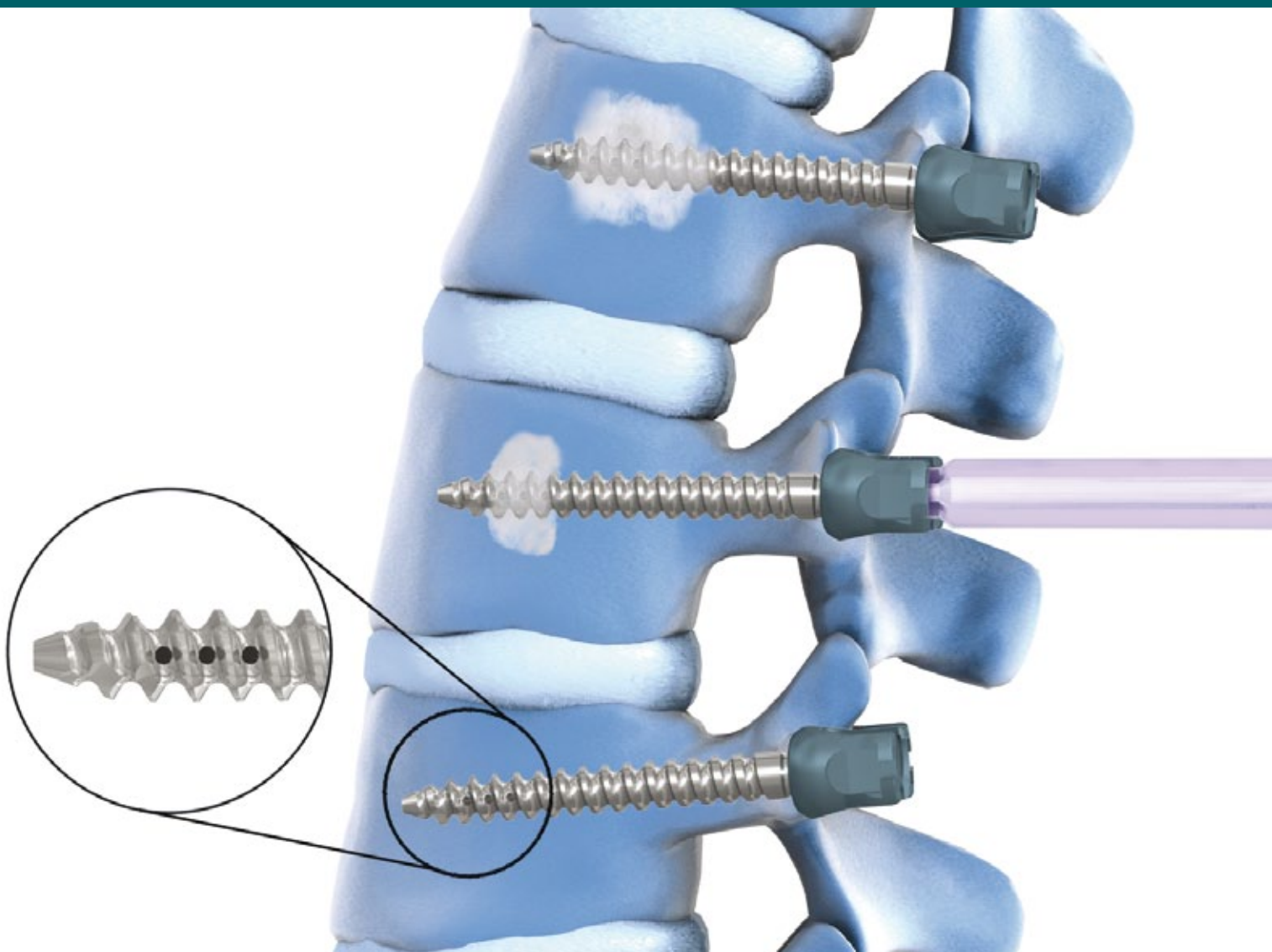


Mantis AUGMENTABLE Spinal System

Pedicle Screw Augmentation System
of the Xia Family for Open and
Percutaneous Approach

Surgical Technique



Mantis AUGMENTABLE Spinal System

Surgical Technique

Table of Contents

Acknowledgments	3
Introduction	3
Key Design Features	4
Preoperative Planning	6
Surgical Procedure	7
1. Percutaneous Approach – Using Mantis AUGMENTABLE Spinal System as Add-On to Mantis Spinal System.....	7
1.1. Patient Positioning.....	7
1.2. Pedicle Preparation, Screw Insertion and Adjustment.....	7
1.3. Access Proper Screw Placement.....	10
1.4. Attachment of Delivery Unit	11
1.5. Handling CORTOSS Bone Augmentation Material	13
1.6. Attach Construct	20
1.7. Revision of the Mantis AUGMENTABLE Spinal System	21
2. Open Approach – Using Mantis AUGMENTABLE Spinal System as Add-On to Xia 3 Spinal System	22
2.1. Patient Positioning.....	22
2.2. Pedicle Preparation and Screw Insertion	22
2.3. Access Proper Screw Placement.....	24
2.4. Attachment of Delivery Unit	25
2.5. Handling CORTOSS Bone Augmentation Material.....	27
2.6. Attach Construct	34
2.7. Revision of the Mantis AUGMENTABLE Spinal System	35
Catalog Information	36
Indications	37
Contraindications	37
Contraindications related to CORTOSS Bone Augmentation Material	37
Warnings related to Stryker CORTOSS Bone Augmentation Material	38
Precations related to Stryker CORTOSS Bone Augmentation Material	38
Preoperative Precautions	38
Postoperative Care	39
Adverse Effects	39

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Introduction

Mantis AUGMENTABLE Spinal System is built on the successful heritage of the Xia Family. It is a comprehensive system providing solutions for the most demanding surgical needs in stabilization of the thoracic, lumbar and sacral regions of the spine in both open and percutaneous applications.

Stryker Spine is proud to introduce the latest product of the Xia Family: Mantis AUGMENTABLE Spinal System; an Add-On system to Xia 3 and Mantis Spinal Systems specifically designed as a stabilization solution for the aging spine.

Mantis AUGMENTABLE Spinal System has been developed to provide the possibility for pedicle screw augmentation with CORTOSS bone augmentation material (BAM) for improved anchorage of pedicle screws in vertebrae of reduced bone quality. The system was designed as a simple add-on option to our existing products Mantis – for percutaneous applications and Xia 3 – for open applications.

Mantis AUGMENTABLE Spinal System is based upon the same design rationale and philosophy that has made Xia one of the leading spinal systems in the market.

Important

This Surgical Technique sets forth detailed, recommended procedures for using the Mantis AUGMENTABLE Spinal System. It offers guidance that you should heed but as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required.

Always refer to the package insert, product label and/or instructions before using any Stryker implant or instrument.

Note: No acid or alkaline solvents should be used in the cleaning of anodized components.

Note: Upon the completion of each surgical procedure, use adequate suction and irrigation to ensure the removal of any existing non-implantable materials.

Note: This is intended as a guide only. There are multiple techniques, and as with any surgical procedure, a surgeon should be thoroughly trained before proceeding.

Mantis AUGMENTABLE Spinal System

Surgical Technique

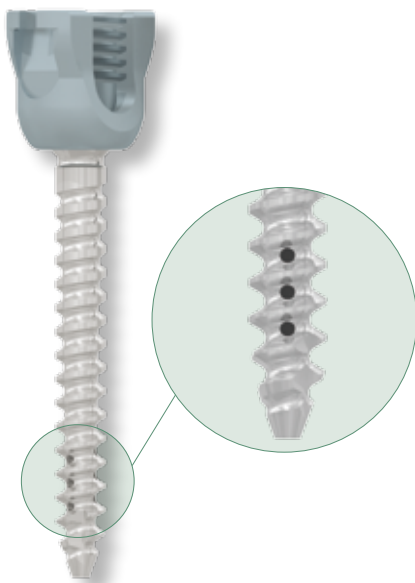
Posterior Stabilization of the Spine with Reduced Bone Quality: **Mantis AUGMENTABLE Spinal System & CORTOSS Bone Augmentation Material – An Easy to Use and Safe Solution for Patient and Surgeon**

For Safe Construct Formation and Pedicle Screw Augmentation

Mantis AUGMENTABLE Fenestrated Screw

For Secure Hold in Vertebra with Normal and Reduced Bone Quality with Enhanced Leakage Control during Augmentation Procedure

- > For solid bone purchase and optimal fit in cortical bone pedicle and cancellous bone vertebral body



Bi-diameter cannulation and optimized fenestration design and pattern

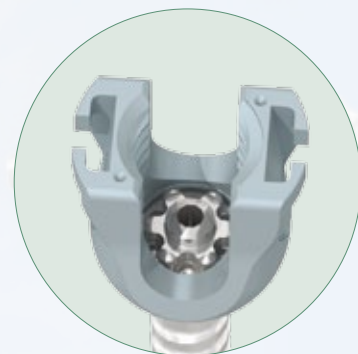
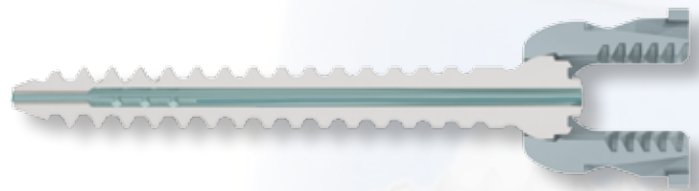
- > Increased cannulation diameter for low flow resistance during injection of augmentation material
- > Reduced diameter at screw tip to minimize outflow of augmentation material from screw tip
- > Three rows of three fenestrations in 120° distribution for low flow resistance and even distribution of augmentation material during the injection process

Implant Design Based on Proven Xia Heritage

- > Typical Xia screw shank design
- > Cortical / cancellous thread design with conical major and cylindrical minor diameter
- > Xia 3 6-point star feature on bone screw for minimized toggle at screw/screwdriver interphase, quick assembly and intuitive engagement between screw and screwdriver



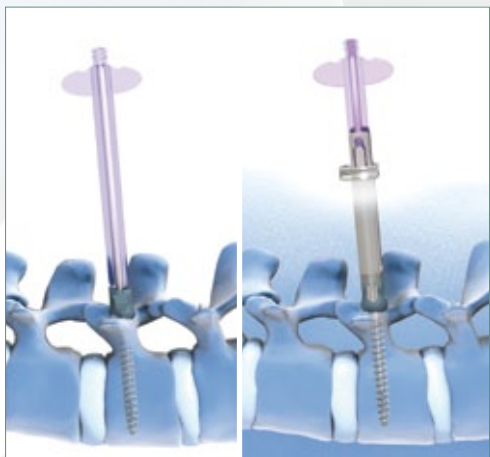
- > Mantis Screw Head accepts both 5.5 mm/6.0 mm Rod Diameters for open and percutaneous approach and maximum versatility in construct formation
- > Xia closure mechanism with buttress thread blocker for minimized cross threading and head splaying during closure of the construct



For Safe and Easy Augmentation in Both Open and Percutaneous Application

Secure Delivery Unit Assembly on the Screw for Safe CORTOSS Application

> **Special Screw Delivery Unit Interface** for tight closure, easy alignment and minimized risk of leakage into the screw head



open approach

percutaneous approach



- > **Standard Luer-Lock interface** for easy attachment of CORTOSS application unit
- > **Single use and sterile pre-packed Delivery Unit** for easy management
- > **Translucent design of Delivery Unit** for better visual control of CORTOSS advancement during augmentation procedure

Ease of Use through Proven Standard Technique in Open and Percutaneous Approach

> **Limited number of Add-On instruments in open and percutaneous approach** for easy and intuitive handling in the OR

With CORTOSS Bone Augmentation Material – an innovative composite material that functions as an anchoring agent to restore the mechanical conditions necessary for proper fixation of bone screws in weak, poor quality bone

Specific Bone Bonding Chemistry – Hydrophilic formulation enables CORTOSS to coat and support the existing trabecular structure. Post implantation, the bioactive glass components create an environment that, in animal studies, has been proven to facilitate bone growth directly to the implant.*

Safety – Reduced exothermic reaction ($\leq 50\text{ C}^\circ$) and minimal monomer release*

Ease of use – Mix on Demand System for unlimited working time and procedural flexibility

Control – Start/Stop delivery system, constant paste-like viscosity during injection

CORTOSS has been clinically proven to meet the standard set by the safety and effectiveness of PMMA for vertebral augmentation.*



* References on file with Stryker

Mantis AUGMENTABLE Spinal System

Surgical Technique

Preoperative Planning

Mantis AUGMENTABLE Spinal System is an Add-On system only. To perform the entire surgical procedure care must be taken to have the complete kits of either Mantis Spinal System for percutaneous procedures or Xia 3 Spinal System for Degenerative Application for open procedures available.

This surgical technique outlines steps being specific and supplementary for the use of Mantis AUGMENTABLE Spinal System with CORTOSS Bone Augmentation Material.

As the Mantis AUGMENTABLE Spinal System will be used with either Mantis Spinal System or Xia 3 Spinal System, please refer to the respective surgical technique guides for percutaneous or open procedures. For specific instructions and details on handling of CORTOSS, please refer to the CORTOSS surgical technique guide.

Note: Handling knowledge of CORTOSS is required when using the Mantis AUGMENTABLE Spinal System.

Surgical Procedures

1. Percutaneous Approach – Using Mantis AUGMENTABLE Spinal System as Add-On to Mantis Spinal System

A complete Mantis Spinal System kit should be available as well as the Mantis AUGMENTABLE Spinal System instruments and implants.

1.1. Patient Positioning

> As with the Mantis Spinal System, the **Mantis AUGMENTABLE Spinal System** can be used under local, epidural, spinal or general anaesthesia. General anaesthesia is commonly used since it is the most comfortable for the patient.



Figure 1

> Position the patient on the operating table in the prone position. Care should be taken to pad all bony prominences. To facilitate venous drainage, the abdomen should not be compressed. Prep and drape the patient in the usual sterile manner for posterior fusion with pedicle screw fixation.

1.2. Pedicle Preparation, Screw Insertion and Adjustment

> For each Mantis AUGMENTABLE screw, define the appropriate entry point, insert K-wire, proceed with dilation and open the pedicle as defined in Mantis Spinal System Surgical Technique Guide.

> The Mantis AUGMENTABLE Screws are self-tapping.

Note: Tapping is not recommended in osteoporotic bone as it may decrease the pullout strength of the screws.

Note: In case of tapping, care should be taken to use an undersized tap for the procedure.

Mantis AUGMENTABLE Spinal System

Surgical Technique

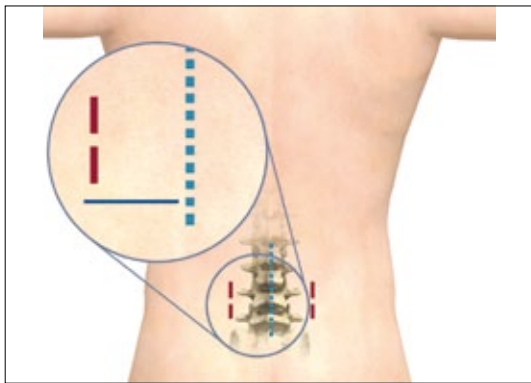









Figure 2

> Based on patient anatomy, select the appropriate screw length and diameter and the appropriate length of Mantis blade. Assemble the Mantis blades to the screw head.

Mantis AUGMENTABLE Screws portfolio (sterile pre-packed):

	Screw Ø		Screw Length (mm)			
			40	45	50	55
	5.5 mm	482885	(40S)	(45S)	(50S)	
	6.5 mm	482886		(45S)	(50S)	(55S)
	7.5 mm	482887		(45S)	(50S)	(55S)

Additional sizes of Mantis AUGMENTABLE fenestrated polyaxial screws are available upon request (see table below):

	Screw Ø		Screw Length (mm)					
			40	45	50	55	60	65
	5.5 mm	482885				(55S)	(60S)	
	6.5 mm	482886					(60S)	(65S)
	7.5 mm	482887					(60S)	(65S)
	8.5 mm	482888		(45S)	(50S)	(55S)	(60S)	(65S)

Note: Only Mantis Blade lengths 1 thru 3 are compatible with the Mantis AUGMENTABLE Spinal System.

Instrument Bar

Screwdriver assembly for percutaneous application of Mantis AUGMENTABLE Polyaxial Screws

- > Assemble the polyaxial screwdriver utilizing the **Mantis AUGMENTABLE Polyaxial Screwdriver Shaft (48288311)** with the **Mantis Screwdriver (48281310)**. The Mantis AUGMENTABLE Polyaxial Screwdriver Shaft is compatible with the Outer Shaft and Locking Nut of the Mantis Screwdriver and should be used in place of the Mantis Polyaxial Screwdriver Inner Shaft. The Mantis AUGMENTABLE Polyaxial Screwdriver is assembled using the same method as the Mantis Polyaxial Screwdriver.
- > The Mantis AUGMENTABLE Polyaxial Screwdriver can then be attached to any of the cannulated modular Mantis Handles (**T Ratchet - 48231200; Round Ratchet - 48231300; T Non-Ratchet - 48231205; Round Non-Ratchet - 48231305**) using the quick release mechanism.
- > Place a **Mantis AUGMENTABLE Screw** on the distal end of the Screwdriver and lock into place.
- > Insert the screw as defined in Mantis Spinal System Surgical Technique Guide.

5.5 mm	482885(40)S-(60)S	
6.5 mm	482886(45)S-(65)S	
7.5 mm	482887(45)S-(65)S	
8.5 mm	482888(45)S-(65)S	

Mantis AUGMENTABLE Fenestrated Polyaxial Screw

48288311 
Mantis AUGMENTABLE Polyaxial Screwdriver Shaft

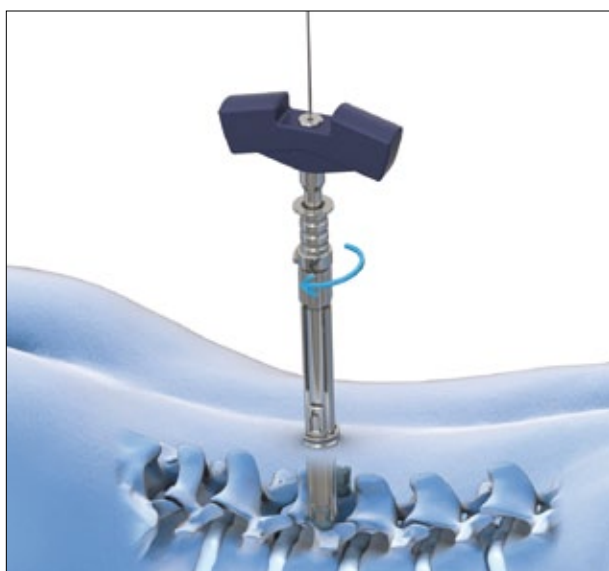


Figure 3

Mantis AUGMENTABLE Spinal System

Surgical Technique



1.3. Assess Proper Screw Placement

- > Prior to augmenting screws, verify proper screw placement and assess the cortical shell of the vertebral body for perforations using fluoroscopy as indicated in Figure 4.
- > To achieve an optimal result with the augmentation process, the cloud of bone augmentation material (BAM) should form in the vertebral body closer to the anterior wall.

Note: The fenestrations of the Mantis AUGMENTABLE Screws need to extend beyond the pedicle walls and into the vertebral body.

Note: If perforation of the cortical shell of the vertebra is detected special care must be taken during BAM injection due to increased risk of extravasation.

Caution: Take care as BAM extravasation may occur if the screw length is too long or the screw is placed bi-cortically as the screw tip may penetrate the anterior cortex of the vertebral body.

Note: Height adjustment of Mantis AUGMENTABLE Screws can be achieved by using the Mantis AUGMENTABLE Polyaxial Screwdriver Shaft directly attached to a Mantis Handle.

Figure 4

Instrument Bar

48288001S
Mantis AUGMENTABLE Delivery Unit



48288002
Mantis AUGMENTABLE Alignment Guide



1.4. Attachment of Delivery Unit

> Insert the **Mantis AUGMENTABLE Delivery Unit (48288001S)** into the screw head of the Mantis AUGMENTABLE Polyaxial Screw engaging with only the first thread while fixating the screw head by holding the blades.

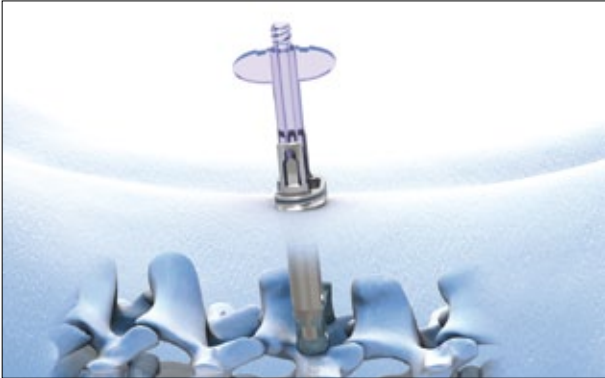


Figure 5

> Insert the **Mantis AUGMENTABLE Alignment Guide (48288002)** into the Delivery Unit – screw head construct (Figure 6).

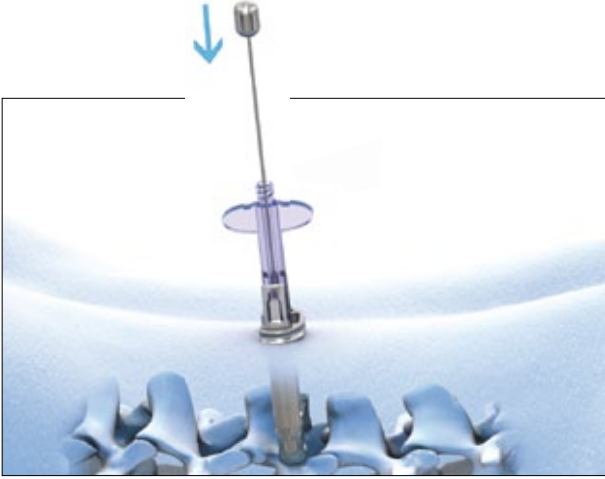


Figure 6

Mantis AUGMENTABLE Spinal System

Surgical Technique

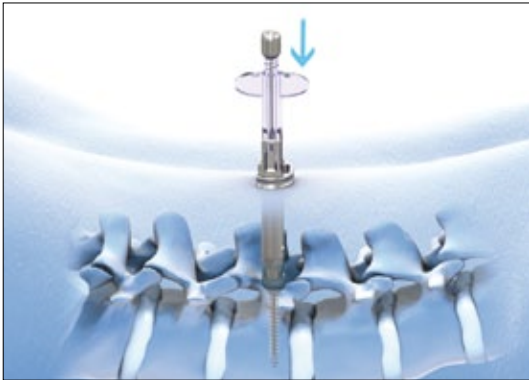


Figure 7

- > With the Alignment Guide fit within the cannulation of the screw shank, the polyaxial screw head and bone shank will properly align with the Delivery Unit (Figure 8).
- > Fully thread the Delivery Unit into the screw head and finger tighten by using the Mantis blades of the Mantis Screw/Assembly as a counter torque.

Note: Care should be taken to ensure the Delivery Unit is fully seated within the screw head to prevent leakage of the augmentation material.

- > Remove the Alignment Guide.

Note: The Delivery Unit is a single use disposable instrument and is provided sterile pre-packed. It is recommended to have extra Delivery Units available during the surgical procedure in case they are needed.

Note: The Alignment Guide can only be used with Mantis AUGMENTABLE screws. The Mantis AUGMENTABLE screw cannulation is $\text{Ø} 1.9 \text{ mm}$ compared to the Mantis screw cannulation of $\text{Ø} 1.4 \text{ mm}$. The Alignment Guide is $\text{Ø} 1.5 \text{ mm}$. This feature will help ensure the appropriate screws are identified and augmented.

Note: The Alignment Guide is a reusable instrument. The instrument should be replaced if it is bent or has BAM on its surface.

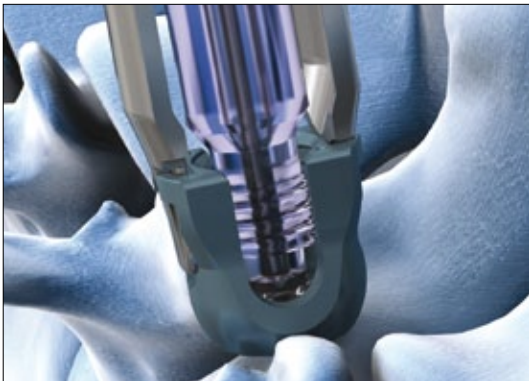


Figure 8

Instrument Bar

1.5. Handling CORTOSS Bone Augmentation Material

Preparing CORTOSS

- > Attach CORTOSS Cartridges 10 cc (2101-0000) or 5 cc (2101-0002) to CORTOSS Delivery Gun (2110-0008).
- > Press and hold the Piston Release Button on the rear of the Delivery Gun.
- > Using the Piston Rack finger loop, pull the Pistons into the Delivery Gun housing until fully retracted.



Figure 9

- > Open the Cartridge Door of the Delivery Gun.



Figure 10

- > Hold the Cartridge so that the numbered side faces up.



Figure 11

Note: The Cartridge Notch (arrow) opposite the numbered surface will engage the Delivery Gun.

2101-0000, 10 cc
2101-0002, 5 cc

CORTOSS Cartridges



2110-0008

CORTOSS Delivery Gun



2110-0031, pack of 3

CORTOSS Mix-tip



2110-0507

ALIQUOT Flexible Extension



Mantis AUGMENTABLE Spinal System

Surgical Technique



Figure 12

- > Place the Cartridge, volume increment side up, into the Delivery Gun and fully seat.
- > Close the Cartridge Door to lock the Cartridge in place.



Figure 13

- > Push the Piston Rack fully forward until the piston stops within the cartridge.
- > Remove the Cartridge Cap by rotating it one quarter turn in a counter-clockwise direction. A gentle toggle of the cap may facilitate its removal.



Figure 14

- > Balance the plungers by slowly squeezing the trigger of the Delivery Gun to express a small amount of material from the Cartridge.
- > Wipe any excess material from the end of the Cartridge.

Note: CORTOSS BAM is delivered sterile and needs to be stored refrigerated (2 - 8°C or 35 - 46°F) in a dry location.

Instrument Bar

- > **CORTOSS Mix-tip (2110-0031)** is the delivery nozzle that blends the CORTOSS pastes initiating the polymerization process.
- > Attach a Mix-tip to the Cartridge by aligning the v-spike on the Mix-tip with the corresponding v-notch on the Cartridge. Press the Mix-tip firmly against the Cartridge housing and rotate the lock ring one quarter turn clockwise until it meets its mechanical stop.

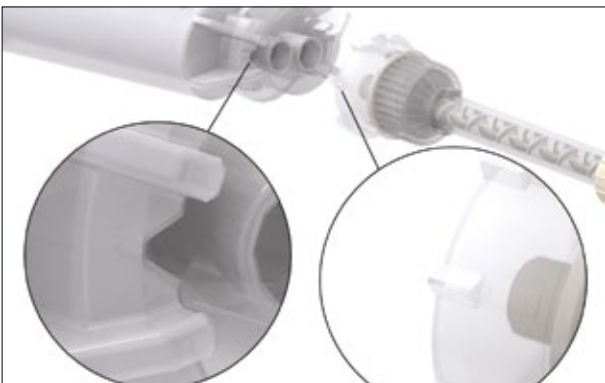


Figure 15

Note: DO NOT SQUEEZE THE TRIGGER AT THIS STAGE. CORTOSS STARTS POLYMERIZING WHEN THE BONE AUGMENTATION MATERIAL COMBINES IN THE MIX-TIP. SQUEEZING THE TRIGGER ACTIVATES THIS PROCESS.

CORTOSS Injection Option A – Direct Application Using Delivery Gun

- > Attach the CORTOSS Delivery Gun/Cartridge/Mix-tip construct directly onto the Delivery Unit /Mantis Screw construct.
- > The **Aliquot Flexible Extension (2110-0507)** is an optional attachment that can be used to reduce the exposure of the surgeon to radiation by allowing the gun/Mix-tip assembly to be bent away from the surgical/ radiation field. The Flexible Extension is attached directly to the Mix-tip.

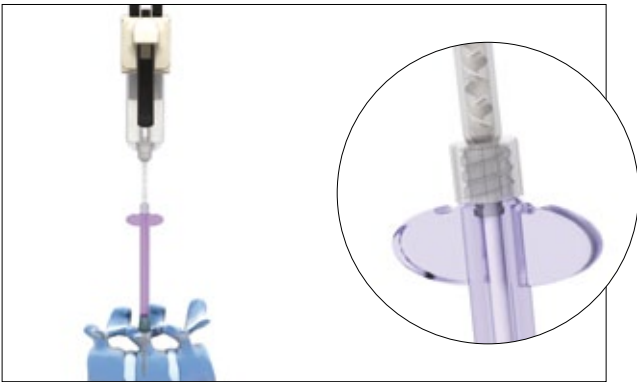




Figure 16

Note: The Delivery Gun/Cartridge/Mix-tip construct has a certain lever arm. Care must be taken to avoid displacement of the Delivery Unit from the Delivery Unit/screw interface during the process of CORTOSS application.

2101-0010	
CORTOSS Cartridges 10cc	
2110-0008	
CORTOSS Delivery Gun	
2110-0031, pack of 3	
CORTOSS Mix-tip	
2110-0507	
ALIQUOT Flexible Extension	

Mantis AUGMENTABLE Spinal System

Surgical Technique

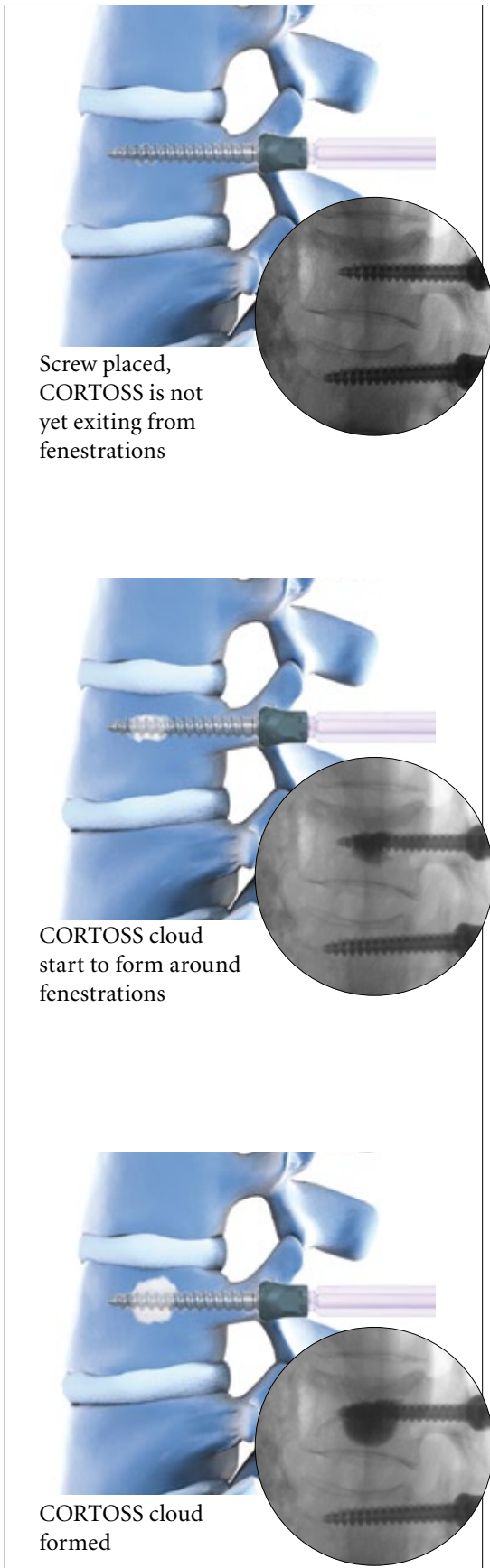


Figure 17

CORTOSS Injection

- > Slowly squeeze the trigger of the Delivery Gun to inject CORTOSS.
- > Monitor the advancement of CORTOSS through the Mix-tip and the Delivery Unit. Under fluoroscopic control, slowly inject CORTOSS until the augmentation material starts to extrude from the screw perforations. Check for CORTOSS leakage outside the vertebral body or into the spinal canal.
- > Continue with the injection procedure while monitoring under fluoroscopy; a growing cloud pattern of CORTOSS should form around the distal third of the pedicle screw. Screw augmentation is complete when a screw has been augmented with a total volume of approximately 2 cc CORTOSS per screw for vertebrae in the lumbar and thoracolumbar areas.

Note: Injecting too much augmentation material (over-fill) or injecting the augmentation material too quickly will increase the chance of leakage.

Note: If material does leak outside the vertebral body or in the circulation system during the procedure, injection should be stopped immediately.

Note: CORTOSS flow stops immediately when trigger of Delivery Gun is released.

Note: The Delivery Unit contains a volume of 1 cc.

Note: CORTOSS has a dispersed fill pattern.

- > Once the screw has been augmented, remove the Mix-tip or Aliquot Flexible Extension from the Delivery Unit.
- > Leave the Delivery Unit in place following the injection of CORTOSS.
- > CORTOSS needs to set approximately 2 - 4 minutes at body temperature before the Delivery Unit can be removed to avoid leakage of the material into the screw head.
- > With CORTOSS set, remove the Delivery Unit from the Mantis AUGMENTABLE screw and check for any remnant of CORTOSS in the screw head. Any remnants need to be removed using forceps.

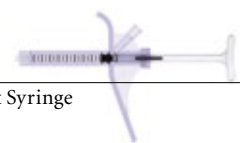
Note: CORTOSS sets in 2-4 minutes at body temperature, 3.5 - 8 minutes at room temperature.

Note: Should CORTOSS set in the Mix-tip remove the item, discard it, and use a new one.

Instrument Bar

2110-0513

ALIQUOT Side-Port Syringe



2110-0507

ALIQUOT Flexible Extension



CORTOSS Application Option B – CORTOSS Injection Using CORTOSS Aliquot Side-Port Syringes

- > Prepare the **Aliquot Side-port Syringe (2110-0513)**.
- > Pull back the Syringe plunger completely and ensure the plunger is in the locked position. If not locked, rotate 90°.

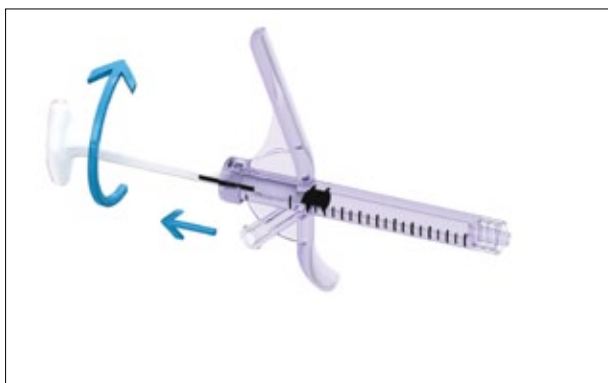


Figure 18

- > Attach the Mix-tip to the Side-Port syringe and attach to the Mantis AUGMENTABLE screw/Delivery Unit construct.



Figure 19

Note: The Side Port Syringe and Delivery Unit accommodate approximately 1 cc of CORTOSS each. The Mix-tip and Flexible Extension accommodate approximately 0.8 and 0.5 ccs of CORTOSS respectively.

- > Optionally the **Aliquot Flexible Extension (2110-0507)** can be attached at the tip of the Side-port Syringe. The Flexible extension can be used to reduce exposure of the surgeon to radiation.

Mantis AUGMENTABLE Spinal System

Surgical Technique

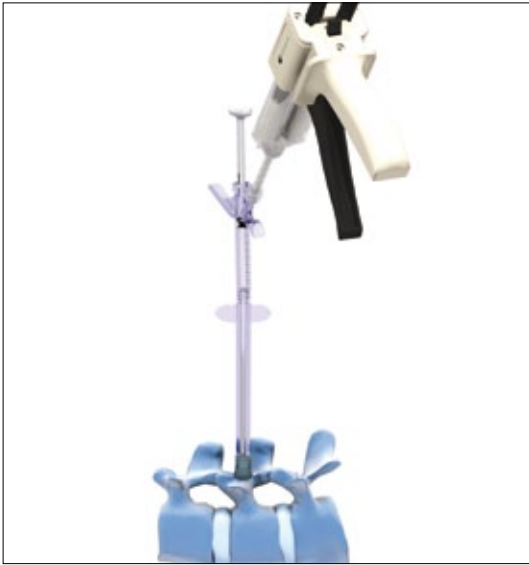


Figure 20

CORTOSS Injection

- > Slowly squeeze the trigger of the Delivery Gun to inject CORTOSS.
- > Monitor the advancement of CORTOSS through the Mix-tip, the Aliquot Syringe and the Delivery Unit.
- > Under fluoroscopic control, slowly inject CORTOSS until the augmentation material starts to extrude from the screw perforations.
- > When a cloud of approximately 1 cc CORTOSS has been formed around the screw, unlock the Aliquot syringe plunger and inject the remaining 1cc CORTOSS directly with the syringe. For convenience the Delivery Gun can be removed from the side port of the syringe prior to CORTOSS injection with the syringe.
- > Check for CORTOSS leakage outside the vertebral body or into the spinal canal.
- > Continue with the injection procedure monitoring under fluoroscopy (as indicated in Figure 21); a growing cloud pattern of CORTOSS should form around the distal third of the pedicle screw. Screw augmentation is complete when a screw has been augmented with a total volume of approximately 2 cc CORTOSS per screw for vertebrae in the lumbar and thoracolumbar areas.

Note: Injecting too much augmentation material (over-fill) or injecting the augmentation material too quickly will increase the chance of leakage.

Note: If material does leak outside the vertebral body or in the circulation system during the procedure, injection should be stopped immediately.

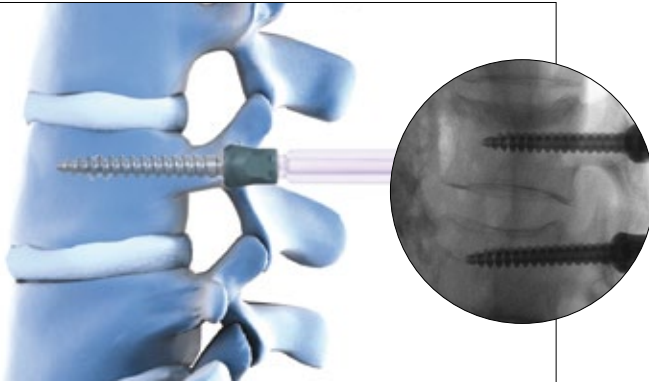
Note: The Delivery Unit contains a volume of 1 cc.

Note: CORTOSS has a dispersed fill pattern.

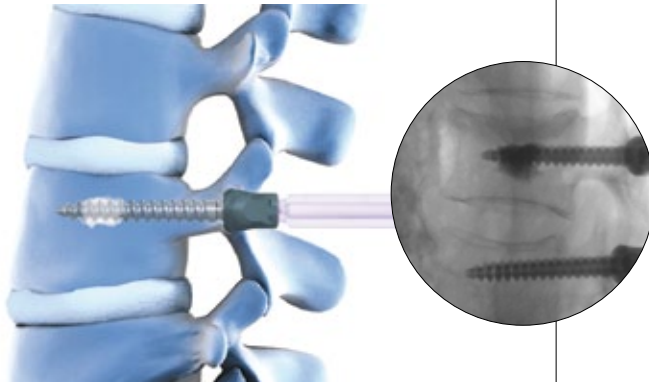
- > Once the screw has been augmented, remove the syringe from the Delivery Unit. Leave the Delivery Unit in place following the injection of CORTOSS.
- > CORTOSS needs to set approximately 2- 4 min at body temperature before the Delivery Unit can be removed to avoid leakage of the material into the screw head.
- > With CORTOSS set, remove the Delivery Unit from the Mantis AUGMENTABLE screw and check for any remnant of CORTOSS in the screw head. Any remnants need to be removed using forceps.

Note: CORTOSS sets in 2-4 minutes at body temperature, 3.5-8 minutes at room temperature.

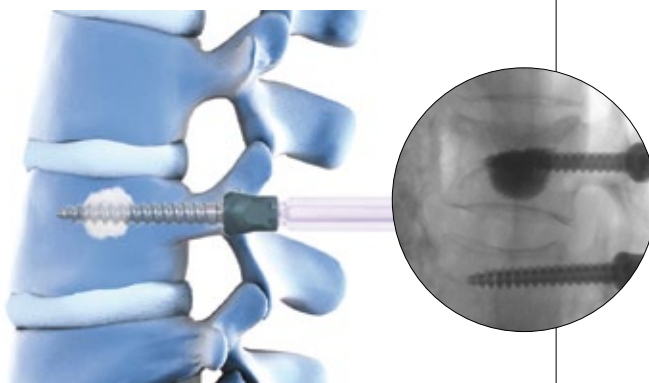
Note: Should CORTOSS set in the Mix-tip remove the item, discard it, and use a new one.



Screw placed, CORTOSS is not yet exiting from fenestrations



CORTOSS cloud start to form around fenestrations



CORTOSS cloud formed

Figure 21

Mantis AUGMENTABLE Spinal System

Surgical Technique

1.6. Attach Construct

The rod length and contour is determined using the appropriate rod template and the Mantis rod contouring components.

Mantis Rod Templates:

Mantis Rod Template Straight L 30 - 100 MM (48286001)

Mantis Rod Template Straight L 110 - 200 MM (48286002)

Mantis Rod Template Pre-bent L 30 - 35 MM (48287001)

Mantis Rod Template Pre-bent L 40 - 65 MM (48287002)

Mantis Rod Template Pre-bent L 70 - 130 MM (48287003)

Note: Mantis Rod Templates are not for implantation, rod templates can be identified by the flattened end when compared to standard rods.

Note: Do not cut or bend Mantis Rod Templates.

Note: Mantis Rod Templates are compatible with 6.0 mm diameter Mantis rods only. The length designations on the 6.0 mm diameter rods indicate the total length of the rod including the leading tip and hex end whereas the length designations on the 5.5 mm diameter rods indicate the working length of the rod and does not include the leading tip or hex end.

- > The length designation is for reference only as cutting or bending the rod may change the length of the rod.
- > Continue with the rod insertion, closing construct and final tightening surgical procedure steps from the Mantis Spinal System Surgical Technique Guide.

Note: Ensure that CORTOSS is fully hardened before performing any correction maneuvers.

Note: In case rod reduction, compression or distraction is necessary, please refer to the procedural steps described in the Mantis Spinal System Surgical Technique Guide. Extreme care should be taken as persuasion and compression/distraction maneuvers on screws in osteoporotic bone and screws that have been augmented might lead to loosening of the augmented screws resulting in construct failure.

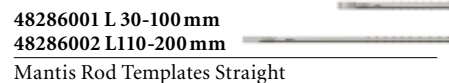
Instrument Bar

1.7. Revision of the Mantis Augmentable Spinal System

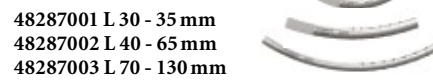
A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, changes in device positioning, etc.

If necessary, the Mantis AUGMENTABLE implants can be removed with use of the **Xia Universal Tighener (03807008)**, **Mantis Blocker Inserter (48287008)** or the **Xia 3 Universal Tightener (48237008)** and the **Xia 3 Polyadjustment Driver (48237033)**, **Xia 3 Polyaxial Screwdriver (48231330)** or **Mantis Polyaxial Screwdriver (48281310)** with the **Mantis AUGMENTABLE Polyaxial Screwdriver Shaft (48288311)**.

The surgeon must use his/her professional judgment to determine the appropriate revision strategy taking into consideration patient health, the nature of the problem and/or device failure, the patient's bone quality, and the surgeon's expertise with other spinal treatments and instrumentation.



Mantis Rod Templates Straight



Mantis Rod Template Pre-bent

Mantis AUGMENTABLE Spinal System

Surgical Technique



Figure 22

2. Open Approach – Using Mantis AUGMENTABLE Spinal System as Add-On to Xia3 Spinal System

A complete Xia3 Spinal System for Degenerative Application kit should be available as well as the Mantis AUGMENTABLE Spinal System instruments and implants.

2.1. Patient Positioning

As with the Xia3 Spinal System, the Mantis AUGMENTABLE Spinal System can be used under local, epidural, spinal or general anaesthesia. General anaesthesia is commonly used since it is the most comfortable for the patient and allows immediate postoperative neurological assessment.

> Position the patient on the operating table in the prone position. Care should be taken to pad all bony prominences. To facilitate venous drainage, the abdomen should not be compressed. Prep and drape the patient in the usual sterile manner for posterior fusion with pedicle screw fixation.

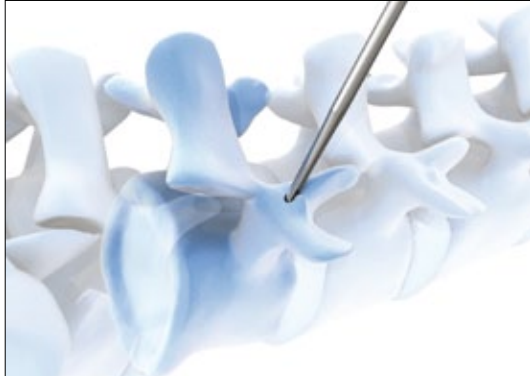


Figure 23

2.2. Pedicle Preparation and Screw Insertion

> Open and prepare the pedicles and insert screws as defined in the Xia3 Spinal System Surgical Technique Guide.

> The Mantis AUGMENTABLE Screws are self-tapping.

Note: Tapping is not recommended in osteoporotic bone as it may decrease the pullout strength of the screws.

Note: In case of tapping care should be taken to use an undersized tap for the procedure.

> Based on patient anatomy, select the appropriate screw length and diameter.

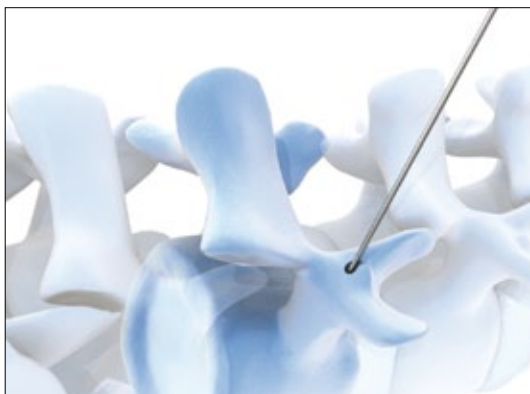









Figure 24





Mantis AUGMENTABLE Screws portfolio (sterile pre-packed):

	Screw Ø		Screw Length (mm)			
			40	45	50	55
	5.5 mm	482885	(40S)	(45S)	(50S)	
	6.5 mm	482886		(45S)	(50S)	(55S)
	7.5 mm	482887		(45S)	(50S)	(55S)

5.5 mm	482885(40)S-(60)S	
6.5 mm	482886(45)S-(65)S	
7.5 mm	482887(45)S-(65)S	
8.5 mm	482888 (45)S-(65)S	

Mantis AUGMENTABLE Fenestrated Polyaxial Screw

Additional sizes of Mantis AUGMENTABLE fenestrated polyaxial screws are available upon request (see table below).

	Screw Ø		Screw Length (mm)				
			40	45	50	55	60
	5.5 mm	482885				(55S)	(60S)
	6.5 mm	482886					(60S) (65S)
	7.5 mm	482887					(60S) (65S)
	8.5 mm	482888		(45S)	(50S)	(55S)	(60S) (65S)

Insert the Mantis AUGMENTABLE screws using the **Xia 3 Polyaxial Screwdriver (48231330)**.

Mantis AUGMENTABLE Spinal System

Surgical Technique



2.3. Assess Proper Screw Placement

- > Prior to augmenting screws, verify proper screw placement and assess the cortical shell of the vertebral body for perforations using fluoroscopy.
- > To achieve an optimal result with the augmentation process, the cloud of bone augmentation material (BAM) should form in the vertebral body close to the anterior wall.

Note: The fenestrations of the Mantis AUGMENTABLE screws need to extend beyond the pedicle walls and into the vertebral body.

Note: If perforation of the cortical shell of the vertebra is detected special care must be taken during BAM injection of bone augmentation material due to increased risk for extravasation.

Caution: Take care as augmentation material extravasation may occur if the screw length is too long or the screw is placed bi-cortically as the screw tip may penetrate the anterior cortex of the vertebral body.

Note: Height adjustment of the Mantis AUGMENTABLE Screws can be achieved by using the **Xia 3 Polyadjustment Driver (48237033)**.

Figure 25

2.4. Attachment of Delivery Unit

- > Insert the **Mantis AUGMENTABLE Alignment Guide (48288002)** into the **Mantis AUGMENTABLE Delivery Unit (48288001S)**.



Figure 26

- > Use the Alignment Guide to guide the Delivery Unit to the Mantis AUGMENTABLE screw head by introducing the tip of the Alignment Guide into the cannulation of the screw.
- > Guide the Delivery Unit into the screw head and engage with only the first thread.

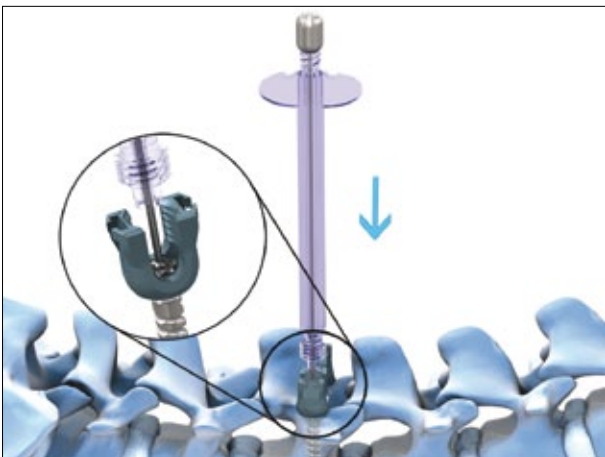


Figure 27

48288001S

Mantis AUGMENTABLE Delivery Unit

48288002

Mantis AUGMENTABLE Alignment Guide

Mantis AUGMENTABLE Spinal System

Surgical Technique

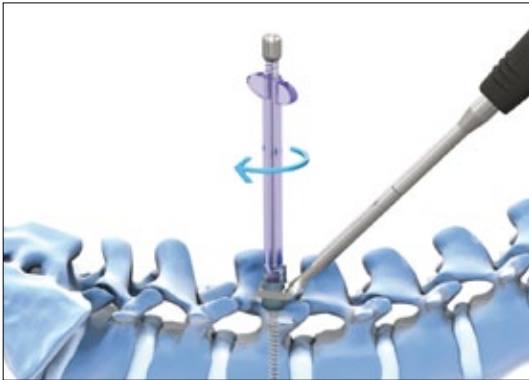


Figure 28

- > With the Alignment Guide sitting within the cannulation of the screw shank, the polyaxial screw head and bone shank will properly align with the Delivery Unit.
- > Use **Mantis AUGMENTABLE Polyaxial Screw Head Holder (48288000)** as counter torque while fully engaging the Delivery Unit into the screw head and finger tighten.

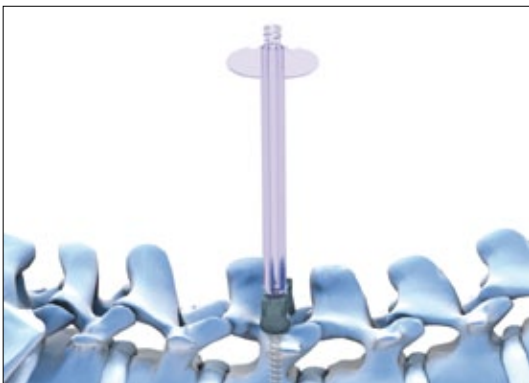


Figure 29

- > Care should be taken to ensure the Delivery Unit is fully seated within the screw head to prevent leakage of the augmentation material.
- > Remove the Alignment Guide.

Note: The Delivery Unit is a single use disposable instrument and is provided sterile pre-packed. It is recommended to have extra Delivery Units available during the surgical procedure in case they are needed.

Note: The Alignment Guide is a multiple use instrument. The instrument should be replaced if it is bent or has BAM on its surface.



Figure 30

2.5. Handling CORTOSS Bone Augmentation Material

Preparing CORTOSS

- > Attach CORTOSS Cartridges 10 cc (2101-0000) or 5 cc (2101-0002) to CORTOSS Delivery Gun (2110-0008).
- > Press and hold the Piston Release Button on the rear of the Delivery Gun.
- > Using the Piston Rack finger loop, pull the Pistons into the Delivery Gun housing until fully retracted.



Figure 31

- > Open the Cartridge Door of the Delivery Gun.



Figure 32

- > Hold the Cartridge so that the numbered side faces up.



Figure 33

Note: The Cartridge Notch (arrow) opposite the numbered surface will engage the Delivery Gun.

2101-0000, 10 cc
2101-0002, 5 cc



CORTOSS Cartridges

2110-0008

CORTOSS Delivery Gun



2110-0031, pack of 3

CORTOSS Mix-tip



48288000

Mantis AUGMENTABLE Screw Head Holder



2110-0507

ALIQUOT Flexible Extension



Mantis AUGMENTABLE Spinal System

Surgical Technique



Figure 34

- > Place the Cartridge, volume increment side up, into the Delivery Gun and fully seat.
- > Close the Cartridge Door to lock the Cartridge in place.



Figure 35

- > Push the Piston Rack fully forward until the piston stops within the cartridge.
- > Remove the Cartridge Cap by rotating it one quarter turn in a counter-clockwise direction. A gentle toggle of the cap may facilitate its removal.



Figure 36

- > Balance the plungers by slowly squeezing the trigger of the Delivery Gun to express a small amount of material from the Cartridge.
- > Wipe any excess material from the end of the Cartridge.

Note: CORTOSS Bone Augmentation Material is delivered sterile and needs to be stored refrigerated (2 - 8°C or 35 - 46°F) in a dry location.

- > **CORTOSS Mix-tip (2110-0031)** is the delivery nozzle that blends the CORTOSS pastes initiating the polymerization process.
- > Attach a **Mix-tip** to the **Cartridge** by aligning the v-spike on the Mix-tip with the corresponding v-notch on the Cartridge. Press the Mix-tip firmly against the Cartridge housing and rotate the lock ring one quarter turn clockwise until it meets its mechanical stop.

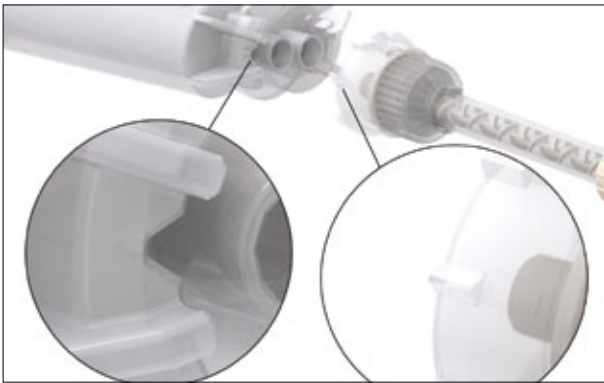


Figure 37

Note: DO NOT SQUEEZE THE TRIGGER AT THIS STAGE. CORTOSS POLYMERIZATION STARTS WHEN THE BONE AUGMENTATION MATERIAL COMBINES IN THE MIX-TIP. SQUEEZING THE TRIGGER ACTIVATES THIS PROCESS.

CORTOSS Injection Option A – Direct Application Using Delivery Gun

- > Attach the CORTOSS Delivery Gun/Cartridge/Mix-tip construct directly onto the Delivery Unit /Mantis Screw construct.



Figure 38

Note: The Delivery Gun/Cartridge/Mix-tip construct has a certain lever arm. Care must be taken to avoid displacement of the Delivery Unit from the Delivery Unit / screw interface during the process of CORTOSS application.

- > The **Aliquot Flexible Extension (2110-0507)** is an optional attachment that can be used to reduce the exposure of the surgeon to radiation by allowing the gun/Mix-tip assembly to be bent away from the surgical/radiation field. The Flexible Extension is attached directly to the Mix-tip.

2101-0010

CORTOSS Cartridges 10cc



2110-0008

CORTOSS Delivery Gun



2110-0031, pack of 3

CORTOSS Mix-tip



2110-0507

ALIQUOT Flexible Extension



Mantis AUGMENTABLE Spinal System

Surgical Technique



Figure 39

CORTOSS Injection

- > Slowly squeeze the trigger of the Delivery Gun to inject CORTOSS.
- > Monitor the advancement of CORTOSS through the Mix-tip and the Delivery Unit. Under fluoroscopic control, slowly inject CORTOSS until the augmentation material starts to extrude from the screw perforations. Check for CORTOSS leakage outside the vertebral body or into the spinal canal.
- > Continue with the injection procedure while monitoring under fluoroscopy; a growing cloud pattern of CORTOSS should form around the distal third of the pedicle screw. Screw augmentation is complete when a screw has been augmented with a total volume of approximately 2 cc CORTOSS per screw for vertebrae in the lumbar and thoracolumbar areas.

Note: Injecting too much augmentation material (over-fill) or injecting the augmentation material too quickly will increase the chance of leakage.

Note: If material does leak outside the vertebral body or in the circulation system during the procedure, injection should be stopped immediately.

Note: CORTOSS flow stops immediately when trigger of Delivery Gun is released.

Note: The Delivery Unit contains a volume of 1 cc.

Note: CORTOSS has a dispersed fill pattern.

- > Once the screw has been augmented, remove the Mix-tip or Aliquot Flexible Extension from the Delivery Unit.
- > Leave the Delivery Unit in place following the injection of CORTOSS.
- > CORTOSS needs to set approximately 2- 4 minutes at body temperature before the Delivery Unit can be removed to avoid leakage of the material into the screw head.
- > With CORTOSS set, remove the Delivery Unit from the Mantis AUGMENTABLE screw and check for any remnant of CORTOSS in the screw head. Any remnants need to be removed using forceps.

Note: CORTOSS sets in 2 - 4 minutes at body temperature, 3.5 - 8 minutes at room temperature.

Note: Should CORTOSS set in the Mix-tip remove the item, discard it, and use a new one.

CORTOSS Application Option B – CORTOSS Injection Using CORTOSS Aliquot Side-Port Syringes

- > Prepare the **Aliquot Side-port Syringe (2110-0513)**.
- > Pull back the Syringe plunger completely and ensure the plunger is in the locked position. If not locked, rotate 90°.

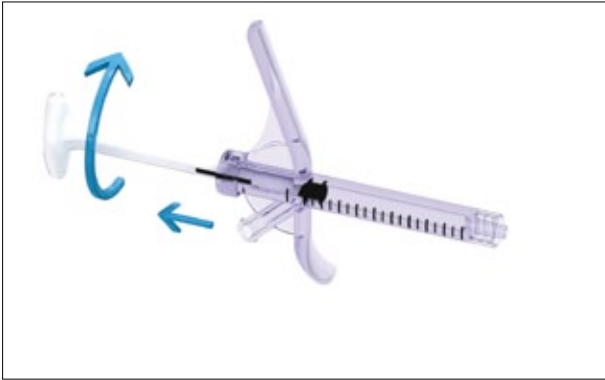


Figure 40

- > Attach the Mix-tip to the Side-Port syringe and attach to the Mantis AUGMENTABLE screw/Delivery Unit construct.



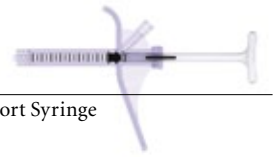
Figure 41

Note: The Side Port Syringe and Delivery Unit accommodate approximately 1 cc of CORTOSS each. The Mix-tip and Flexible Extension accommodate approximately 0.8 and 0.5 ccs of CORTOSS respectively.

- > Optionally the **Aliquot Flexible Extension (2110-0507)** can be attached at the tip of the Side-port Syringe. The Flexible extension can be used to reduce exposure of the surgeon to radiation.

2110-0513

ALIQUOT Side-Port Syringe



2110-0507

ALIQUOT Flexible Extension



Mantis AUGMENTABLE Spinal System

Surgical Technique



Figure 42

CORTOSS Injection

- > Slowly squeeze the trigger of the Delivery Gun to inject CORTOSS.
- > Monitor the advancement of CORTOSS through the Mix-tip, the Aliquot Syringe and the Delivery Unit. Under fluoroscopic control, slowly inject CORTOSS until the augmentation material starts to extrude from the screw perforations.
- > When a cloud of approximately 1cc CORTOSS has been formed around the screw, unlock the Aliquot syringe plunger and inject the remaining 1cc CORTOSS directly with the syringe. For convenience, the Delivery Gun can be removed from the side port of the syringe prior CORTOSS injection with the syringe.
- > Check for CORTOSS leakage outside the vertebral body or into the spinal canal.
- > Continue with the injection procedure monitoring under fluoroscopy (as indicated in Figure 43); a growing cloud pattern of CORTOSS should form around the distal third of the pedicle screw. Screw augmentation is complete when a screw has been augmented with a total volume of approximately 2 cc CORTOSS per screw for vertebrae in the lumbar and thoracolumbar areas.

Note: Injecting too much augmentation material (over-fill) or injecting the augmentation material too quickly will increase the chance of leakage.

Note: If material does leak outside the vertebral body or in the circulation system during the procedure, injection should be stopped immediately.

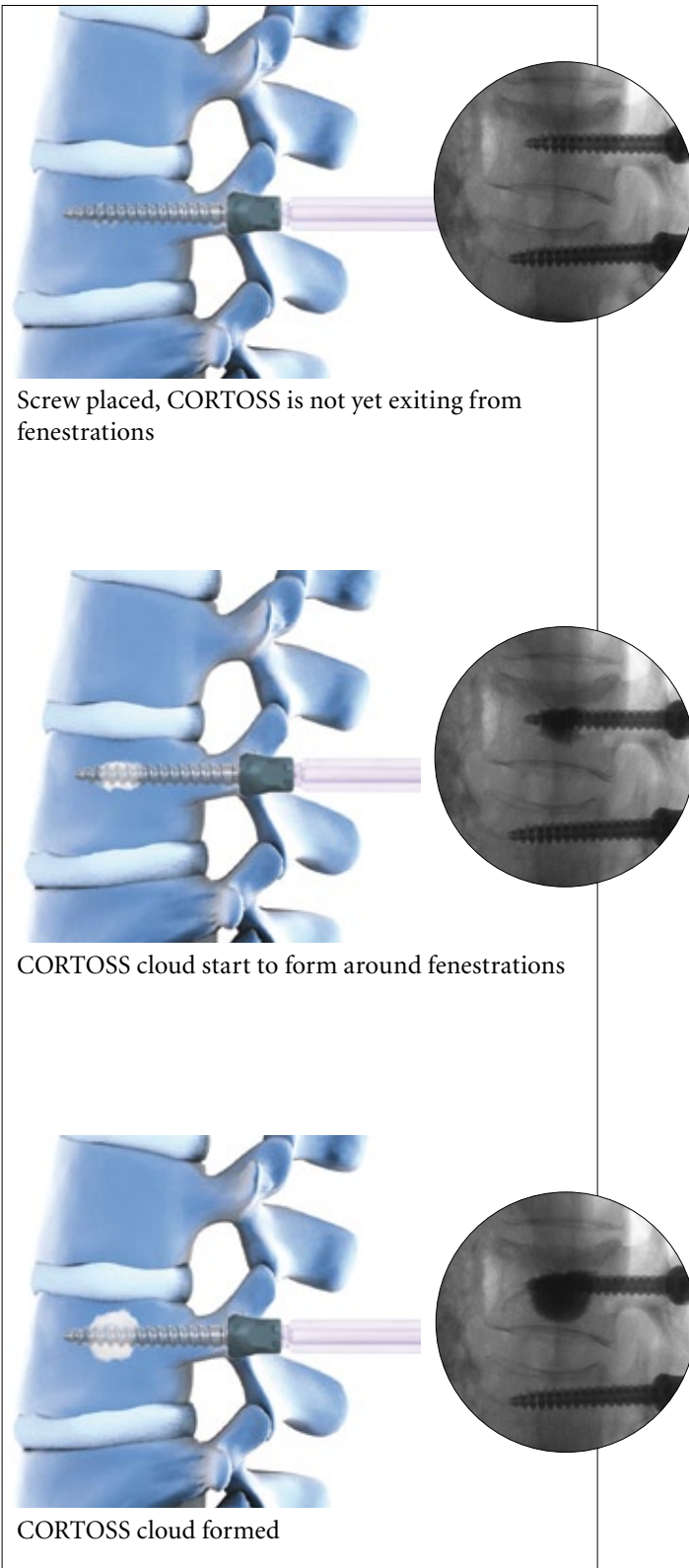
Note: The Delivery Unit contains a volume of 1 cc.

Note: CORTOSS has a dispersed fill pattern.

- > Once the screw has been augmented, remove the syringe from the Delivery Unit. Leave the Delivery Unit in place following the injection of CORTOSS.
- > CORTOSS needs to set approximately 2 - 4 minutes at body temperature before the Delivery Unit can be removed to avoid leakage of the material into the screw head.
- > With CORTOSS set, remove the Delivery Unit from the Mantis AUGMENTABLE screw and check for any remnant of CORTOSS in the screw head. Any remnants need to be removed using forceps.

Note: CORTOSS sets in 2 - 4 minutes at body temperature, 3.5 - 8 minutes at room temperature.

Note: Should CORTOSS set in the Mix-tip remove the item, discard it, and use a new one.



Screw placed, CORTOSS is not yet exiting from fenestrations

CORTOSS cloud start to form around fenestrations

CORTOSS cloud formed

Figure 43

Mantis AUGMENTABLE Spinal System

Surgical Technique

2.6. Attach Construct

> Continue with rod selection, rod insertion and closing of the construct as outlined in the Xia 3 Spinal System Surgical Technique Guide.

Note: Ensure that CORTOSS is fully hardened before performing any correction maneuvers.

Note: In case rod persuasion is necessary at the level of a Mantis AUGMENTABLE screw, the **Mantis Persuader (48284065)** should be used to apply additional force to bring the rod to the implant. Extreme care should be taken when using the Mantis Persuader on screws in osteoporotic bone and screws that have been augmented as the reduction maneuver might lead to loosening of the screws resulting in construct failure.

Note: The Mantis Blades must be used with the Mantis AUGMENTABLE screws when the Mantis Persuader is used. Please refer to the Mantis Spinal System Surgical Technique Guide for steps to attach the Mantis Blades and use of the Persuader.

Note: In case rod persuasion is necessary at the level of a Xia 3 screw, the **Xia 3 Persuader (48237016)** or **Xia 3 One Handed Persuader (48237015)** should be used to apply additional force to bring the rod to the implant.

Note: In case compression or distraction is necessary, please refer to the procedural steps described in the Xia 3 Spinal System Surgical Technique Guide. Extreme care should be taken as compression/distraction maneuvers might lead to loosening of the augmented screws resulting in construct failure.

Construct Tightening

Once any necessary correction procedures have been performed and the spine is fixed in a satisfactory position, the final tightening of the Mantis AUGMENTABLE Screw is done by utilizing the **Mantis AUGMENTABLE Anti-Torque Key (48288880)** and the **Xia 3 Torque Wrench (48237028)**.

2.7. Revision of the Mantis AUGMENTABLE Spinal System

A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, changes in device positioning, etc.

If necessary, the Mantis AUGMENTABLE implants can be removed with use of the **Xia Universal Tighener (03807008)**, **Mantis Blocker Inserter (48287008)** or the **Xia 3 Universal Tightener (48237008)** and the **Xia 3 Polyadjustment Driver (48237033)**, **Xia 3 Polyaxial Screwdriver (48231330)** or **Mantis Polyaxial Screwdriver (48281310)** with the **Mantis AUGMENTABLE Polyaxial Screwdriver Shaft (48288311)**.

The surgeon must use his/her professional judgment to determine the appropriate revision strategy taking into consideration patient health, the nature of the problem and/or device failure, the patient's bone quality, and the surgeon's expertise with other spinal treatments and instrumentation.

48288880

Mantis AUGMENTABLE
Anti-Torque Key



48237028

Xia 3 Torque Wrench



Mantis AUGMENTABLE Spinal System

Surgical Technique

Catalog #	Description
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Implants

Mantis AUGMENTABLE FENESTRATED Polyaxial Screws, sterile pre-packed



482885(40)S-(50)S, (55)S*, (60)S*	Ø 5.5 mm
482886(45)S-(55)S, (60)S*, (65)S*	Ø 6.5 mm
482887(45)S-(55)S, (60)S*, (65)S*	Ø 7.5 mm
482888(45)S*-(65)S*	Ø 8.5 mm

* Additional implant sizes are available upon request.

Instruments



48288311	Mantis AUGMENTABLE Polyaxial Screwdriver Shaft
48288002	Mantis AUGMENTABLE Alignment Guide
48288000	Mantis AUGMENTABLE Screw Head Holder
48288880	Mantis AUGMENTABLE Anti-Torque Key

Disposables



48288001S	Mantis AUGMENTABLE Delivery Unit, sterile pre-packed, single use
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CORTOSS Bone Augmentation Material



2101-0000	CORTOSS Cartridges, 10 cc
2101-0002	CORTOSS Cartridges, 5 cc
2110-0008	Delivery Gun
21100-0027	Delivery Gun, unsterile, multiple use
2110-0031	Mix-tips, Luer, 3 pack, sterile pre-packed
2110-0513	ALIQUOT Side-port Syringe, 1 cc, sterile pre-packed, single use
2110-0507	ALIQUOT Flexible Extension 2-inch, 3 pack, sterile pre-packed

INDICATIONS

When used with Stryker CORTOSS, bone augmentation material, the Mantis AUGMENTABLE screws are intended for posterior, non-cervical pedicle fixation as an adjunct to fusion in patients with diminished bone quality such as osteoporosis for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

CONTRAINDICATIONS

The contraindications listed below may be relative or absolute and must be taken into account by the physician when making his decision. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Fever or leukocytosis
- Patients with clotting disorders
- Patients with severe cardiac and/or pulmonary insufficiency
- Pregnancy
- Any patient with known hypersensitivity or allergy to any of the components in Stryker CORTOSS bone augmentation material.
- Patients with any contra-indication to Stryker CORTOSS Bone Augmentation Material.
- Pedicular /vertebra posterior wall defects, damage or fracture
- Any case not needing a bone graft and fusion
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any patient having inadequate tissue coverage over the operative site
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Any patient unwilling to follow postoperative instructions
- Any case not described in the indications
- Fractures and tumors with loss of anterior support and primary or metastatic tumors involving the spine
- Osteoporosis when used without bone augmentation material
- Severe Osteoporosis
- Previous history of infection or active infection
- Excessive local inflammation
- Open wounds
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spine which can lead to failure of the fixation of the device or to failure of the device itself.
- 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.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Any 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 count (WBC), or a marked left shift in the WBC differential count.

CONTRAINDICATIONS RELATED TO STRYKER CORTOSS BONE AUGMENTATION MATERIAL

- Skeletally immature patients
- Infected site
- Severe vertebral fracture classified as burst fracture with $\geq 20\%$ narrowing of the spinal canal
- Vertebral fracture with neurological deficits or radiculopathy
- Bleeding disorder
- Areas where the stability of the void or defect site would be solely maintained by CORTOSS
- Areas where CORTOSS would cross a fracture line if natural healing of the fracture line is desired
- Defect site stabilization is not possible

Mantis AUGMENTABLE Spinal System

Surgical Technique

- Rigid internal fixation is not advisable
- Breach of the pedicle wall when augmenting pedicle screws. Injection of CORTOSS in this situation will carry a high risk of leakage into the spinal canal or neural foramen.

The above list of contraindications is not exhaustive.

WARNINGS RELATED TO STRYKER CORTOSS BONE AUGMENTATION MATERIAL

- For safe and effective use of CORTOSS Bone Augmentation Material, the physician should have specific training, experience, and thorough familiarity with the properties, handling characteristics, and application of the CORTOSS composite.
- The safe and effective use of CORTOSS Bone Augmentation Material has not been established for intradural placement.
- When using CORTOSS in or around the spine, articulating joints or soft tissues, use good visualization techniques, including fluoroscopy, to minimize the risk associated with the flow of CORTOSS into the spinal canal, neural foramina, paravertebral soft tissues, adjacent discs, the epidural space of the vertebral column, articular spaces, soft tissues or the venous system. Leakage of the material into these locations may compromise the quality of the procedure, resulting in less than optimal clinical results.

PRECAUTIONS RELATED TO STRYKER CORTOSS BONE AUGMENTATION MATERIAL

- Exercise care to avoid inclusions of tissue and fluid in the CORTOSS compound bolus. Such inclusions may lead to less than optimal material properties.
- Exercise care to avoid over-fill of vertebral bodies or screw holes with the CORTOSS material. Over-fill may result in flow of excess material outside the treatment area.
- When using CORTOSS for screw hole augmentation, prepare the treatment area by removing all fibrous tissue and debris from the stripped screw hole. If natural healing of the fracture line is desired, prevent CORTOSS from crossing the fracture line. This is because CORTOSS is a nonresorbable material and allowing CORTOSS to cross the fracture line may inhibit the healing process.
- Good principles of surgery and aseptic technique must be followed to minimize the chance of infection. Deep wound infection is a serious post-operative complication and may require removal of the implant.
- CORTOSS must be stored refrigerated (2-8 °C or 35-46 °F) in a dry location. Storing the material outside these parameters may result in a longer set time and may compromise the mechanical characteristics of the product.
- When delivering CORTOSS, avoid rapid pumping of the delivery gun. This causes excessive pressure build up within the cartridge and could cause the cartridge to rupture or the Mix-tip to dislodge.

PREOPERATIVE PRECAUTIONS

Anyone using STRYKER Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from STRYKER Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

STRYKER Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by STRYKER Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable STRYKER Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization. Refer to STRYKER Spine Instruments package insert for the decontamination, cleaning, and sterilization parameters. The Instruments package insert can be requested from a distributor or from STRYKER Spine directly.

POSTOPERATIVE CARE

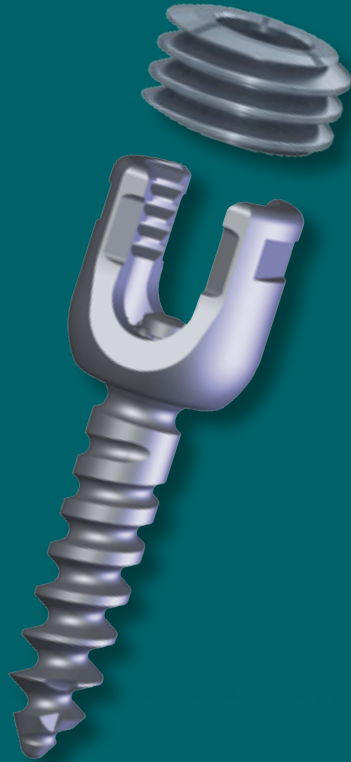
Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

Refer to Stryker CORTOSS Bone Augmentation Material package insert for information regarding the potential adverse effects associated to the use of this material.



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