5 x 16mm	UM180-00-16
Drill, 2.5 x 18mm	UM180-00-18
Temporary Fixation Screw	UM180-00-25

We're not just a cage company... anymore

US0113 R3 / 2017-06

100 years

Over A Century Of Innovation

uNion

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