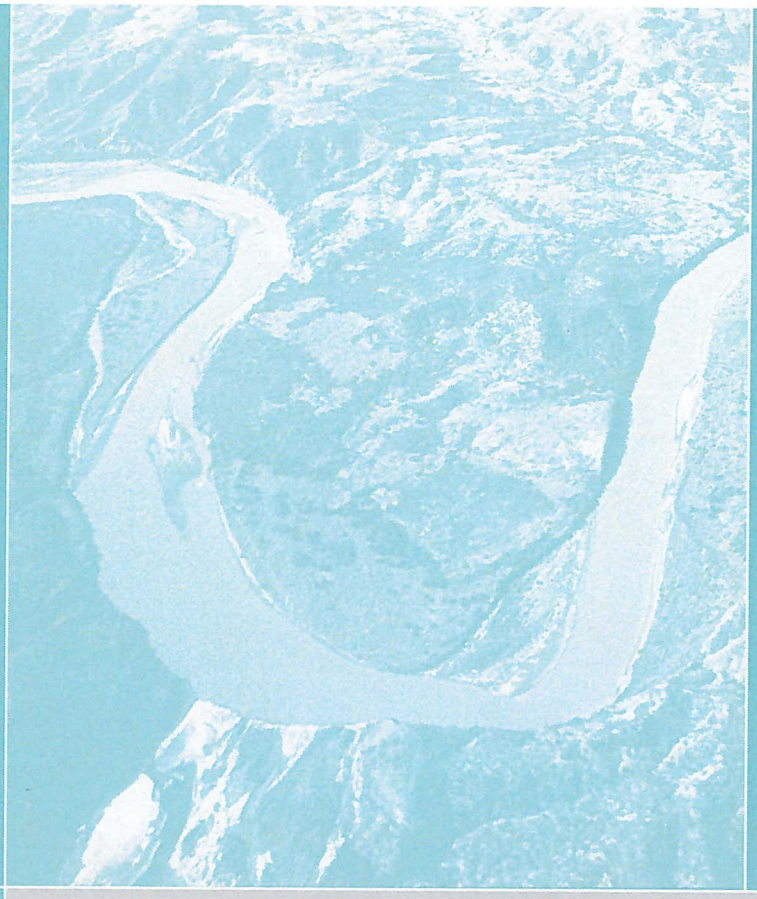

NILE™
ALTERNATIVE FIXATION

Surgical Technique

NILE

Alternative Fixation Spinal System

As Described By:

John P. Kostuik, MD
Co-Founder, Past Chairman & Chief Medical Officer – K2M, Inc.
Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery
Past President – Scoliosis Research Society (SRS)
& North American Spine Society (NASS)

K2M
COMPLEX SPINE INNOVATIONS™

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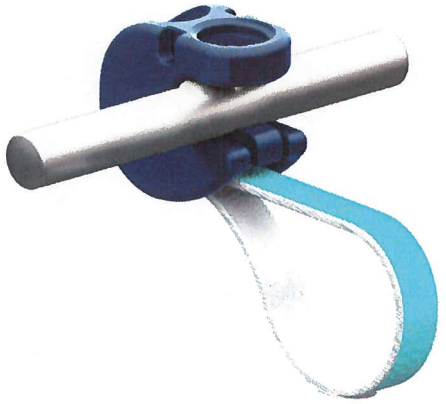
Band Options:

DESCRIPTION	CATALOG NUMBER
Band, 3 mm	5416-F03730-SG
Band, 4 mm	5416-F04730-SG

Clamp Options:

DESCRIPTION	CATALOG NUMBER
Ø4.5 mm Clamp	5401-84500
Ø5.5 mm Clamp	5401-85500
Ø4.5 mm Rail Clamp	5401-84500H
Ø5.5 mm Rail Clamp	5401-85500H
Set Screw	3001-10002



FEATURES & BENEFITS

NILE™ Alternative Fixation Spinal System

Band

- Woven to Provide Strength & Maintain Structure
- Two Leader Length Options to Accommodate Various Techniques
- Familiar Handling Characteristics of the Leader Material
- Color-coded to Indicate Orientation
- Smooth Surface Finish
- Wide & Narrow Options to Accommodate Varying Patient Anatomy

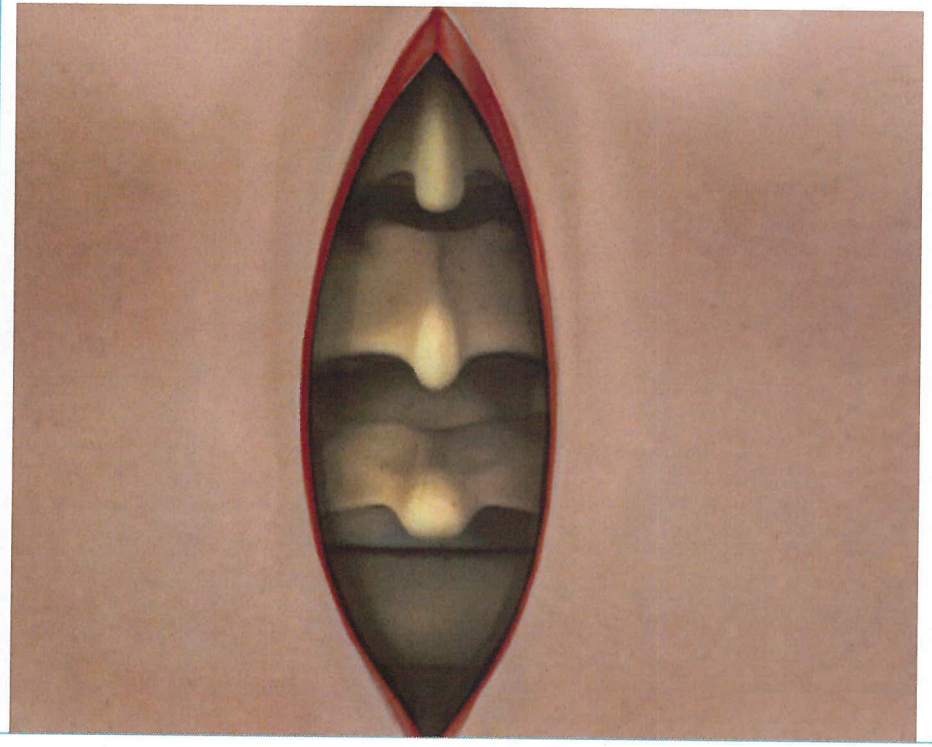
Tensioner

- Intuitive & User-Friendly
- Small, Simple, One-piece Construction
- No Assembly Required
- Quick Grab & Release
- One Tensioner Fits All
- Adjustable Travel Distance That Allows for Large Reduction
- Controlled Reduction

Clamps

- Low-profile
- Band & Rod Locking Mechanisms Independent of Each Other
- Audible Click & Tactile Feedback Upon Rod Engagement
- Allows Compression & Distraction Along the Rod
- Four Sizes Fit Four Rods & Two MESA Rail™ Sizes

NILE™ ALTERNATIVE FIXATION SPINAL SYSTEM SURGICAL TECHNIQUE



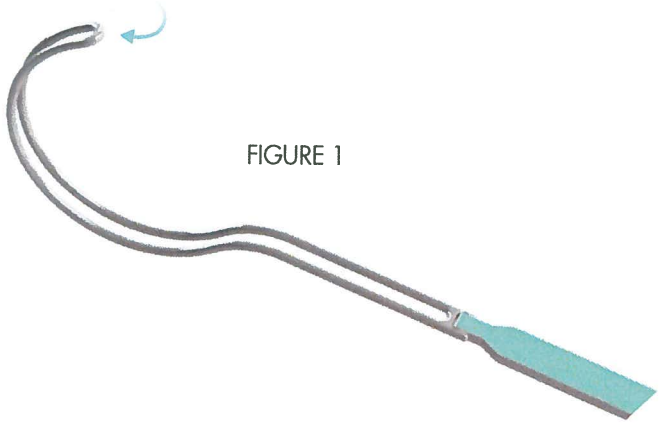


FIGURE 1

EXPOSURE & PREPARATION

Instrumented levels are based on surgeon preference and patient pathology. This manual is intended to be used as a guideline for correction techniques with the NILE™ Alternative Fixation Spinal System.

Position the patient for a posterior approach. Prepare the lamina for band passage by removing at least 5 mm of the ligamentum flavum on both the cephalad and caudal ends of the lamina.

BAND PASSAGE

Shape one side of the Leader into a C-shape by bending it around a handle of a cobb elevator (Fig 1).

Sublaminar: Special care should be taken when passing bands during sublaminar use. Carefully pass the bent Leader underneath the lamina caudal to cephalad.

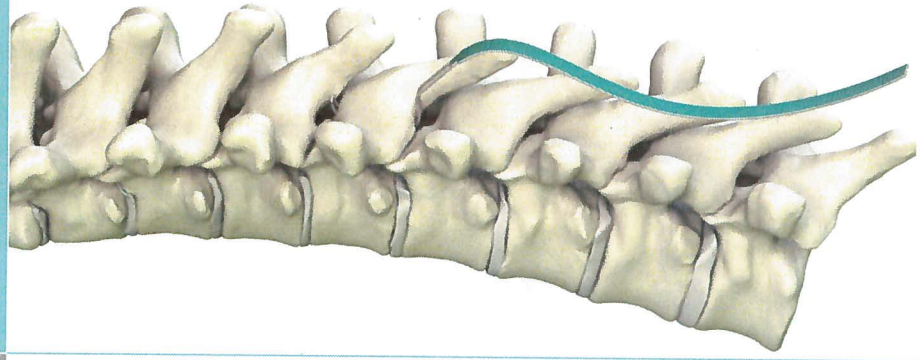
Transverse Process: Remove tissues around the transverse process and create the pathway. Pass the band around the transverse process from caudal to cephalad margin.

It is recommended not to twist the band during passage. To avoid pushing the band into the dura, maintain upward pressure against the anterior aspect of the lamina by pulling up on the tip of the band while advancing the malleable Leader.

LEADER FORCEPS

LEADER HOOK

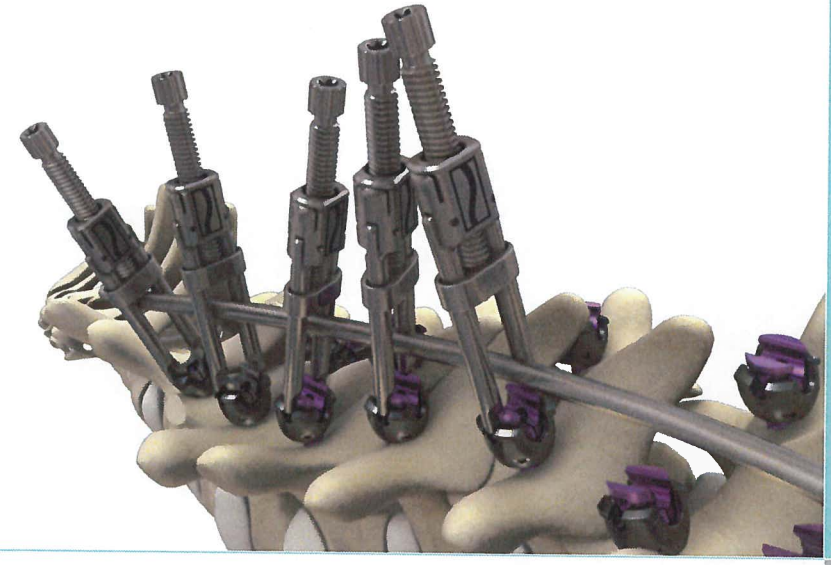
FIGURE 2



BAND PASSAGE

When the tip of the Leader is visible on the other side, grab the tip with Leader Forceps, or insert the Leader Hook into the hoop of the Leader tip for a more stable passage of the band (Fig 2).

Repeat the steps if additional bands are needed. The bands may be laid outside of the wound until ready to attach to the clamp.



ROD INSERTION

An assortment of clamps, hooks, and screws is available with this product. If using pedicle screws or hooks in the construct, insert all screws/hooks prior to rod placement. After all fixation points are in place, the rod is selected and cut to an appropriate length.

Place the rod over the screws and/or hooks. Confirm both ends of the band are positioned underneath the rod. If using MESA® Deformity Systems or MESA® Small Stature Spinal System screws, apply Deformity Crickets® on the screws to allow sequential reduction.

For detailed information on K2M pedicle screw and hook instrumentation, please refer to the appropriate surgical technique.

TENSIONER

SHORT SCREWDRIVER, SIZE 20

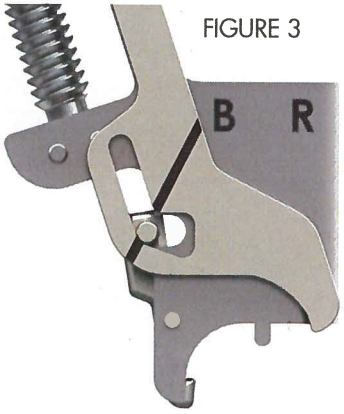


FIGURE 3

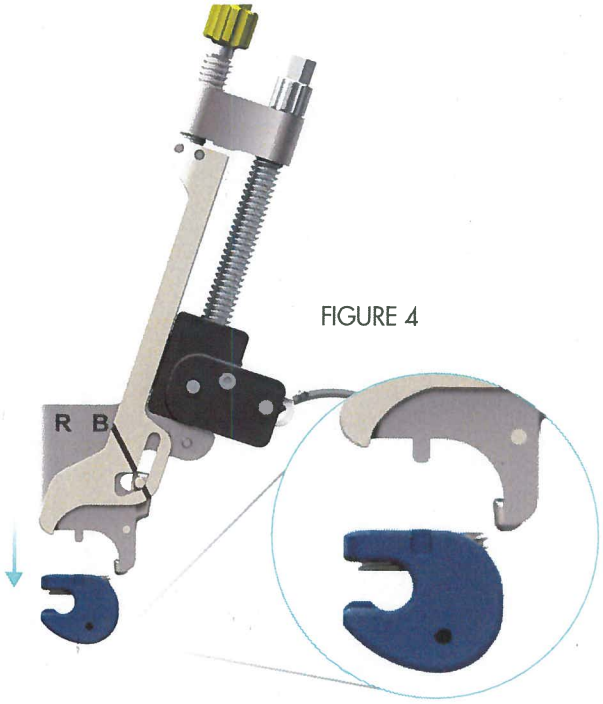


FIGURE 4

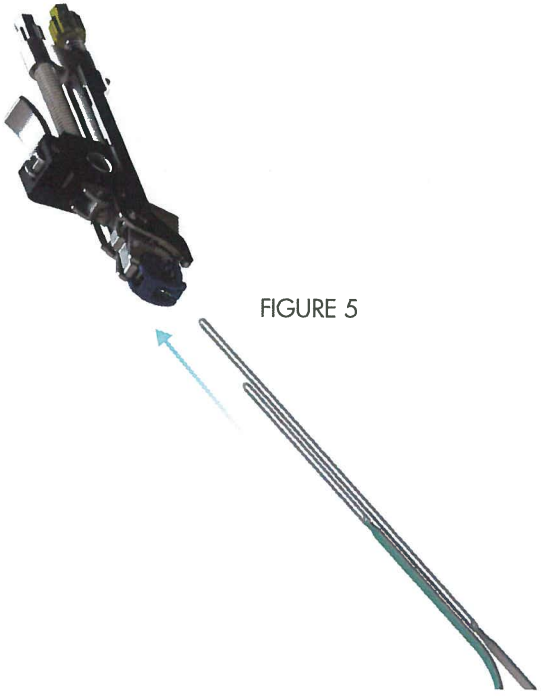


FIGURE 5

CLAMP TENSIONER ASSEMBLY

Hold the clamp set screw side up with one hand and the Tensioner with the other.

Make sure the pin above the Tensioner feet is in-line with the laser marking located on the sides of the claw. If the pin is not in-line with the laser marking, turn the gold knob on top of the Tensioner clockwise to bring the pin up, or counter-clockwise to bring the pin down (Fig 3).

Hold the clamp set screw side up. Push the Tensioner down on the clamp. An audible click will be heard when the clamp is engaged (Fig 4).

BAND CLAMP PASSAGE

Once all clamps are attached to the Tensioners, pass the bands through each clamp (Fig 5).

To ensure smooth passage of the bands through the clamp, confirm the band set screw is raised by turning the set screw counter-clockwise using the Short Screwdriver, Size 20 through the band set screw hole on the Tensioner, labeled 'B'.

Stack one Leader on top of another. Pass both Leaders simultaneously through the clamp from the open end.

SOCKET DRIVER

FIGURE 6

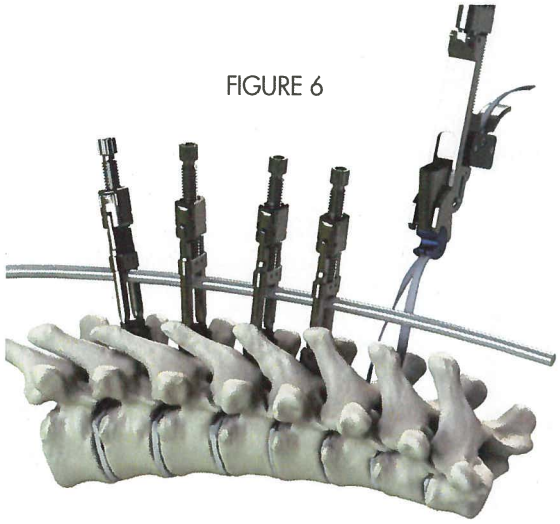


FIGURE 7

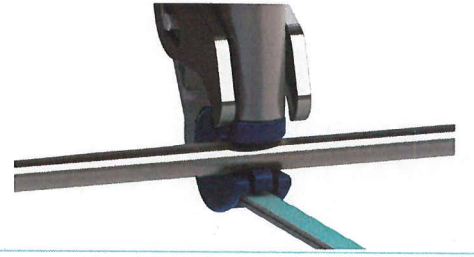


FIGURE 8

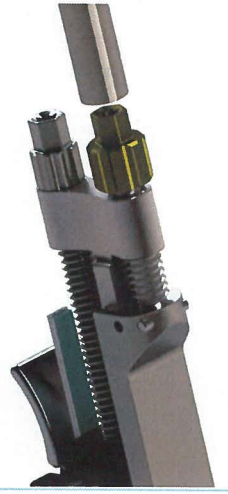


FIGURE 9

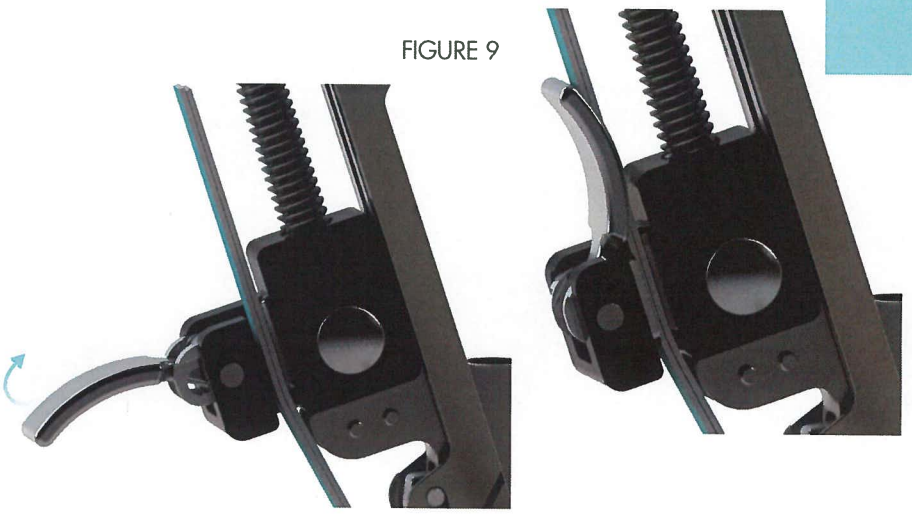
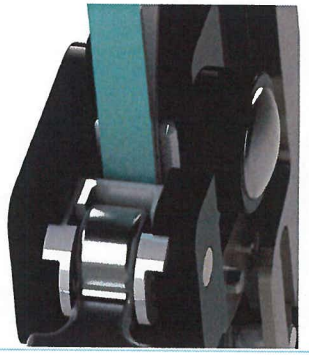


FIGURE 10



CONNECTION TO ROD

Hold the distal ends of the band with one hand, applying slight tension, and slide the clamp-Tensioner assembly down along the band toward the rod (Fig 6). Push the clamp onto the rod (Fig 7). An audible click will be heard when the clamp is properly engaged.

Reduce the claw of the Tensioner by turning the gold knob clockwise using fingers, the Socket Driver, or the Short Screwdriver, Size 20 until tight to secure the clamp onto the rod (Fig 8). This will prevent the clamp from twisting when reducing.

TENSIONER ATTACHMENT

Push the round button on the side of the carrier and slide the carrier down toward the patient as far as possible to maximize reduction capability.

To attach the band to the Tensioner, overlap the bands and insert the bands simultaneously into the latch. Fasten the band by flipping the lever upwards to lock the band to the carrier (Fig 9).

Ensure the bands are not twisted inside the latch and are clearly overlapping on top of one another (Fig 10).

RATCHETING T-HANDLE

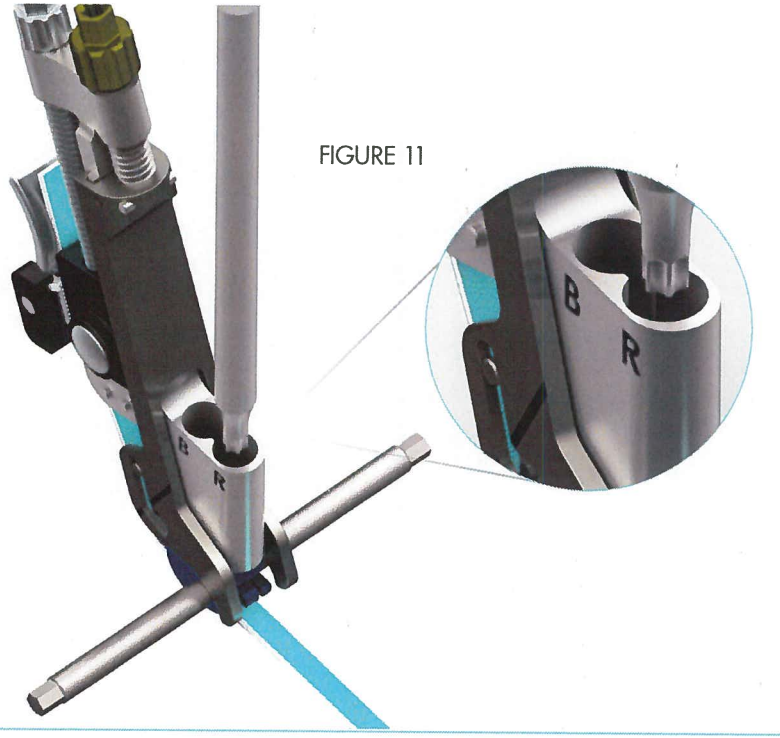


FIGURE 11

FIGURE 12

REDUCTION

Before starting any reduction maneuver, provisionally tighten the rod set screw through the set screw hole labeled 'R' using the Short Screwdriver, Size 20 (Fig 11).

Reduction is performed by turning the silver knob clockwise using fingers, the Socket Driver, or the Short Screwdriver, Size 20 with Handle.

If additional reduction is required, provisionally tighten the band set screw through the hole labeled 'B' to hold tension, and release the bands by flipping the lever down.

Push the button on the side of the carrier and slide it down along the threads. Lock the band onto the Tensioner again, and loosen the band set screw. Repeat the reduction maneuver as described in the previous step.

NOTE: The Short Driver, Size 20 is also available upon request. Use with the Ratcheting T-Handle in the set.

FINAL TIGHTENING

Once desired tension on the band is achieved, final tighten the rod set screw through the set screw hole labeled 'R' using the Torque Limiting Shaft, Size 20 and Torque Limiting Handle, 6 Nm. Final tighten the band set screw using the same Screwdriver and handle through the band set screw hole labeled 'B' (Fig 12).

FIGURE 13

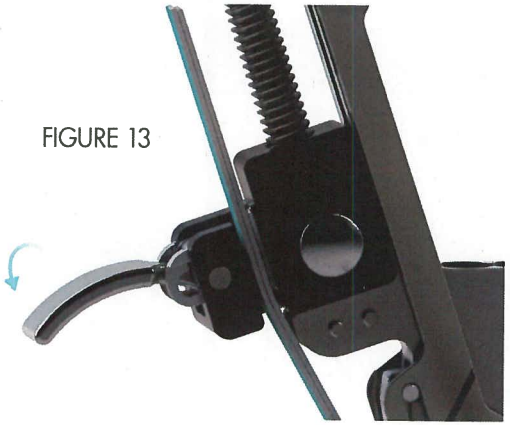
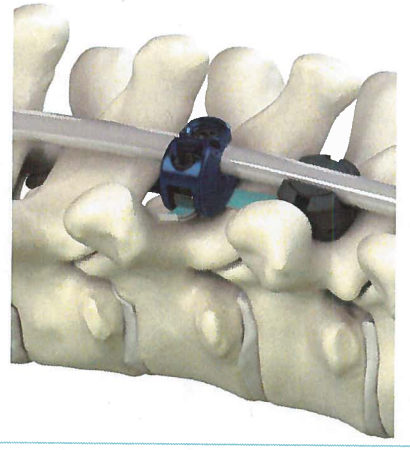


FIGURE 14



TENSIONER DISENGAGEMENT

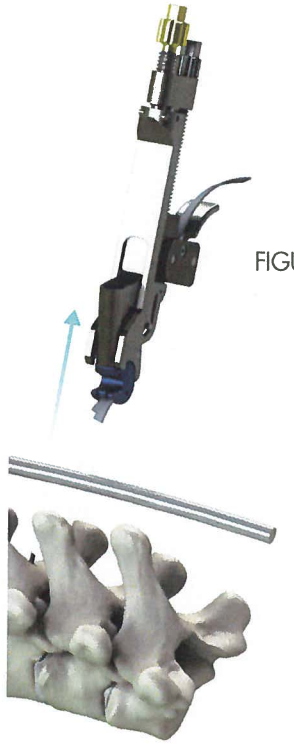
To remove the band from the Tensioner, flip the lever on the carrier down and disengage the band (Fig 13).

Remove the Tensioner from the clamp by turning the gold knob counter-clockwise using fingers, the Socket Driver, or the Size 20 Screwdriver. Gently rock the Tensioner to detach the clamp from the Tensioner.

The excess band is cut 1 cm from the clamp. Using electrocautery, burn the free extremeties of the band to reduce the potential for fraying (Fig 14).

FIGURE 15

FIGURE 16



IMPLANT REMOVAL

To remove or adjust the implant, attach the Tensioner onto the clamp and bring the claw down all the way by turning the gold knob on the Tensioner clockwise (Fig 15).

If removing the implant, cut the band close to the clamp using electrocautery.

Use the Torque Limiting Shaft, Size 20 and the Ratcheting T-Handle to undo the rod set screw. Bring the claw up by turning the gold knob on the Tensioner counter-clockwise.

Gently rock the Tensioner until the implant is disengaged from the rod (Fig 16).

TENSIONER, 30 mm

TORQUE LIMITING SHAFT, SIZE 20

SOCKET DRIVER WITH HANDLE

SHORT SOCKET DRIVER

TORQUE LIMITING HANDLE, 6 Nm

RATCHETING HANDLE

SHORT T20 DRIVER WITH HANDLE

LEADER FORCEPS

LEADER HOOK, T-HANDLE

CLAMP CADDY

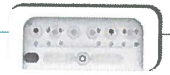
Ø4.5 mm CLAMP

Ø5.5 mm CLAMP

Ø4.5 mm RAIL CLAMP

Ø5.5 mm RAIL CLAMP

SET SCREW



AXIAL CONNECTOR SET SCREW CADDY

DESCRIPTION	CATALOG NUMBER
Tensioner, 30 mm	5401-90015
Torque Limiting Shaft, Size 20	5401-90006
Socket Driver with Handle	5401-90005
Short Socket Driver	5401-90014
Torque Limiting Handle, 6 Nm	3001-90020
Ratcheting Handle	2601-90027
Short T20 Driver with Handle	5401-90000
Leader Forceps	5401-90001
Leader Hook, T-Handle	5401-90002

DESCRIPTION	CATALOG NUMBER
Clamp Caddy	5401-90008
Ø4.5 mm Clamp	5401-84500
Ø5.5 mm Clamp	5401-85500
Ø4.5 mm Rail Clamp	5401-84500H
Ø5.5 mm Rail Clamp	5401-85500H
Set Screw	3001-10002
Axial Connector Set Screw Caddy	3001-90054

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the following system: NILE™ Alternative Fixation. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

DESCRIPTION
The Nile Alternative Fixation System implants are comprised of bands, clamps and set screws designed to attach to titanium or cobalt chrome rods. The band is manufactured from polyethylene terephthalate (PET) and the clamps and set screws are made from titanium alloy in accordance with ASTM F136. Once the bands are secured the stainless steel tips are detached and are not intended to be implanted.

INDICATIONS
The NILE Alternative Fixation Spinal System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The NILE Alternative Fixation Spinal System may also be used in conjunction with other medical implants made of similar metals whenever 'wiring' may help secure the attachment of other implants.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
Unless specifically labeled as STERILE, K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION
Non-Sterile Devices
Packaged components are packaged individually in sealed poly bags. Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles were validated to an SAL of 10-6 using the biological indicator (BI) overkill method however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	270°F (132°C)	4 minutes	30 minutes
Outside USA	Prevacuum	273°F (134°C)	3 minutes	30 minutes

Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

Sterile Devices
Components labeled as STERILE are gamma irradiated.

CAUTION: Do not use if package is damaged. If the tamper proof seals or sterile packaging appear to be compromised or damaged, return the package and its contents to K2M.

CAUTION: The implants are intended for single use only. Do not attempt to clean or resterilize the implants. Reprocessing of single use devices may introduce risks associated with guaranteeing sterility assurance.

STORAGE
Store sterile packages in a well-ventilated area that provides protection from dust, insects, moisture, and vermin. Recommended storage temperatures are between 50-100°F (10-38°C).

INSTRUCTIONS FOR USE
(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

CONTRAINDICATIONS
1. K2M spinal systems are contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS
1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

ADDITIONAL POTENTIAL ADVERSE EVENTS FOR PEDIATRIC PATIENTS
The implanting surgeon should consider carefully the size and type of implants most suitable for the pediatric patient's age, size, weight and skeletal maturity..

Since pediatric patients may have additional growth potential following implant surgery the likelihood of a subsequent removal and/or revision surgery is greater than in adult patients.

WARNINGS AND PRECAUTIONS
1. The NILE Alternative Fixation Spinal System is intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers.
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use the surgeon should be specifically trained in the use of this spinal system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of neurological injury during implantation as well as metal fatigue leading to bending or breakage of the device.
3. Patient selection and compliance is extremely important. Based on fatigue testing results, the NILE Alternative Fixation Spinal System has been determined to be substantially equivalent to predicate devices however, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
4. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
5. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals (e.g. titanium and stainless steel) in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.
8. The K2M spinal implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
9. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

ADDITIONAL WARNINGS AND PRECAUTIONS FOR PEDIATRIC PATIENTS
The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

The use of fixation in the pediatric patient may present additional risks when patients are of smaller stature and skeletally immature.

Pediatric patients may have smaller spinal structures that may increase the risk of malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may have reduced longitudinal spinal growth or may be at risk for rotational spinal deformities ("crankshaft phenomenon") due to continued differential growth of the anterior spine.

Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

Additional fixation is required at the cephalad and caudal ends of the construct in scoliosis surgery, especially in case of obesity, extreme kyphosis or muscular weakness, except where additional fixation would increase the risk to the patient.

Band passage around the transverse process and interspinous fixation are only to be performed in adult patients. Special care should be taken when passing bands during sublaminar use. Prepare the lamina for band passage by removing at least 5mm of the ligamentum flavum on both the cephalad and caudal ends of the lamina. To avoid pushing the band into the dura, maintain upward pressure against the anterior aspect of the lamina by pulling up on the tip of the band while advancing the malleable leader.

PREOPERATIVE
1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative testing (simple bend and where necessary, stretch testing) should identify degree of correction possible without neurological damage and levels to be spanned using techniques similar to other spinal fusion procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Check expiration date and integrity of sterile packaging.

OPERATIVE
1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Rods may be prebent to the degree of correction determined by preoperative testing however reverse bends should be avoided.
3. The use of two rods and crosslinking the rods will provide a more rigid construct.
4. The placement of implants should be checked radiographically prior to assembly of the rod construct.
5. Care should be taken when positioning the implants to avoid neurological damage.
6. Use of bone cement will make removal of the implants difficult and should be avoided.

POSTOPERATIVE
1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

K2M Inc., 751 Miller Dr. SE
Leesburg, VA (703) 777-3155

K2M, Inc.
751 Miller Drive SE
Leesburg, Virginia 20175
USA
PH 1.866.526.4171 • 1.571.919.2000
FX 1.866.862.4144

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
PH +31.70.345.8570
FX +31.70.346.7299

K2M

www.K2M.com

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Actual device color may vary.
Consult product catalog for details.

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