



RAVENTM Surgical Technique Anterior Lumbar Plate System

#### Raven Anterior Plate

#### Introduction

The ChoiceSpine RAVEN™ Anterior Lumbar Plate System is a versatile system of implants and instruments designed to simplify and improve the efficiency of anterior lumbar spine fusion. The RAVEN Anterior Plate features an integrated single-step screw blocking mechanism for fast insertion and fixation to the anterior lumbar spine. Streamlined instrumentation facilitates a simplified surgical approach and ensures excellent control during the procedure. The instrumentation also allows the user to simultaneously insert the RAVEN plate with the ChoiceSpine Harrier-SA interbody, eliminating surgical steps and reducing O.R. time.

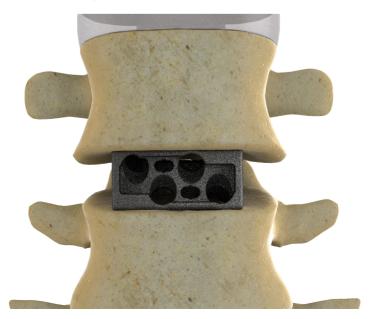
## **System Features**

- Four-Screw Design
- Combined insertion with HARRIER-SA lumbar interbody
- Integrated single-step screw blocking mechanism
- Variable screw angulation
- Streamlined Instrumentation

#### **DETAILED OPERATIVE TECHNIQUE**

# **Exposure and Graft/Interbody Trialing**

The patient is placed in the supine position, then the operative site is prepared and draped in the usual fashion. Standard techniques for dissection is utilized to expose the targeted fusion level in the lumbar spine. Fluoroscopy is used to confirm the appropriate disc level has been exposed. A throrough discectomy is performed and the cartilaginous endplates are removed at the operative level. The size of the disc space is measured with sequential trials until the desired fit is achieved and the matching graft or interbody size is selected to restore the normal disc space height.



# After exposure, disc preparation, and trialing has been completed, the Raven Anterior Plate may be implanted in one of two ways:

- 1. A plate-only technique, after the lumbar interbody has been placed.
- 2. A combined plate/interbody technique, with an appropriate ChoiceSpine Harrier-SA™ lumbar interbody by way of instrumentation that is provided.

# Plate Selection

# **Raven Anterior Plate System Size Offerings**

Anterior Plate Offerings				
Plate Size (mm)	Screw to Screw Length (A) (mm)	Overall Length (B) (mm)	25.20 14.20	
15	15	26		
17	17	28		
18.5	18.5	29.5	14 A B	
20	20	31		
22	22	33	T20 Hex <u>alobe</u> /	
24	24	35		

The Raven Anterior Lumbar Plates that correspond with the ChoiceSpine Harrier-SA interbodies are available in screw-to-screw lengths ranging from 17mm to 24mm. The suggested pairing is included in the table below.

Screw Offerings			
Diameter	Length (mm)		
ø5.0 Self - Tapping Screw	20, 25, 30, 35	<b>Elimintaina arababa</b>	
ø5.0 Self - Tapping Screw	20, 25, 30, 35		

ALIF Pairing Sizes		
Harrier SA ALIF Interbody Height (mm)	Raven ALIF Plate Screw-to-Screw Length (mm)	
12	17	
13.5	18	
15	20	
17	22	
19	24	

NOTE: The pairing in the table above ensure the closest possible screw insertion point to the anterior corners of the lumbar interbody/vertebral endplates without interference between the screws and interbody. A larger plate can be selected for a given interbody, if desired.

WARNING: Do not attempt to bend the Raven Anterior Plates. It is designed such that the screw holes will rest near the anterior corners of the interbody and vertebral endplates. Therefore, contouring is not necessary. Bending the plate could cause unknown damage to the plate and possibly render it unusable.

# **Screw Selection and Preparation Options**

The Raven Anterior Lumbar Plate System has been designed with simplicity in mind and allows for direct screw placement after plate insertion. The system includes Ø5.0mm and Ø5.5mm variable angle screws in lengths from 20mm to 35mm by 5mm increments.

Angulation Range				
Neutral Screw Axis: 25° Cranial/Caudal and 10° Lateral		Maximum Screw Angles Shown		
ø5.0 Screw	10° Cone Around Neutral Screw Axis	Cranial Lateral 20° /		
ø5.5 Screw	5° Cone Around Neutral Screw Axis			

If pre-drilling is preferred, two methods are provided to correspond with the desired technique for plate implantation: 1) Using the Combination Awl/Drill with incorporated Guide Sleeve or 2) Using the Drill Guide and Drill provided. These methods are described with each respective plate insertion technique.

NOTE: Stay within the limits of screw angulation when drilling for and inserting screws to ensure the screw blocking mechanism engages properly.

# Plate-Only Technique

#### **Step 1a: Plate Placement**

After selecting a plate, place it onto the lumbar spine using the Anterior Plate Holder. The Anterior Plate can be attached to the Anterior Plate Holder while seated in the Anterior Plate Caddy. Align Inserter and Anterior Plate mating features. Push Anterior Inserter outer sleeve forward until a hard stop is reached. Keep downward pressure on the sleeve and rotate sleeve in a clockwise position until the Anterior Inserter is attached to the desired fit. Center the Anterior Plate over the lumbar interbody in the disc space. Proper placement can be verified visually by confirming that the screw holes are not obstructed by the interbody.

# Step 2a: Screw Hole Preparation

Use the Anterior Plate Holder and selected screw preparation instrument (Combination Awl/Drill, Drill, and/or Awl) to prepare screw holes. Hold the plate in the desired position over the interbody. Attach the ¼" Square Quick Connect Handle to the selected screw preparation instrument. Insert the instrument into a screw pocket in the Raven plate and gently apply pressure while rotating penetrate the vertebral body. Repeat this step for preparation of the second screw hole. Figures below demonstrate use of the Plate Holder and screw preparation instruments. The screw preparation instruments allow for Ø3.0x20mm of bone penetration.



Screw Preparation with Awl



Screw Preparation with Combination Awl/Drill Instruments

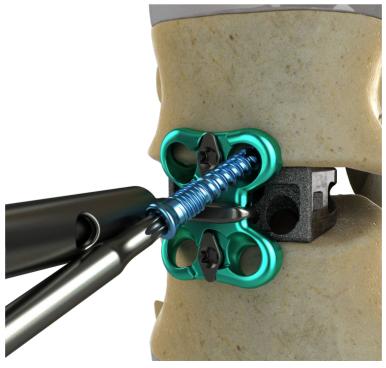
NOTE: The Variable Angle Guide is available for use with the Awl and/or Drill. Marked bands on the proximal end of the instrument align with the proximal end of the guide to indicate penetration depth of instrument.



Step 3a: Screw Insertion

Remove the selected screw preparation instrument from the surgical site prior to screw insertion. The Plate Holder may remain in place, if desired, to maintain plate location while starting screws. Select the appropriate diameter and length of screw and attach it to the Screwdriver, as shown below. Advance the screw until it is fully seated in the plate. Repeat steps for placement of the second screw. Take care to stay within the limits of screw angulation so that the screw blocker can be rotated over a portion of the screw heads and engage the locking features on the face of the plate. Remove the Anterior Plate Inserter by rotating the outer sleeve counterclockwise until the inserter releases from the implant. Placement of remaining two screws is accomplished after removing the inserter.

NOTE: The cranial and caudal pairs of screws must be inserted in the plate before engaging the screw blocker to cover the screw heads.



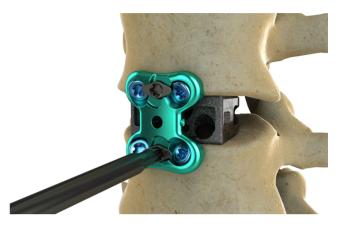
**Screw Implantation** 

# Step 4a: Screw Blocker (Cam) Engagement

Engage the screw blockers after placement of all four screws. To engage, insert the Screwdriver into the T20 hexalobe at the center of the cam. Gently rotate the cam clockwise 90° until engagement of the cam in the locked position is both felt and seen. The cam does not require aggressive force to turn. Cam engagement is demonstrated in figures below.



cam enagement



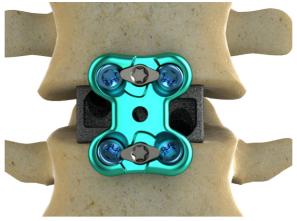


Unlocked Screw Blocker



Locked Screw Blocker

WARNING: Numerous rotations of the cam causes deformation of its locking feature. Do not repeatedly engage/disengage the screw blocker to/from the locked position. The user should verify correct screw placement BEFORE engaging the cam. It should be noted that the screw blocker is NOT required for securing the screws to the plate. It is a backup mechanism to prevent screws from backing out of the plate and potentially causing local tissue irritation if screws become loose. Do not attempt to over-rotate the cam once cam reaches its "locked" position.



**Completed Construct** 

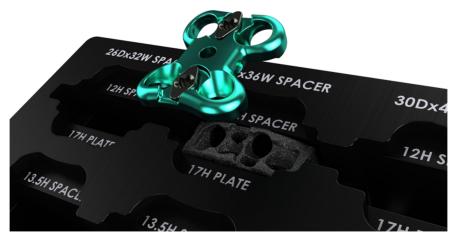
## Combined Plate and Interbody Insertion Technique

The Raven Anterior Plate/Cage Inserter is configured to accept both the Raven Plate and ChoiceSpine Harrier-SA interbody implants.

NOTE: This method does NOT permanently or semi-permanently integrate the Raven Anterior Lumbar Plate to the Harrier SA interbody. Joining the implants is achieved solely through use of the Anterior Plate/Cage Inserter instrument. Prepare the disc space and vertebral bodies for implant insertion and determine the appropriate size of interbody per the Harrier SA interbody surgical technique.

## Step 1b. Coupling the Plate and Interbody

Place the selected Harrier SA interbody, packed with bone graft, into the appropriately marked space present in the Raven Loading Block (images below). Make sure that the interbody is face-up, exposing the screw holes. Select the appropriate Raven Anterior Plate using the table on page 4 and the Loading Block markings as a guide. Place the Raven Plate face-up and centered above the interbody.



Anterior Plate Inserted into Loading Block

Align the Anterior Plate/Cage Inserter features with the Raven Anterior Plate and Harrier-SA corresponding features. Rotate the knob on the Plate/Cage Inserter until the desired attachment is achieved.



Anterior Plate/Cage Inserter Attached to Raven Plate and Harrier-SA Interbody

## Step 2b. Plate and Interbody Insertion

The assembled construct is now ready to be placed into the prepared lumbar disc space.



Assembly during Implantation

Impact the construct into the disc space until the Raven Plate is seated flush against the vertebral bodies



Assembly in Final Position

CAUTION: Do not use excessive force when impacting the plate and interbody into place.

# **Step 3b: Screw Preparation**

See the Plate-Only Technique Screw Preparation section for screw preparation information. Preparation technique information for the Combined Plate/Interbody Insertion Technique is identical to the Plate-Only Technique. The Screw preparation instruments can be used while the Anterior Plate/Cage Inserter is attached for two of the four plate screws. The Inserter will have to be removed to prepare the remaining two screw holes.

## **Step 4b: Screw Insertion**

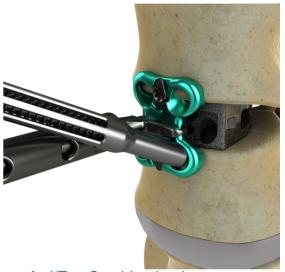
See the plate-only technique screw insertion section for screw insertion information. Insertion technique information for the Combined Plate/Interbody insertion technique is identical to the plate-only technique. The Screwdriver is used to implant two screws while the Anterior Plate/Cage Inserter is attached. Remove the Inserter by rotating the Anterior Plate/Cage Inserter knob counterclockwise until the inserter releases from the implants.

# Step 5b: Screw Blocker (Cam) Engagement

See the Plate-Only Technique Screw Blocker (Cam) Engagement section for Screw Blocker information.

### **Implant Removal**

Use the Raven Screwdriver to rotate the cams to the unlocked position, fully exposing the screw heads for screwdriver access. Insert the Screwdriver into each screw head and reverse the screw from the vertebral body and plate. Attach the Anterior Plate Inserter or other grasping instrument to remove the plate from the surgical site.



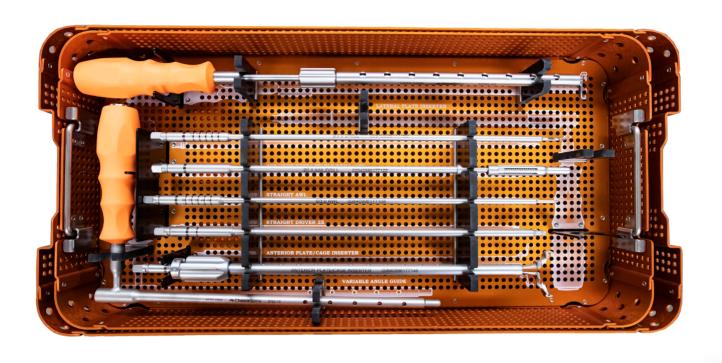
Awl/Tap Combination Instrument
Used with Anterior Plate/Cage
Inserter



Unlocking of cam



Removal of Screw





#### **Description:**

The Raven Lumbar Plate System is an anterior/anterolateral/lateral plate system that may be used in the thoracic, lumbar, and sacral spine (T1-S1). The Raven Lumbar Plate System consists of plates and screws manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, as well as associated manual general surgical instrumentation. The implants are available in a variety of sizes to accommodate various patient anatomies.

#### Indications for Use:

The Raven Lumbar Plate System Anterior and Lateral Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- · Pseudoarthrosis;
- Spondylolysis;
- Spondylolisthesis;
- · Spinal stenosis;
- Tumors;
- Trauma (i.e. Fractures or Dislocation);
- Deformities (i.e. Scoliosis, Kyphosis or Lordosis);
- Failed Previous Fusion

The Raven Lumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

#### Contraindications:

Contraindications include, but are not limited to:

- •Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any spinal instrumentation system.
- Any entity or condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis, osteopenia) is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, foreign body sensitivity. In addition, the patient's occupation, activity level, or mental capacity may be relative contraindications to this. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stress on the implant during bony healing and may be at a higher risk of implant failure and nonunion.
- Active systemic infection or infections localized to the site of the proposed implantation are contraindications

- to implantation.
- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to implantation.

#### **Precautions:**

The implantation of anterior or lateral plate spinal systems must be performed only by experienced spinal surgeons with specific training in the use of this spinal plate system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

#### Warnings:

- •The Choice Spine Raven Lumbar Plate System is not intended for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic or lumbar spine.
- •The implants are single use only.
- •The system components are supplied non-sterile therefore need to be sterilized before use.
- When using the plate anteriorly, always orient the plant along the midline of the spine.
- To optimize bony union, perform an anterior microdiscectomy or corpectomy as directed.
- To facilitate fusion, a sufficient quantity of autologous or allogeneic bone or other appropriate material should be used.
- Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- Do not reuse implants. Discard used, damaged or suspect implants. Reuse of single use devices could result in injury or re-operation due to breakage or infection. Do not re-sterilize single use implants that come in contact with body fluids.
- •When choosing a metallic implant system, the surgeon should consider factors such as: levels of implantation, patient weight, patient activity level, and other patient specific conditions which may impact the performance of the system as it relates to fatigue of the implants.
- The Choice Spine Raven Lumbar Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Raven Lumbar Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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