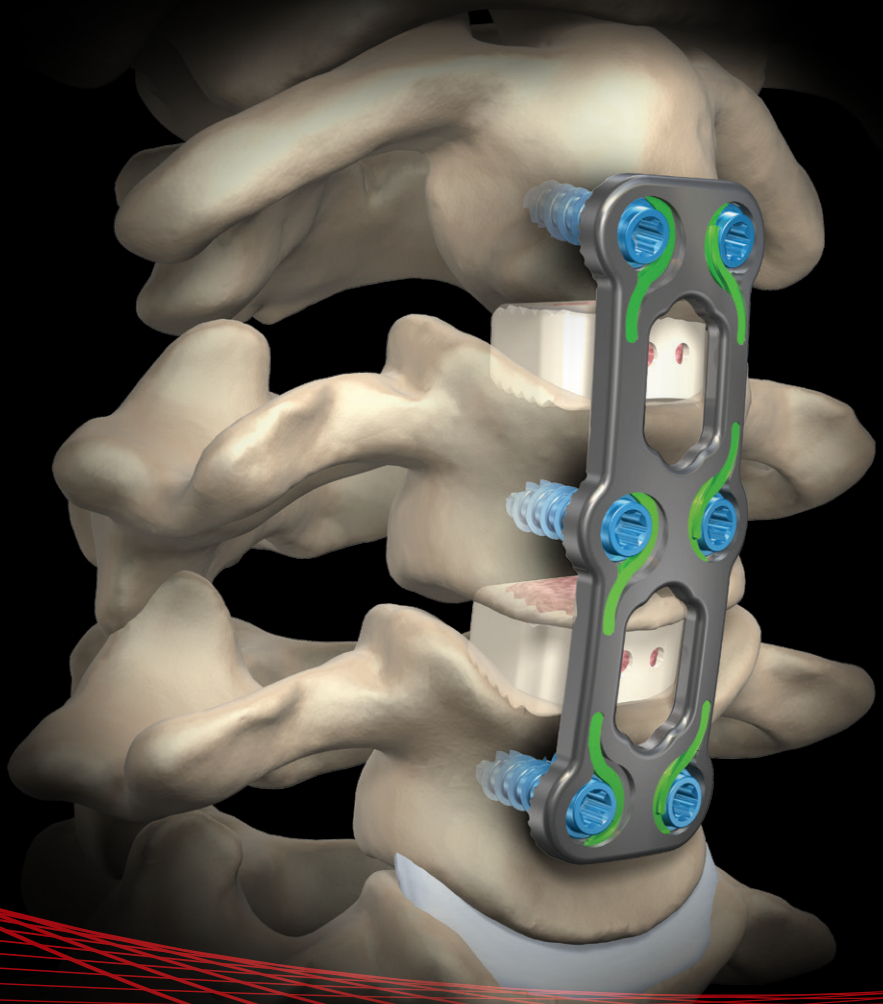
# Nakoma-SL



## *Anterior Cervical Plating System*
## ***Surgical Technique***

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# Nakoma-SL

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## Indications for Use:

The Nakoma ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The Nakoma ACP System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following indications:

- 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
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudoarthrosis
- Failed previous fusions
- Spondylolisthesis
- Spinal Stenosis

## Device Description:

The Nakoma ACP System is intended for anterior screw fixation to the cervical spine. The Nakoma ACP system consists of a variety of shapes and sizes of bone plates and screws. The components are manufactured from titanium alloy (Ti 6Al 4V ELI) as described by ASTM F136. Components of the Nakoma ACP System should not be used with components from any other system or manufacturer. The Nakoma ACP System components are provided non-sterile. The products need to be steam sterilized by the hospital prior to use.

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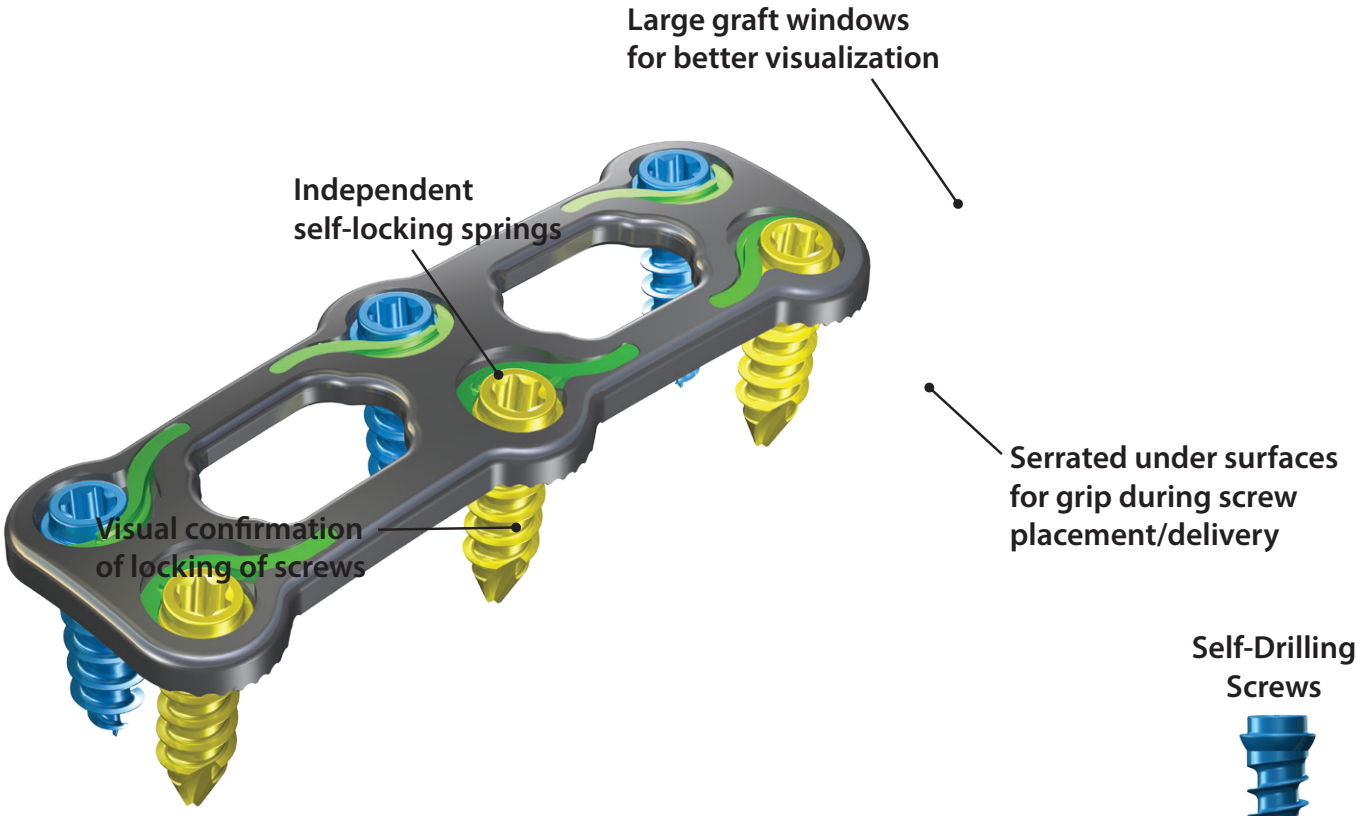
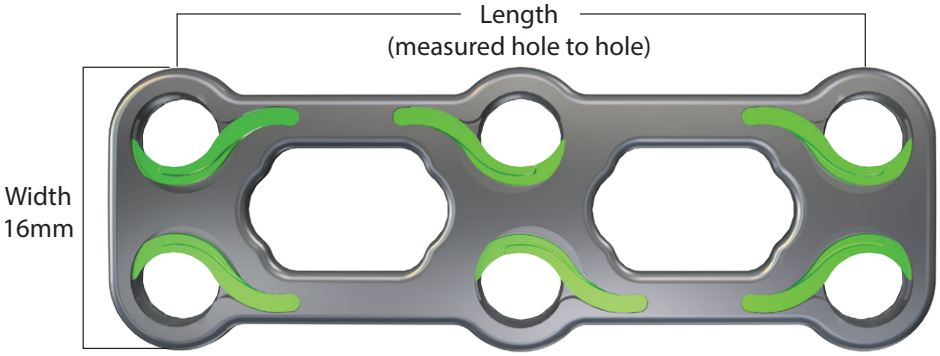
# Key Features



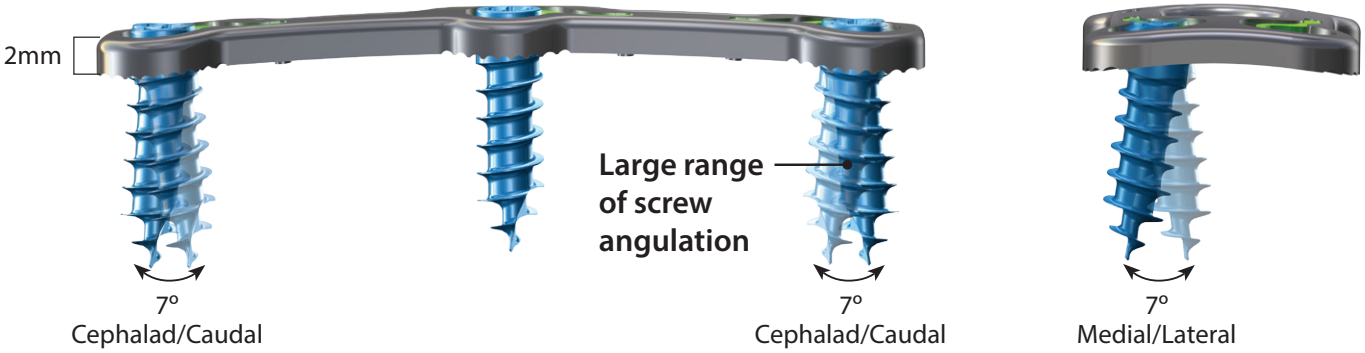

Self-Drilling Screws




Fixed and variable options

Self-Tapping Screws

## Low Profile



# Nakoma-SL

## Instruments

Bone Awl

Drill

Tap

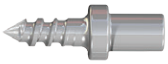
Screwdriver

Screw Removal Tool

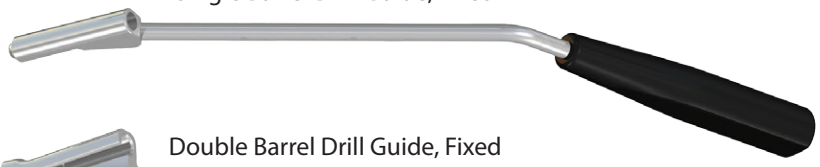
In-line Handle, Manual, Spin Cap

In-line Handle, Manual

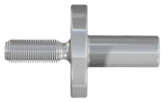
Fixation Pin



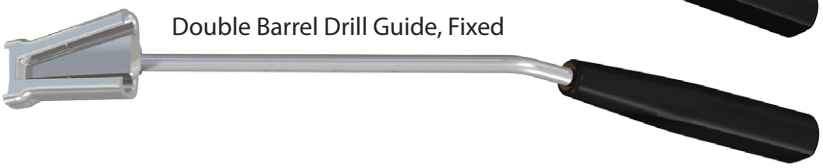
Single Barrel Drill Guide, Fixed



Cage Fixation Pin



Double Barrel Drill Guide, Fixed



Neuro-Caliper

Plate Holder

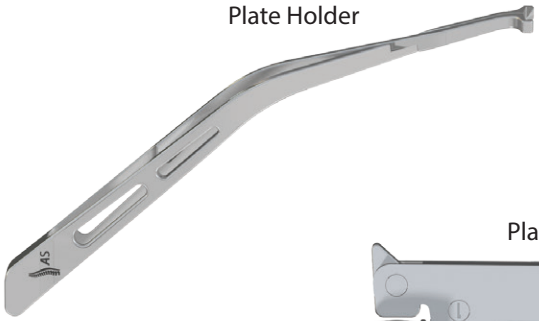
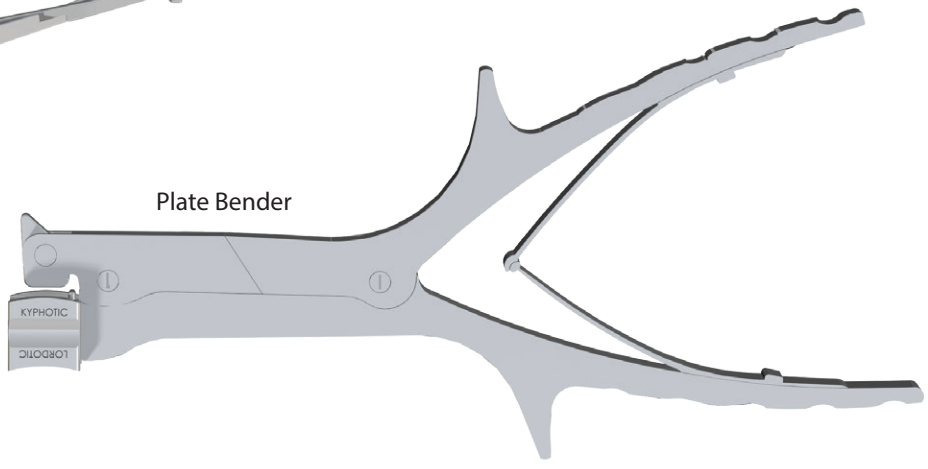


Plate Bender



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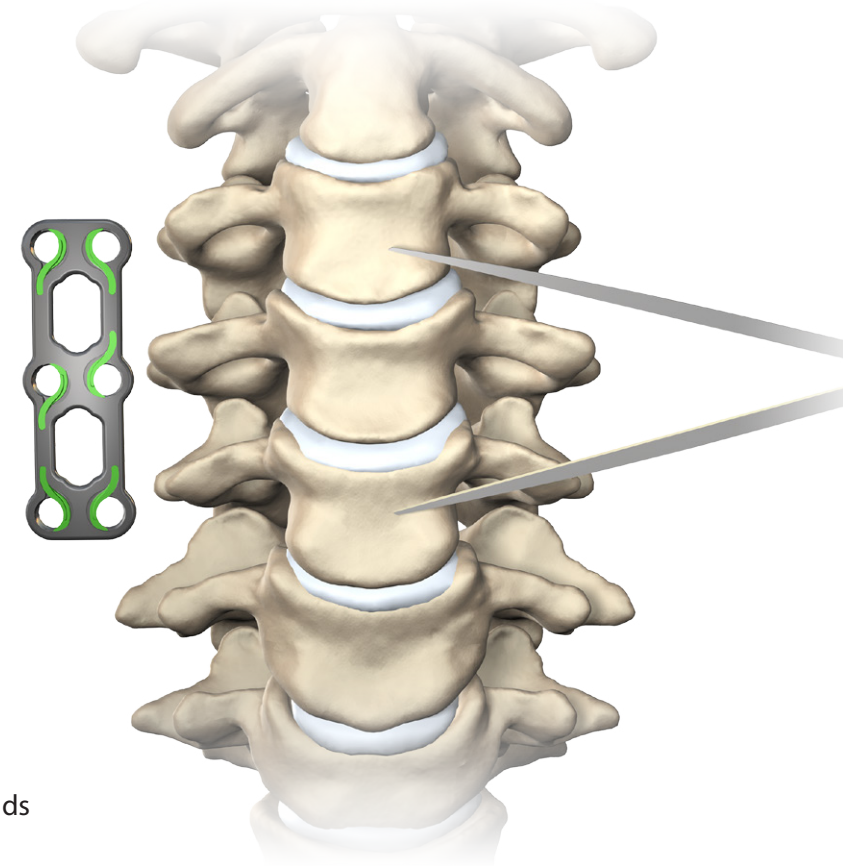
## *Anterior Cervical Plating System*
## *Surgical Technique*

### Step 1: Preoperative Planning

The patient is placed in the supine position on the operating table. A standard anterior approach to the cervical spine is performed using one of several incision techniques. A transverse incision parallel to the skin folds of the neck can be utilized for one- or two-level procedures. An oblique incision along the anterior border of the sternocleidomastoid can be utilized for longer level procedures.

The anterior cervical spine is exposed through tissue dissection and fascial plane release. A discectomy or corpectomy is performed and the interbody fusion area prepared. A bone graft or PEEK anterior cervical interbody implant is then inserted into the prepared disc space.

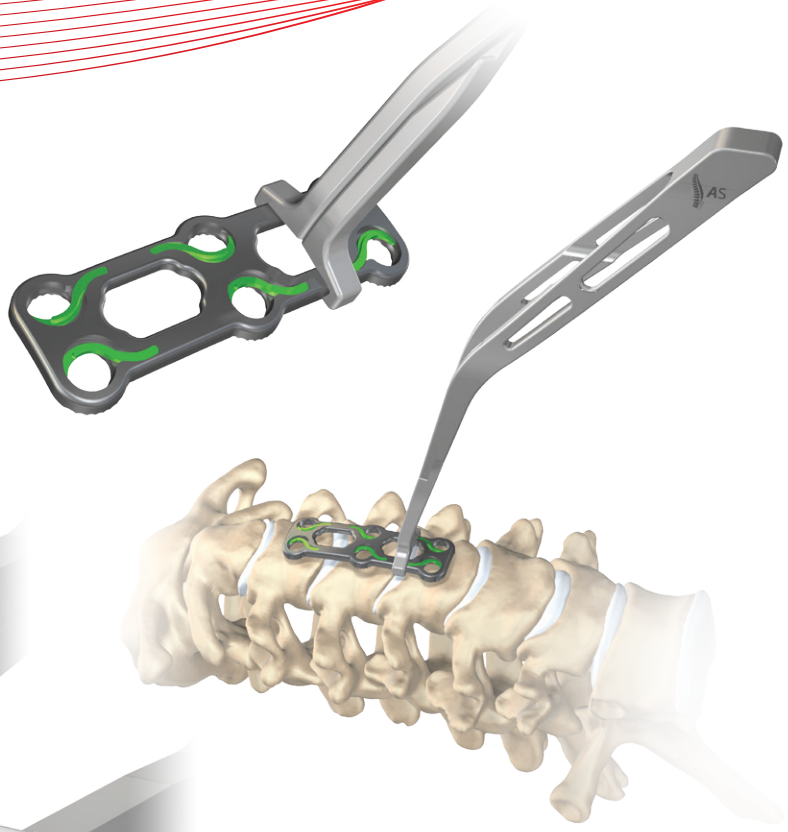


### Step 2: Plate Selection

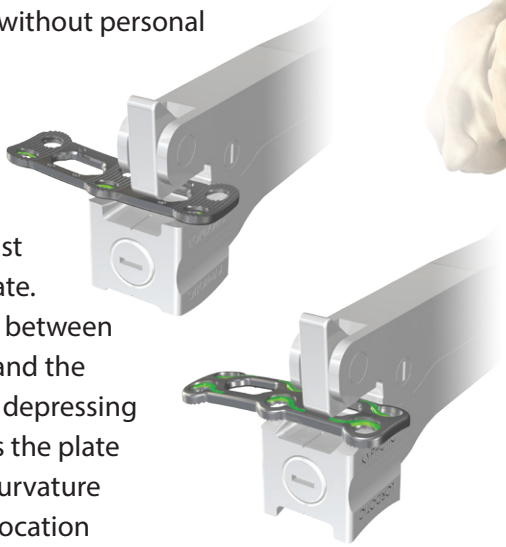
To select the appropriate Nakoma Anterior Cervical Plate, the center of the cephalad hole to the center of the caudal hole can be measured using the Caliper. The distance between the desired fixation points on the appropriate vertebrae is measured and corresponds to the appropriate plate. In the event the distance measured fall between the two sizes, it is usually recommended to use the smaller size to prevent interference with adjacent disc space.

## Step 3: Plate Placement

Once the appropriate size plate has been selected, use the Plate Holder to grip the cervical plate and check to ensure that the plate fits the anatomy. The Plate holder grips the plate in the two cut-outs of the instrument, making it possible to hold and insert the implant without personal contact to the patient.

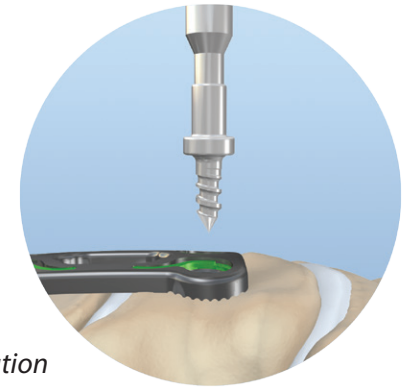


The Plate Bender is designed for single hand operation to adjust the curvature of the plate. Place the cervical plate between the fixed bending jaw and the pivoting anvil head. By depressing the instrument handles the plate is bent to the desired curvature based on incremental location changes and the amount of compression applied to the handles.



***Optional:***

*Temporary stainless steel non-implantable Fixation Pins are available to hold the plate on the vertebral bodies during preparation of the screwholes. Two threaded pins are inserted into diagonally opposite screwholes. After the Fixation Pins are inserted, screws are placed in the remaining holes. Once the screws are secure, remove the Fixation Pins and insert the screws into the vacant holes.*



*Temporary stainless steel non-implantable Cage Fixation Pins are available in 7mm and 10mm lengths to hold the plate on the cervical interbody fusion device during screw hole preparation and screw insertion. The threaded Cage Fixation Pin is inserted into the cervical interbody fusion device through the plate graft window. After the Cage Fixation Pin is inserted, screw holes are prepared and screws are inserted into the plate. Once the screws are secure, remove the Cage Fixation Pin.*

## Step 4: Screw Hole Preparation

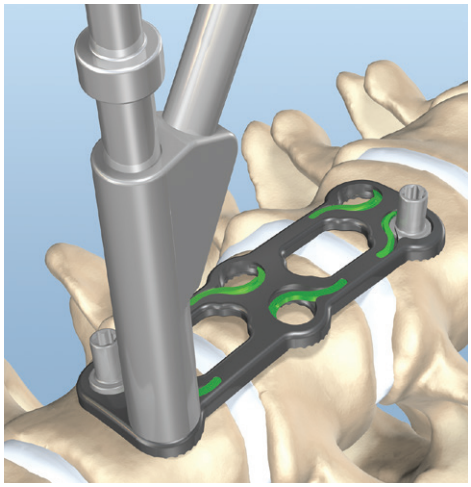
There are a variety of options available for screw-hole preparation. It is important to ensure that the Drill Guide corresponds to the type of screw being implanted. Drill Guides are available in Single Barrel - Fixed and Double Barrel Guide option. The Drill Guide consists of one cannula for the Single Barrel and two cannulas for the Double Barrel. The Drill Guide must be securely affixed to the plate prior to preparation of the screw hole.

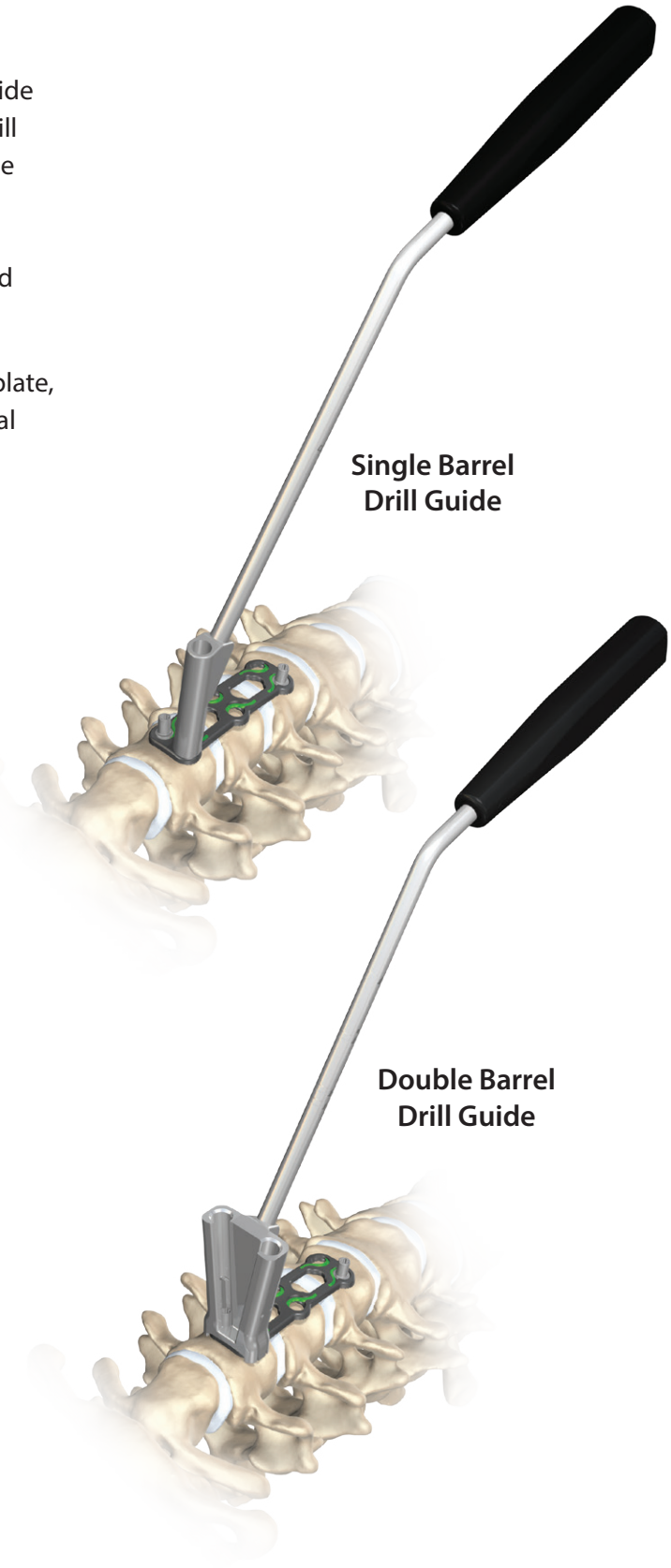
To ensure the Single Barrel Drill Guide fixation to the plate, the cannula of the guide was designed with a spherical surface to match the screw-hole of the plate.

To ensure Double Barrel Drill Guide fixation to the plate, the cannulas of the guide were designed to match the outside profile of the plate. Ensure the Double Barrel Drill Guide is properly mated to the plate prior to hole preparation.

After the correct Drill Guide is chosen, prepare the screw hole using the drill or awl. If using self-drilling screws, use the awl to prepare the hole. Pre-drilling of the hole is not required for self-drilling screws. A tap is also available if needed or desired.

(**NOTE:** Drills, Awl, and Tap will work with all of the Drill Guide options.)

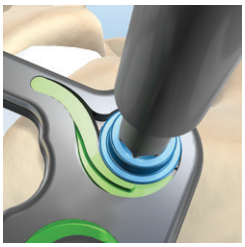


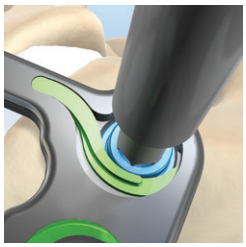


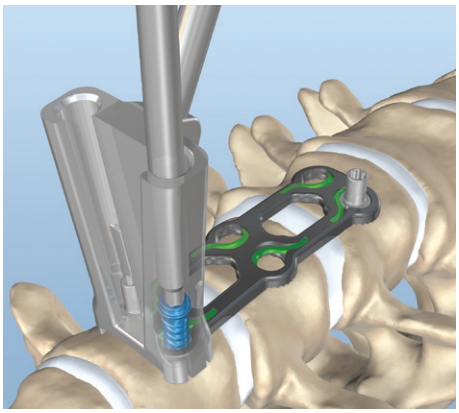
## Step 5: Screw Insertion

Once the screw hole has been prepared, select the appropriate screw. The length and diameter of the screw can be confirmed by using the screw gauges on the screw caddy. Attach the screw to the Screw-driver by inserting the Screwdriver hexalobe into the screw. Insert the Screwdriver with the attached screw into the screw-hole on the plate. Screws can be inserted while the Double Barrel Drill Guide is still fixed to the plate. Advance the screw into the bone and pass the locking spring on the plate until a tactile, visual conformation or audible click is felt or heard.

Once all the screws have been inserted, locking should be ensured by viewing that the lateral edges of the locking springs are positioned over the proximal shoulders of the screws.





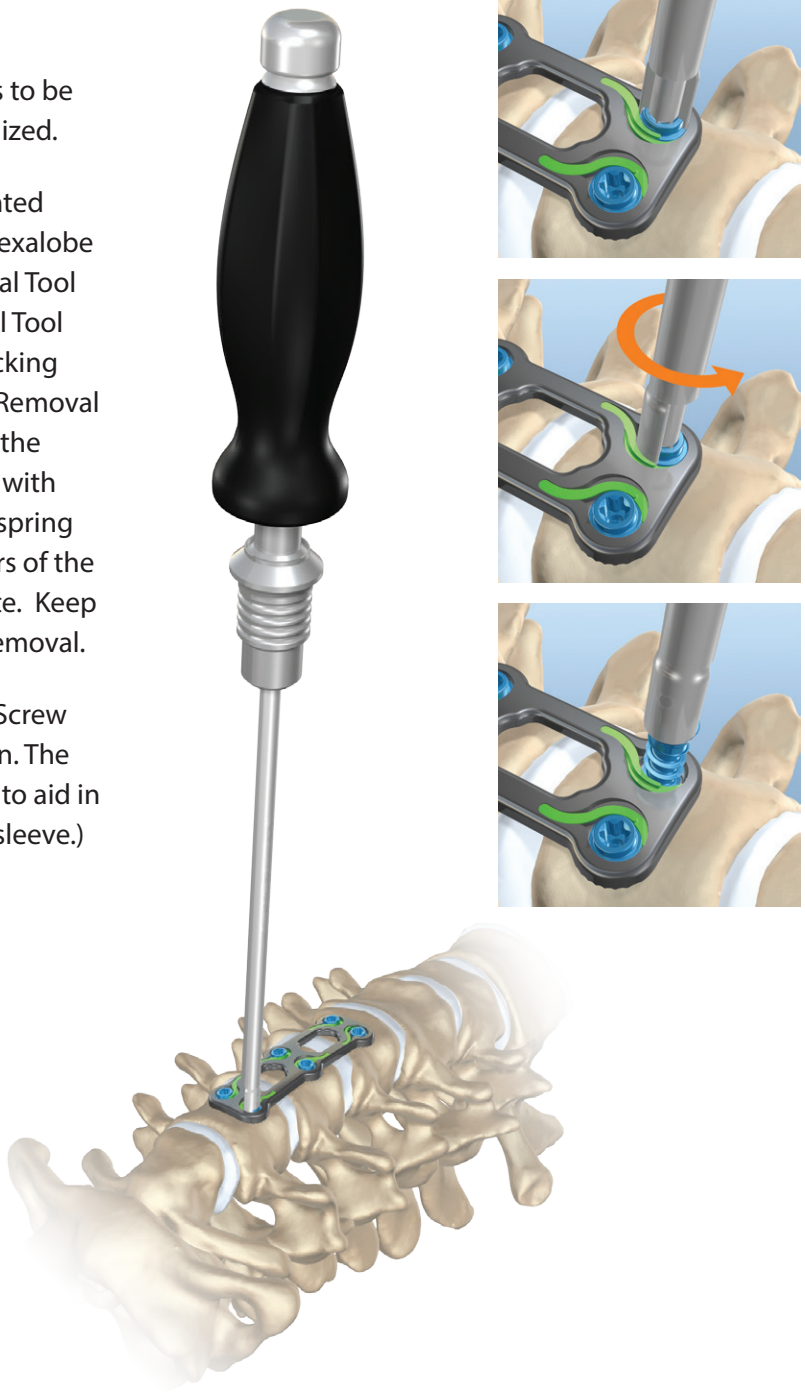


## Step 6: Screw Removal

If a screw has been locked in place but needs to be removed the Screw Removal Tool is to be utilized.

Attach the Screw Removal Tool to the implanted screw by inserting the Screw Removal Tool hexalobe into the screw. The position of Screw Removal Tool should be placed in such that Screw Removal Tool sleeve should be on the lateral side of the locking spring on the plate. As you rotate the Screw Removal Tool counter clockwise to remove the screw, the Screw Removal Tool sleeve comes in contact with the locking spring on the plate. The locking spring will move laterally and the proximal shoulders of the screw will pass the locking spring on the plate. Keep advancing the screw counter clockwise for removal.

(**NOTE:** Care should be taken in placing the Screw Removal Tool sleeve in the correct orientation. The screw might need prior adjustment/rotation to aid in the engagement of the Screw Removal Tool sleeve.)



# Nakoma-SL

## Implant Chart

### Plates – Nakoma-SL

| Part # | Description |
|---|---|
| 3100I-1000 | 12mm X 16mm X 2mm, 1-Level |
| 3100I-1001 | 14mm X 16mm X 2mm, 1-Level |
| 3100I-1002 | 16mm X 16mm X 2mm, 1-Level |
| 3100I-1003 | 18mm X 16mm X 2mm, 1-Level |
| 3100I-1004 | 20mm X 16mm X 2mm, 1-Level |
| 3100I-1005 | 22mm X 16mm X 2mm, 1-Level |
| 3100I-1006 | 24mm X 16mm X 2mm, 1-Level |
| | |
| 3100I-2000 | 26mm X 16mm X 2mm, 2-Level |
| 3100I-2001 | 28mm X 16mm X 2mm, 2-Level |
| 3100I-2002 | 30mm X 16mm X 2mm, 2-Level |
| 3100I-2003 | 32mm X 16mm X 2mm, 2-Level |
| 3100I-2004 | 34mm X 16mm X 2mm, 2-Level |
| 3100I-2005 | 37mm X 16mm X 2mm, 2-Level |
| 3100I-2006 | 40mm X 16mm X 2mm, 2-Level |
| 3100I-2007 | 43mm X 16mm X 2mm, 2-Level |
| 3100I-2008 | 46mm X 16mm X 2mm, 2-Level |
| | |
| 3100I-3000 | 40mm X 16mm X 2mm, 3-Level |
| 3100I-3001 | 43mm X 16mm X 2mm, 3-Level |
| 3100I-3002 | 46mm X 16mm X 2mm, 3-Level |
| 3100I-3003 | 49mm X 16mm X 2mm, 3-Level |
| 3100I-3004 | 52mm X 16mm X 2mm, 3-Level |
| 3100I-3005 | 55mm X 16mm X 2mm, 3-Level |
| 3100I-3006 | 58mm X 16mm X 2mm, 3-Level |
| 3100I-3007 | 61mm X 16mm X 2mm, 3-Level |
| 3100I-3008 | 64mm X 16mm X 2mm, 3-Level |
| 3100I-3009 | 67mm X 16mm X 2mm, 3-Level |
| | |
| 3100I-4000 | 60mm X 16mm X 2mm, 4-Level |
| 3100I-4001 | 64mm X 16mm X 2mm, 4-Level |
| 3100I-4002 | 68mm X 16mm X 2mm, 4-Level |
| 3100I-4003 | 72mm X 16mm X 2mm, 4-Level |
| 3100I-4004 | 76mm X 16mm X 2mm, 4-Level |
| 3100I-4005 | 80mm X 16mm X 2mm, 4-Level |
| 3100I-4006 | 84mm X 16mm X 2mm, 4-Level |
| | |
| 3100I-5000 | 75mm X 16mm X 2mm, 5-Level |
| 3100I-5001 | 80mm X 16mm X 2mm, 5-Level |
| 3100I-5002 | 85mm X 16mm X 2mm, 5-Level |
| 3100I-5003 | 90mm X 16mm X 2mm, 5-Level |
| 3100I-5004 | 95mm X 16mm X 2mm, 5-Level |
| 3100I-5005 | 100mm X 16mm X 2mm, 5-Level |
| 3100I-5006 | 105mm X 16mm X 2mm, 5-Level |

### FIxed Screws – Nakoma-ACP

| Part # | Description |
|---|---|
| 3100I-6000 | Fixed Screw, Self-Tapping, Ø4.0 X 10mm |
| 3100I-6001 | Fixed Screw, Self-Tapping, Ø4.0 X 11mm |
| 3100I-6002 | Fixed Screw, Self-Tapping, Ø4.0 X 12mm |
| 3100I-6003 | Fixed Screw, Self-Tapping, Ø4.0 X 13mm |
| 3100I-6004 | Fixed Screw, Self-Tapping, Ø4.0 X 14mm |
| 3100I-6005 | Fixed Screw, Self-Tapping, Ø4.0 X 15mm |
| 3100I-6006 | Fixed Screw, Self-Tapping, Ø4.0 X 16mm |
| 3100I-6007 | Fixed Screw, Self-Tapping, Ø4.0 X 17mm |
| 3100I-6008 | Fixed Screw, Self-Tapping, Ø4.0 X 18mm |
| 3100I-6009 | Fixed Screw, Self-Tapping, Ø4.0 X 19mm |
| 3100I-6010 | Fixed Screw, Self-Tapping, Ø4.0 X 20mm |
| | |
| 3100I-6500 | Fixed Screw, Self-Tapping, Ø4.5 X 12mm |
| 3100I-6501 | Fixed Screw, Self-Tapping, Ø4.5 X 13mm |
| 3100I-6502 | Fixed Screw, Self-Tapping, Ø4.5 X 14mm |
| 3100I-6503 | Fixed Screw, Self-Tapping, Ø4.5 X 15mm |
| 3100I-6504 | Fixed Screw, Self-Tapping, Ø4.5 X 16mm |
| 3100I-6505 | Fixed Screw, Self-Tapping, Ø4.5 X 17mm |
| 3100I-6506 | Fixed Screw, Self-Tapping, Ø4.5 X 18mm |
| 3100I-6507 | Fixed Screw, Self-Tapping, Ø4.5 X 19mm |
| 3100I-6508 | Fixed Screw, Self-Tapping, Ø4.5 X 20mm |
| | |
| 3100I-9000 | Fixed Screw, Self-Drilling, Ø4.0 X 10mm |
| 3100I-9001 | Fixed Screw, Self-Drilling, Ø4.0 X 11mm |
| 3100I-9002 | Fixed Screw, Self-Drilling, Ø4.0 X 12mm |
| 3100I-9003 | Fixed Screw, Self-Drilling, Ø4.0 X 13mm |
| 3100I-9004 | Fixed Screw, Self-Drilling, Ø4.0 X 14mm |
| 3100I-9005 | Fixed Screw, Self-Drilling, Ø4.0 X 15mm |
| 3100I-9006 | Fixed Screw, Self-Drilling, Ø4.0 X 16mm |
| 3100I-9007 | Fixed Screw, Self-Drilling, Ø4.0 X 17mm |
| 3100I-9008 | Fixed Screw, Self-Drilling, Ø4.0 X 18mm |
| 3100I-9009 | Fixed Screw, Self-Drilling, Ø4.0 X 19mm |
| 3100I-9010 | Fixed Screw, Self-Drilling, Ø4.0 X 20mm |
| | |
| 3100I-9500 | Fixed Screw, Self-Drilling, Ø4.5 X 12mm |
| 3100I-9501 | Fixed Screw, Self-Drilling, Ø4.5 X 13mm |
| 3100I-9502 | Fixed Screw, Self-Drilling, Ø4.5 X 14mm |
| 3100I-9503 | Fixed Screw, Self-Drilling, Ø4.5 X 15mm |
| 3100I-9504 | Fixed Screw, Self-Drilling, Ø4.5 X 16mm |
| 3100I-9505 | Fixed Screw, Self-Drilling, Ø4.5 X 17mm |
| 3100I-9506 | Fixed Screw, Self-Drilling, Ø4.5 X 18mm |
| 3100I-9507 | Fixed Screw, Self-Drilling, Ø4.5 X 19mm |
| 3100I-9508 | Fixed Screw, Self-Drilling, Ø4.5 X 20mm |

### Variable Screws – Nakoma-ACP

| Part # | Description |
|---|---|
| 3100I-8000 | Variable Screw, Self-Tapping, Ø4.0 X 10mm |
| 3100I-8001 | Variable Screw, Self-Tapping, Ø4.0 X 11mm |
| 3100I-8002 | Variable Screw, Self-Tapping, Ø4.0 X 12mm |
| 3100I-8003 | Variable Screw, Self-Tapping, Ø4.0 X 13mm |
| 3100I-8004 | Variable Screw, Self-Tapping, Ø4.0 X 14mm |
| 3100I-8005 | Variable Screw, Self-Tapping, Ø4.0 X 15mm |
| 3100I-8006 | Variable Screw, Self-Tapping, Ø4.0 X 16mm |
| 3100I-8007 | Variable Screw, Self-Tapping, Ø4.0 X 17mm |
| 3100I-8008 | Variable Screw, Self-Tapping, Ø4.0 X 18mm |
| 3100I-8009 | Variable Screw, Self-Tapping, Ø4.0 X 19mm |
| 3100I-8010 | Variable Screw, Self-Tapping, Ø4.0 X 20mm |
| | |
| 3100I-8500 | Variable Screw, Self-Tapping, Ø4.5 X 12mm |
| 3100I-8501 | Variable Screw, Self-Tapping, Ø4.5 X 13mm |
| 3100I-8502 | Variable Screw, Self-Tapping, Ø4.5 X 14mm |
| 3100I-8503 | Variable Screw, Self-Tapping, Ø4.5 X 15mm |
| 3100I-8504 | Variable Screw, Self-Tapping, Ø4.5 X 16mm |
| 3100I-8505 | Variable Screw, Self-Tapping, Ø4.5 X 17mm |
| 3100I-8506 | Variable Screw, Self-Tapping, Ø4.5 X 18mm |
| 3100I-8507 | Variable Screw, Self-Tapping, Ø4.5 X 19mm |
| 3100I-8508 | Variable Screw, Self-Tapping, Ø4.5 X 20mm |
| | |
| 3100I-7000 | Variable Screw, Self-Drilling, Ø4.0 X 10mm |
| 3100I-7001 | Variable Screw, Self-Drilling, Ø4.0 X 11mm |
| 3100I-7002 | Variable Screw, Self-Drilling, Ø4.0 X 12mm |
| 3100I-7003 | Variable Screw, Self-Drilling, Ø4.0 X 13mm |
| 3100I-7004 | Variable Screw, Self-Drilling, Ø4.0 X 14mm |
| 3100I-7005 | Variable Screw, Self-Drilling, Ø4.0 X 15mm |
| 3100I-7006 | Variable Screw, Self-Drilling, Ø4.0 X 16mm |
| 3100I-7007 | Variable Screw, Self-Drilling, Ø4.0 X 17mm |
| 3100I-7008 | Variable Screw, Self-Drilling, Ø4.0 X 18mm |
| 3100I-7009 | Variable Screw, Self-Drilling, Ø4.0 X 19mm |
| 3100I-7010 | Variable Screw, Self-Drilling, Ø4.0 X 20mm |
| | |
| 3100I-7500 | Variable Screw, Self-Drilling, Ø4.5 X 12mm |
| 3100I-7501 | Variable Screw, Self-Drilling, Ø4.5 X 13mm |
| 3100I-7502 | Variable Screw, Self-Drilling, Ø4.5 X 14mm |
| 3100I-7503 | Variable Screw, Self-Drilling, Ø4.5 X 15mm |
| 3100I-7504 | Variable Screw, Self-Drilling, Ø4.5 X 16mm |
| 3100I-7505 | Variable Screw, Self-Drilling, Ø4.5 X 17mm |
| 3100I-7506 | Variable Screw, Self-Drilling, Ø4.5 X 18mm |
| 3100I-7507 | Variable Screw, Self-Drilling, Ø4.5 X 19mm |
| 3100I-7508 | Variable Screw, Self-Drilling, Ø4.5 X 20mm |

## Precautions:

1. Surgical Implants must never be reused.
2. An explanted metal should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. Correct handling of the implants is extremely important.
4. Contouring of metal implants should be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the device when contouring. Alterations will produce defects in the surface finish and internal stresses may become the focal point for eventual breakage. Do not use an implant if damage is suspected.
5. Excessive torque applied to the screws when seating the plate may cause failure of the bone resulting in stripped threads and/or compromised screw purchase.
6. Based on fatigue testing results, when using the Nakoma ACP System, 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.
7. The use of dissimilar metals (e.g., titanium and stainless steel) is prohibited as rapid corrosion can occur.

## Contraindications:

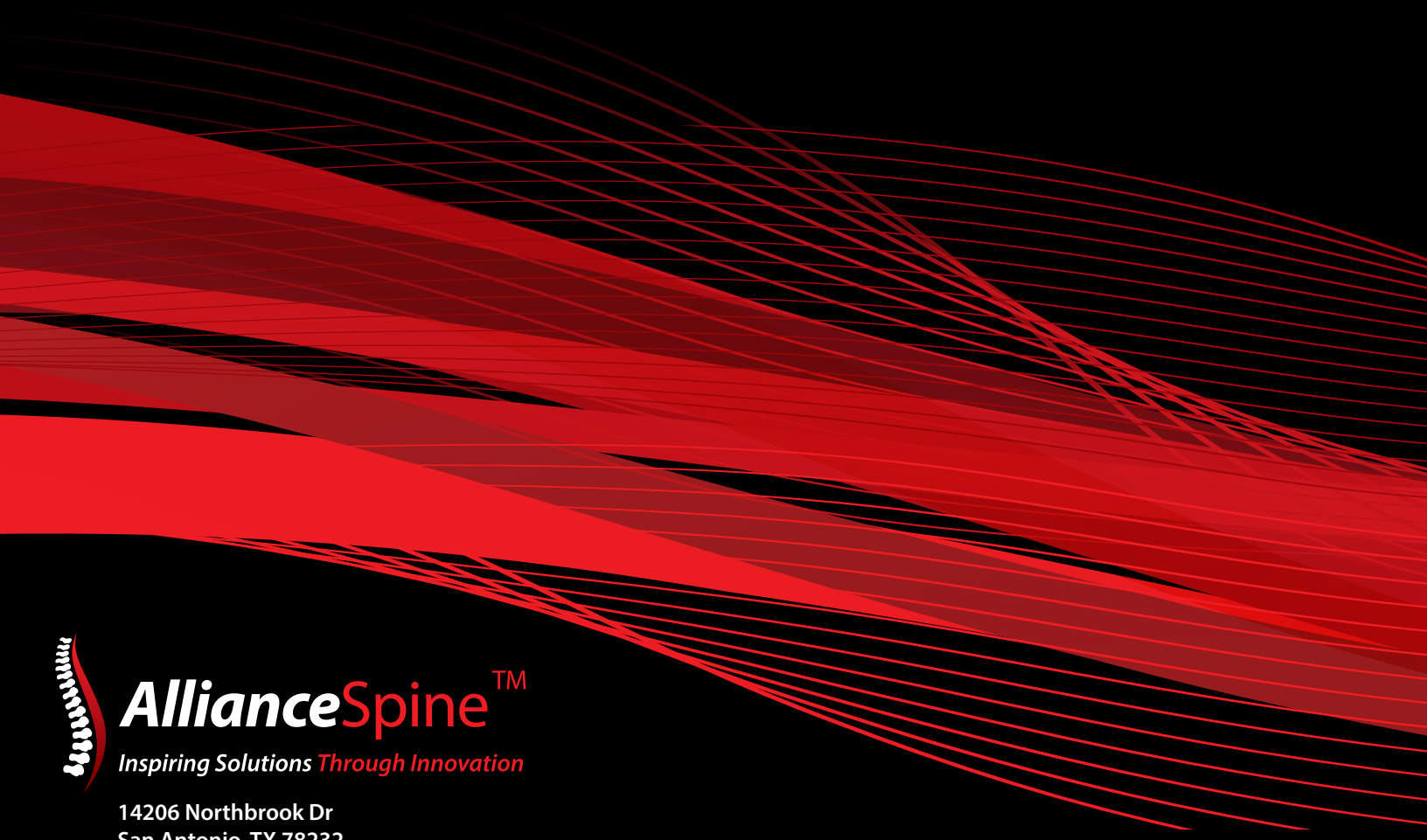
1. Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis
2. Insufficient quality of quantity of bone which would inhibit rigid fixation.
3. Previous history of infection
4. Excessive local inflammation
5. Open wounds
6. Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
7. Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
8. Patients having in adequate tissue coverage of the operative site.
9. Pregnancy
10. A condition of senility, mental illness, or substance abuse. These conditions, among others may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
11. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
12. Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

## Potential Adverse Effects:

1. Bending, disassembly or fracture of any or all implant components. Fatigue fracture of spinal fixation devices, including screw and rods, has occurred.
2. Pain, discomfort, or abnormal sensations due to the presence of the device.
3. Pressure on skin from components where inadequate tissue coverage exists over implant, with potential extrusion through the skin.
4. Dural leak requiring surgical repair.
5. Cessation of growth of the fused portion of the spine.
6. Post-operative change in spinal curvature, loss of correction, height and/or reduction.
7. Non-union (pseudoarthrosis), delayed union.
8. Loosening of the implant or reoperation for device removal
9. Screw back-out possibly leading to esophageal erosion
10. Degenerative changes of instability in segments adjacent to fused vertebral levels.
11. Spinal cord impingement or damage.
12. Vascular damage could result in catastrophic or fatal bleeding.
13. Death
14. Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of the implant.
15. Infection.
16. Loss of neurological function including complete or incomplete paralysis, dysesthesia, hyperesthesia, paraesthesia, appearance or radiculopathy.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSCIAN.
Please refer to the Instructions For Use included with the product for complete instructions, indications, contraindications, and warnings.

# Nakoma-SL





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