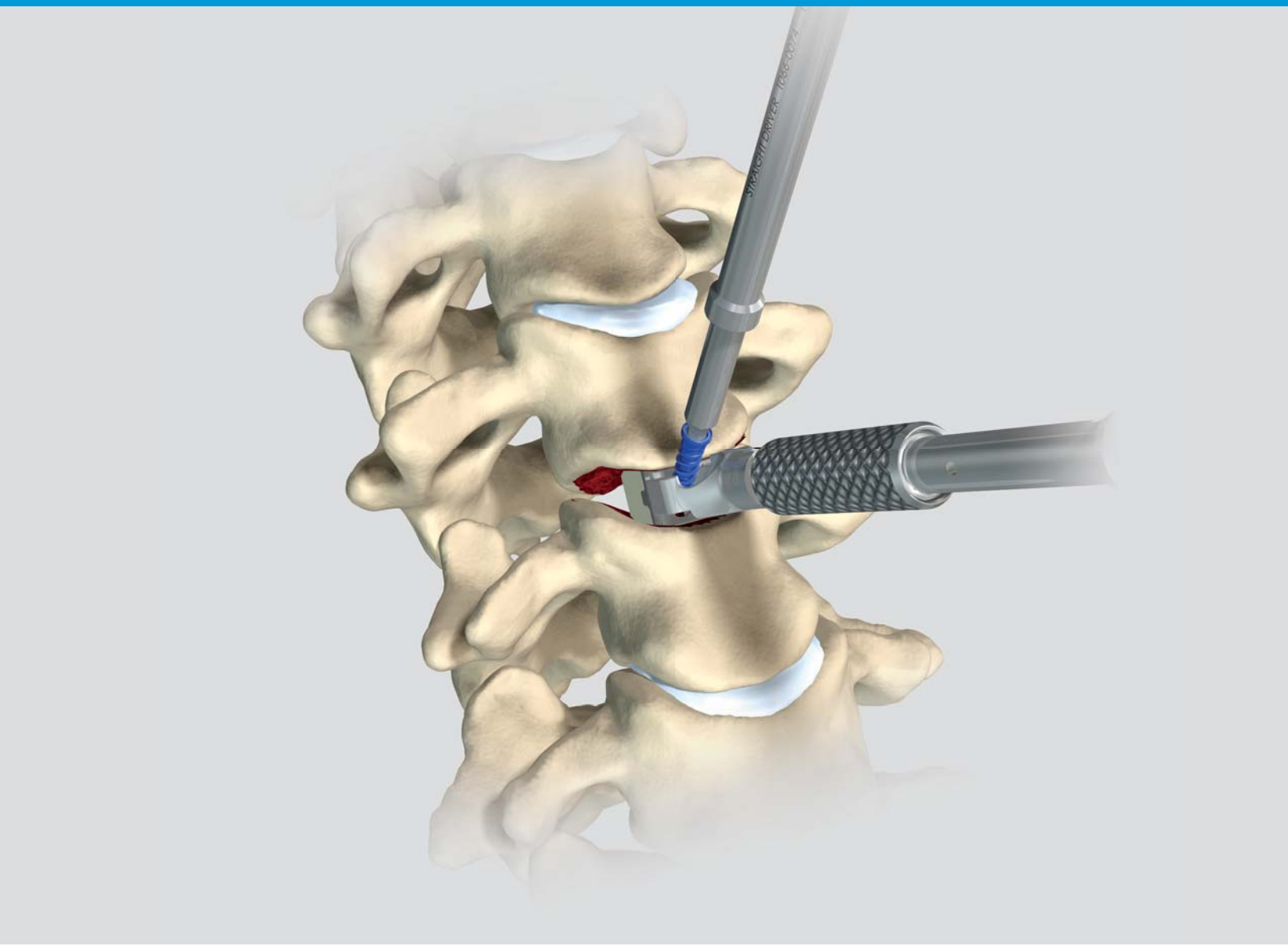
Veyron™-C Anterior Cervical System

Surgical Technique



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Veyron-C Anterior Cervical System
Surgical Technique

Description, Indications & Contraindications

DESCRIPTION

The *Veyron-C* Anterior Cervical System is a stand-alone intervertebral fusion device used to restore biomechanical height and to act as an aid in fusion of the cervical spine in anterior discectomy procedures. The spacer is generally box-shaped with teeth on the superior and inferior surfaces of the device, and is manufactured either from titanium alloy (Ti6Al4V) in accordance with ASTM F136 and Invibio PEEK Optima LT1 in accordance with ASTM F2026, or from Ti6Al4V titanium alloy alone. The spacer may optionally have the teeth plasma coated with medical-grade titanium per ASTM F1580. The spacer is secured in location through the use of Ti6Al4V titanium alloy bone screws. The implants are provided in various sizes and lengths to adjust for variations in patient anatomy.

INDICATIONS

The *Veyron-C* Anterior Cervical System is a stand-alone cervical intervertebral fusion device intended for spinal fusion procedures at one level (C3 – T1 inclusive) in skeletally mature patients for treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Implants are to be implanted via an open, anterior approach and packed with autogenous bone graft. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

CONTRAINDICATIONS

Contraindications for the *Veyron-C* Anterior Cervical System are similar to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems or manufacturers.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- 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 or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.
- Prior fusion at the level(s) to be treated.

Surgical Technique – Guided

Patient Positioning

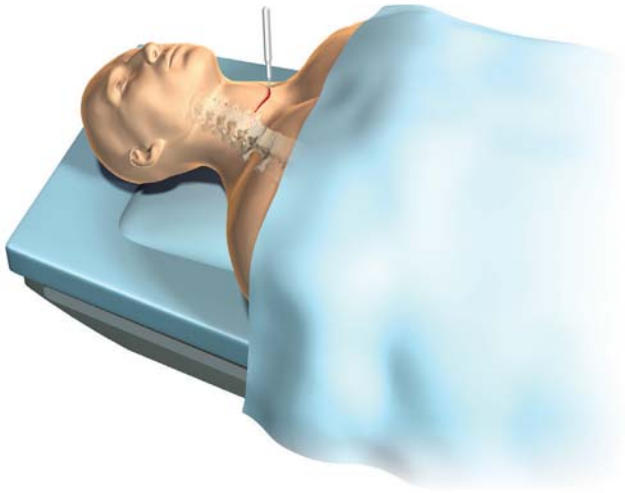


Fig. 1 ▲

Step 1

The patient is positioned on the operating table in the supine position. The patient should be positioned to maintain cervical lordosis.

Exposure and Distraction

Step 2

Create an incision and retract the prevertebral structures. Ensure that you have achieved adequate exposure for the implant, associated instrumentation, and grafting procedure. (Fig. 1)

Using standard methods, distract the disc space. Use caution to avoid over-distraction.

Instruments

Discectomy and Endplate Preparation

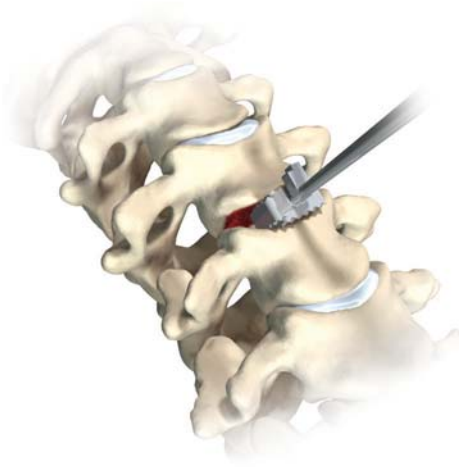


Fig. 2 ▲

Step 3

Perform a discectomy using standard methods and remove the cartilaginous endplate. Use a rasp as necessary to expose the bony endplate, but be careful to avoid exposure of weaker cancellous bone. (Fig. 2)

Implant Sizing

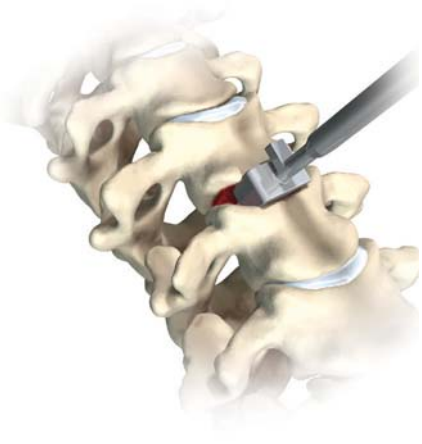


Fig. 3 ▲

Step 4

Trials are provided to determine the appropriate implant size. (Fig. 3)

NOTE: *Removing any interfering anterior osteophytes in the surgical site can enhance the desired positioning of the trial and/or implant.*

Guided Inserter Assembly

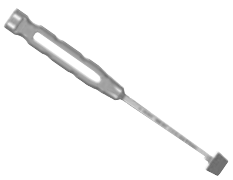
Fig. 4 ▲

Step 5

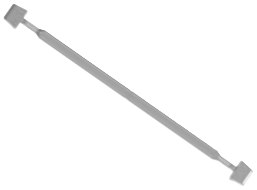
Locate appropriate sized inserter tip.

Slide threaded collar back to expose distal inserter tip and laser marking. (Fig. 4)

Instruments



Rasps (5,7,9,11mm)
16x13 Parallel
07.02218.032–07.02218.035
(T066-069X)



Trials (5–12mm)
16x13 Parallel, 16x13 Lordotic, 18x14 Lordotic
07.02218.036–07.02218.047
(T066-015X, T066-016X, T066-065X)

Modular Inserter Handle
07.02218.057
(T066-0040)

Guided Modular Inserter Tips
(5–12mm)
07.02218.048–07.02218.055
(T066-0050–T066-0057)

Fig. 5 ▲

Rotate the proximal knob to align inner shaft laser mark with outer shaft before you load the tip. (Fig. 5)

Fig. 6 ▲

Once laser marks are aligned, place the appropriate inserter tip. (Fig. 6)

Fig. 7 ▲

Slide threaded collar forward, rotate clockwise to tighten. (Fig. 7)

CAUTION: *Failure to adequately tighten the threaded collar may result in loosening or release of the Inserter tip and/or Implant, resulting in injury.*

Instruments

Implant Loading

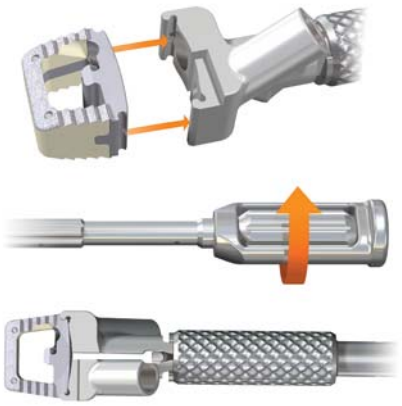


Fig. 8 ▲

Step 6

Load the implant into the modular tip of the inserter by aligning the grooves on the sides of the implant faceplate with the grooves on the modular tip. Turn the proximal knob clockwise to close the inserter and lock onto implant. Visually inspect the inserter-implant interface to ensure that there is no gapping or debris between the inserter jaws and the implant. Manually confirm that there is no motion between the inserter and the implant. (Fig. 8)

CAUTION: *Failure to adequately tighten the proximal knob and confirm the interface may result in loosening or release of the implant, resulting in injury.*

Insertion

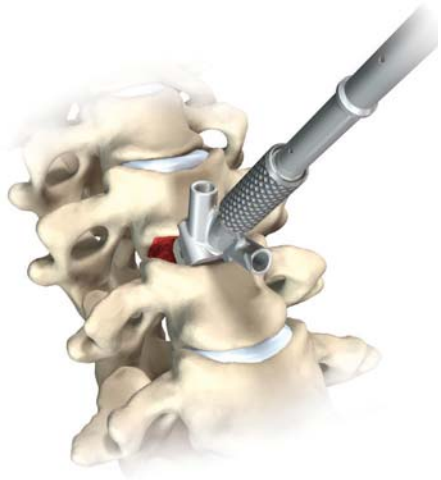


Fig. 9 ▲

Step 7

Pack the implant with bone graft material. Insert the implant into the intervertebral space. A mallet is provided for light tapping if needed. The implant should be placed 1-2mm posterior to the anterior longitudinal ligament. (Fig. 9)

CAUTION: *The implant should be impacted in place with great care and two-handed control. Over impaction of the implant or positioning the implant too far posteriorly can result in neurological injury. Particular caution must be observed when adjusting the implant or manipulating the associated instrumentation to avoid any posterior displacement of the implant.*

Screw Hole Preparation - Awl

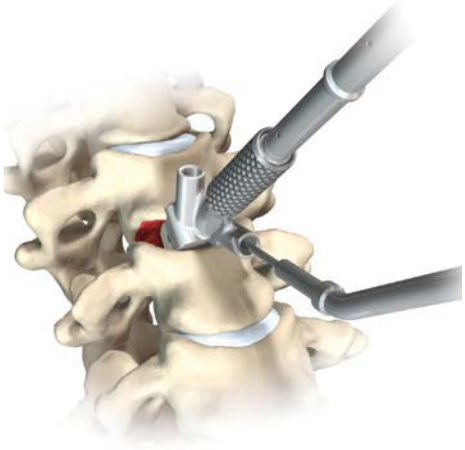


Fig. 10 ▲

Step 8

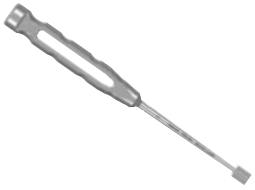
Use the awl to prepare the hole. A straight and fixed angle awl are offered. Push down on the awl handle to push out the awl tip. Use the inserter to guide the awl into the appropriate position. (Fig. 10)

NOTE: *Align the flat on the distal tip of the awl with the locking arm on the implant.*

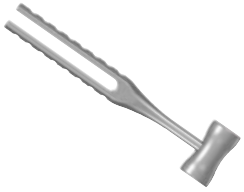
CAUTION: *While placing the bone awl through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.*

Instruments

Graft Packing Block
07.02218.030
(T066-0230)



Graft Packer
07.02218.029
(T066-0225)



Mallet
07.02218.025
(T066-0195)

Guided Awls
07.02218.026 Straight
(T066-0200)
07.02218.027 Fixed Angle
(T066-0205)

Fixed Angle Driver

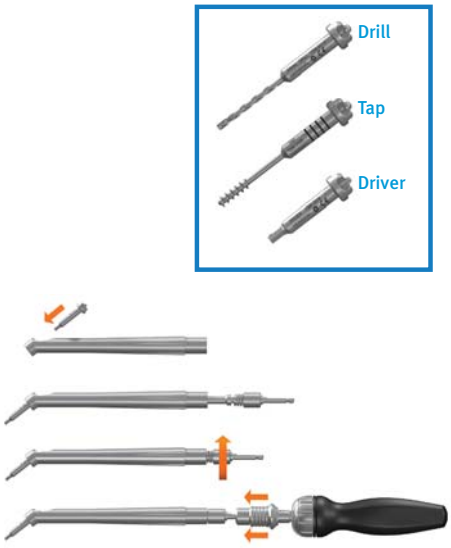


Fig. 11 ▲

Fig. 12 ▲

Screw Hole Preparation - Drill

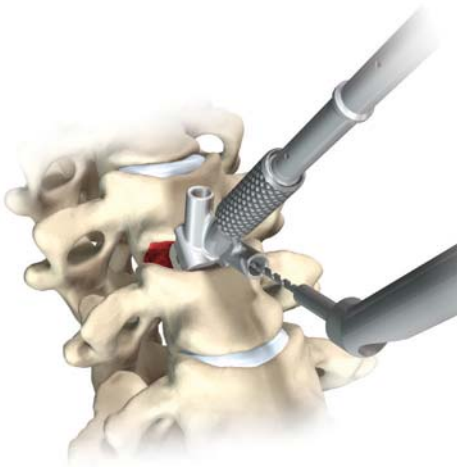


Fig. 13 ▲

Step 9

Attach the appropriate length screw to the self-retaining Screwdriver. A straight and fixed-angle driver are offered. Use the Inserter to guide the Screwdriver into the appropriate position. Repeat steps for second screw. (Fig. 11)

OPTIONAL GUIDE HANDLE

A guide handle is included in the case for use if desired. With the quick connect handle removed, slide the rings of the guide handle down over the fixed-angle driver assembly. Rotate guide handle to the desired direction and tighten the knob. (Fig. 12)

Step 10

The hole may be prepared using a drill if desired. Straight and fixed-angle drills are provided. Drill tips ranging from 12-18mm are available. Use the inserter to guide the drill into the appropriate position. (Fig. 13)

CAUTION: *While placing the drill through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.*

Instruments

Non-Ratcheting Handle
07.02218.031
(X067-0560)

Guide Handle
07.02218.021
(T066-0098)

Screwdriver, Straight
07.02218.011
(T066-0074)

Screwdriver, Fixed Angle
07.02218.009 Sleeve
(T066-0063)
07.02218.010 Shaft
(T066-0068)
07.02218.012 Tip
(T066-0078)

Drills (12,14,16,18mm)
07.02218.017–020 Straight
(T066-0090–0093)
07.02218.013–016 Fixed Angle Tip
(T066-0085–0088)

Screw Hole Preparation - Tap

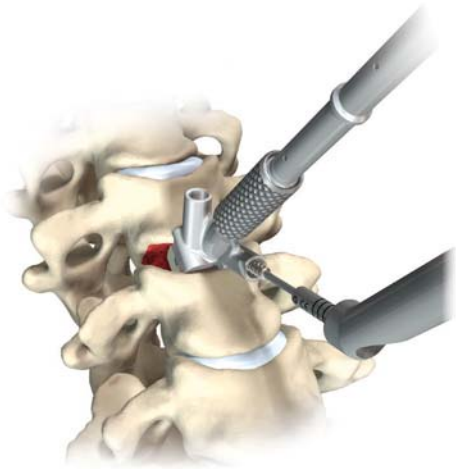


Fig. 14 ▲

Step 11

Remove Drill Tip and replace with Tap Tip.

The hole may be prepared using a tap if desired. A straight and fixed-angle tap are provided. Use the inserter to guide the tap into the appropriate position. (Fig. 14)

NOTE: *Tap until the desired depth is reached using the laser markings on the tap.*

CAUTION: *While placing the tap through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.*

Screw Insertion

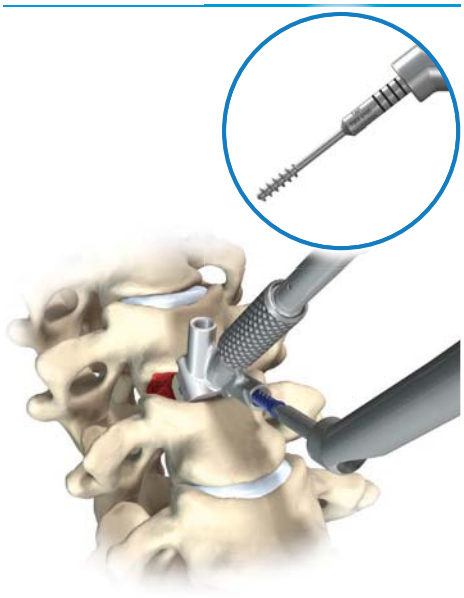


Fig. 15 ▲

Step 12

Remove Tap Tip and replace with Driver Tip.

Attach the appropriate length screw to the self-retaining screwdriver. A straight and fixed-angle driver are offered. Use the inserter to guide the screwdriver into the appropriate position. Repeat steps for second screw. (Fig. 15)

CAUTION: *While placing the screws through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.*

Inserter Removal

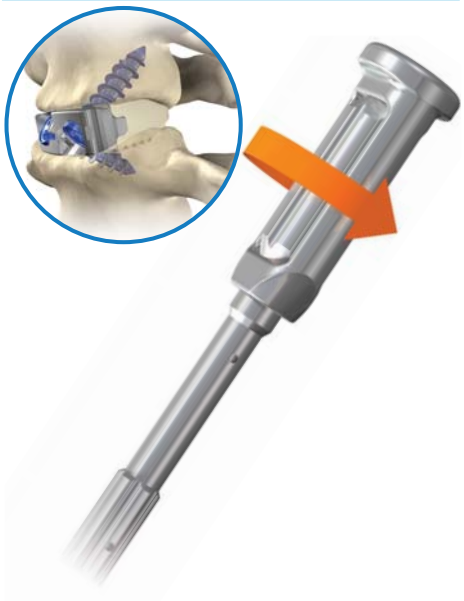


Fig. 16 ▲

Step 13

Once the screws are fully seated, to remove the implant inserter, turn the knob on the proximal end of the inserter counter-clockwise to release it from the implant. Visually confirm that the locking tabs are in front of the screws, and the screws are fully engaged in the implant. (Fig. 16)

CAUTION: *Failure to confirm that the locking tabs are in front of the screws may result in early or late screw loosening.*

Instruments

Tap
07.02218.023 Straight
(T066-0110)
07.02218.022 Fixed Angle Tip
(T066-0105)

Surgical Technique – Freehand

Patient Positioning

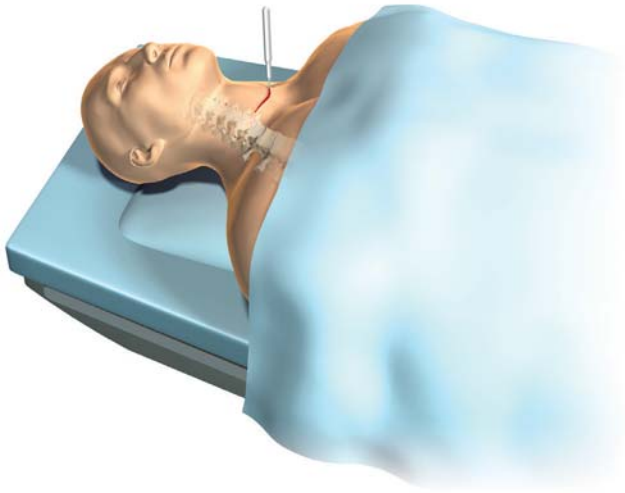


Fig. 17 ▲

Step 1

The patient is positioned on the operating table in the supine position. The patient should be positioned to maintain cervical lordosis.

Exposure and Distraction

Step 2

Create an incision and retract the prevertebral structures. Ensure that you have achieved adequate exposure for the implant, associated instrumentation, and grafting procedure. (Fig. 17)

Using standard methods, distract the disc space. Use caution to avoid over-distraction.

Discectomy and Endplate Preparation

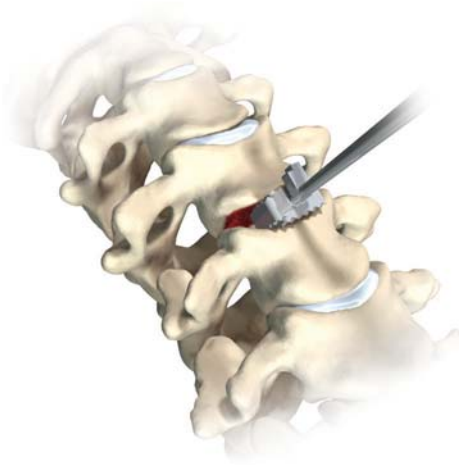


Fig. 18 ▲

Step 3

Perform a discectomy using standard methods and remove the cartilaginous endplate. Use a rasp as necessary to expose the bony endplate, but be careful to avoid exposure of weaker cancellous bone. (Fig. 18)

Implant Sizing

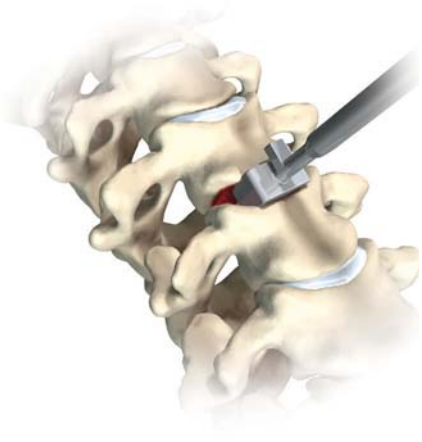


Fig. 19 ▲

Step 4

Trials are provided to determine the appropriate implant size. (Fig. 19)

NOTE: *Removing any interfering anterior osteophytes in the surgical site can enhance the desired positioning of the trial and/or implant.*

Freehand Inserter Assembly

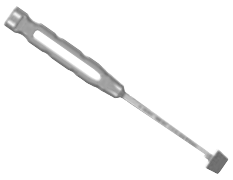
Fig. 20 ▲

Step 5

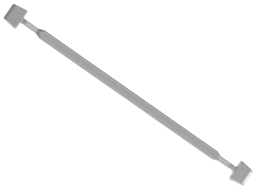
Locate the freehand inserter tip.

Slide threaded collar back to expose distal inserter tip and laser marking. (Fig. 20)

Instruments



Rasps (5,7,9,11mm)
16x13 Parallel
07.02218.032–07.02218.035
(T066-069X)



Trials (5–12mm)
16x13 Parallel, 16x13 Lordotic, 18x14 Lordotic
07.02218.036–07.02218.047
(T066-015X, T066-016X, T066-065X)

Modular Inserter Handle
07.02218.057
(T066-0040)

Freehand Modular Inserter Tip
07.02218.056
(T066-0060)

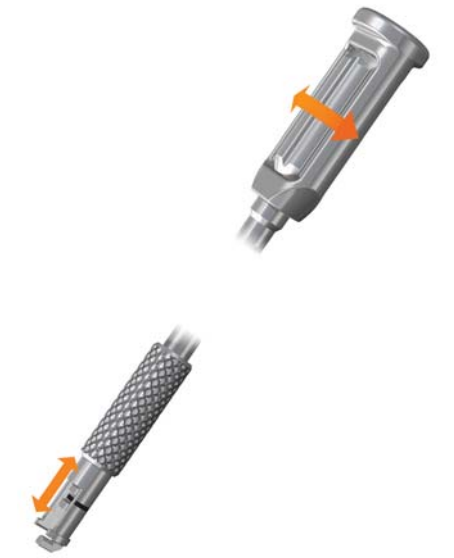


Fig. 21 ▲

Rotate the proximal knob to align inner shaft laser mark with outer shaft before you load the tip. (Fig. 21)

Fig. 22 ▲

Once laser marks are aligned, place the freehand inserter tip.(Fig. 22)

Fig. 23 ▲

Slide threaded collar forward, rotate clockwise to tighten.(Fig. 23)

CAUTION: *Failure to adequately tighten the threaded collar may result in loosening or release of the Inserter tip and/or Implant, resulting in injury.*

Instruments

Implant Loading

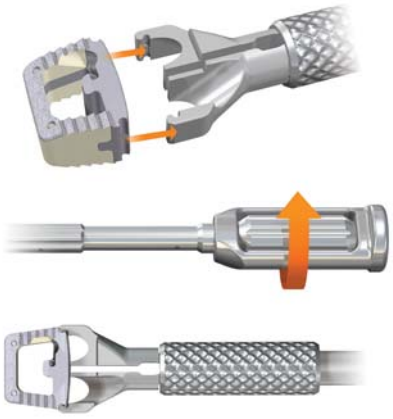


Fig. 24 ▲

Step 6

Load the implant into the modular tip of the inserter by aligning the grooves on the sides of the implant faceplate with the grooves on the modular tip. Turn the proximal knob clockwise to close the inserter and lock onto implant. Visually inspect the inserter-implant interface to ensure that there is no gapping or debris between the inserter jaws and the implant. Manually confirm that there is no motion between the inserter and the implant. (Fig. 24)

CAUTION: *Failure to adequately tighten the proximal knob and confirm the interface may result in loosening or release of the implant, resulting in injury.*

Insertion

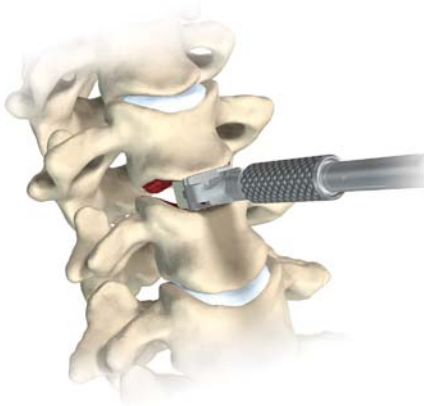


Fig. 25 ▲

Step 7

Pack the implant with bone graft material. Insert the implant into the intervertebral space. A mallet is provided for light tapping if needed. The implant should be placed 1-2mm posterior to the anterior longitudinal ligament. (Fig. 25)

CAUTION: *The implant should be impacted in place with great care and two-handed control. Over impaction of the implant or positioning the implant too far posteriorly can result in neurological injury. Particular caution must be observed when adjusting the implant or manipulating the associated instrumentation to avoid any posterior displacement of the implant.*

Screw Hole Preparation - Awl

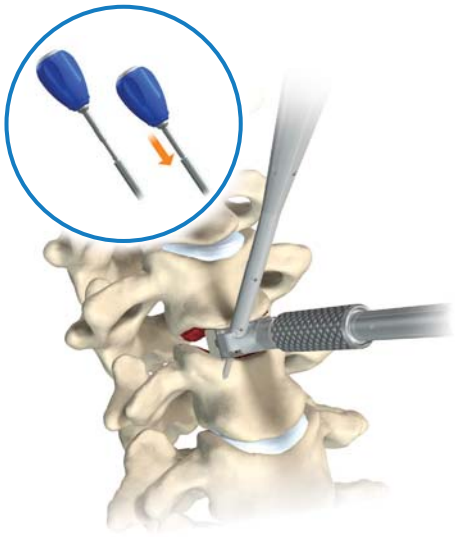


Fig. 26 ▲

Step 8

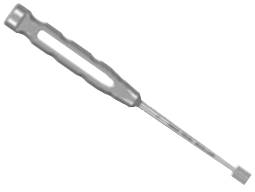
Use the freehand awl to prepare the hole. Push down on the awl handle to push out the awl tip. (Fig. 26)

NOTE: *Align the flat on the distal tip of the awl with the locking arm on the implant.*

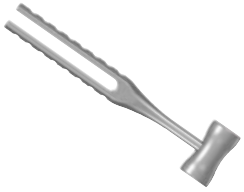
CAUTION: *While placing the bone awl through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.*

Instruments

Graft Packing Block
07.02218.030
(T066-0230)



Graft Packer
07.02218.029
(T066-0225)



Mallet
07.02218.025
(T066-0195)

Freehand Awl
07.02218.008
(T066-0061)

Screw Insertion

Fig. 27 ▲

Step 9

Attach the appropriate length screw to the self-retaining screwdriver. A straight and fixed-angle driver are offered. Use the screwdriver to place the screw into the appropriate position. Repeat steps for second screw. (Fig. 27)

CAUTION: *While placing the screws through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.*

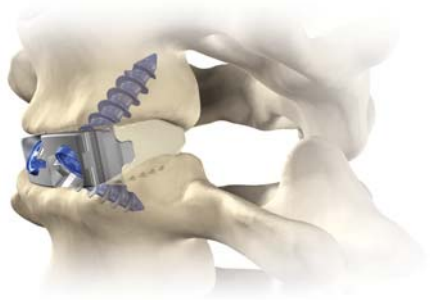


Fig. 28 ▲

CAUTION: *Angulating the screws greater than 3 degrees in any one direction may prevent the screw from engaging the locking mechanism properly. Failure to confirm that the locking tabs are in front of the screws may result in early or late screw loosening.* (Fig. 28)

Inserter Removal

Fig. 29 ▲

Step 10

Once the screws are fully seated, to remove the implant inserter, turn the knob on the proximal end of the inserter counter-clockwise to release it from the implant. (Fig. 29)

Instruments

Non-Ratcheting Handle
07.02218.031
(X067-0560)

Screwdriver, Straight
07.02218.011
(T066-0074)

Revision/Removal Technique

Fig. 30 ▲

Outer sleeve cut out on distal tip aligned with the retaining mechanism

Outer sleeve rotated 180°, moving the retaining mechanism over and allowing the screw to pass

Fig. 31 ▲

Should it become necessary to remove or revise the *Veyron*-C implants, the following steps should be followed:

ATTACH INSERTER WITH FREEHAND TIP
Before the screw(s) are removed, attach the freehand inserter to the implant using the standard technique. Ensure that the inserter is fully engaged to the implant. It may be necessary to remove osteophyte or scar tissue to fully access the inserter engagement slots on the implant.

CAUTION: *While attaching the inserter to an implanted implant, ensure that such attachment does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.*

SCREW REMOVAL
The screw may then be removed from its position using the screw removal tool. The removal tool has an outer sleeve with an eccentric distal tip that, when properly aligned with the retaining tab using the laser marking, can be rotated 180° to push the retaining tab over and out of the screw path. (Fig. 30, 31) This will allow the surgeon to back the screw out past the retaining mechanism by rotating the inner hex shaft counter clockwise.

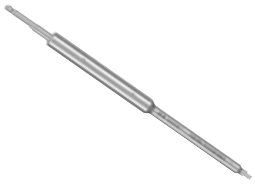
NOTE: *If resistance is felt while trying to rotate the outer sleeve or during the initial counter-clockwise turning of the inner sleeve, the screw may need to be advanced prior to removal. Advance the screw by rotating the inner hex shaft ¼ - ½ turns clockwise to ensure that the screw head is seated beyond the lip of the retaining mechanism prior to screw removal.*

IMPLANT REMOVAL
The forked end of the mallet may be used as a slap hammer to be used on the inserter body to back the implant out of the intervertebral space.

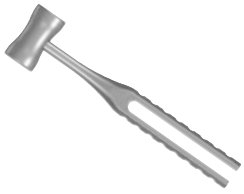
Instruments

Modular Inserter Handle
07.02218.057
(T066-0040)

Freehand Modular Inserter Tip
07.02218.056
(T066-0060)



Screw Removal Tool
07.02218.028
(T066-0213)



Mallet
07.02218.025
(T066-0195)

Instrument Visual Guide

Parallel Rasps, 13x16 (5–11mm)
07.02218.032 – 07.02218.035
(T066-0690 – T066-0696)

Parallel Trials, 13x16 (5–12mm)
07.02218.040 – 07.02218.043
(T066-0160 – T066-0166)

Lordotic Trials, 13x16 (5–12mm)
07.02218.036 – 07.02218.039
(T066-0150 – T066-0156)

Lordotic Trials, 18x14 (5–12mm)
07.02218.044 – 07.02218.047
(T066-0650 – T066-0656)

Modular Inserter Handle
07.02218.057
(T066-0040)

Guided Modular Inserter Tips (5–12mm)
07.02218.048 – 07.02218.055
(T066-0050 – T066-0057)

Freehand Inserter Tip
07.02218.056
(T066-0060)

Graft Packing Block
07.02218.030
(T066-0230)

Graft Packer
07.02218.029
(T066-0225)

Mallet
07.02218.025
(T066-0195)

Tamp
07.02218.024
(T066-0190)

Guide Handle
07.02218.021
(T066-0098)

Non-Ratcheting Handle
07.02218.031 (X067-0560)

Guided Straight Awl
07.02218.026
(T066-0200)

Guided Angled Awl
07.02218.027
(T066-0205)

Freehand Awl
07.02218.008
(T066-0061)

Fixed Angle Drill Tips (12,14,16,18mm)
07.02218.013 – 07.02218.016
(T066-0085 – T066-0088)

Straight Drills (12,14,16,18mm)
07.02218.017 – 07.02218.020
(T066-0090 – T066-0093)

Fixed Angle Tap Tip
07.02218.022
(T066-0105)

Straight Tap
07.02218.023
(T066-0110)

Fixed Angle Driver Tip
07.02218.012
(T066-0078)

Straight Driver
07.02218.011
(T066-0074)

Fixed Angle Driver Shaft
07.02218.010
(T066-0068)

Fixed Angle Driver Sleeve
07.02218.009
(T066-0063)

Screw Removal Instrument
07.02218.028
(T066-0213)

Tray Layouts

Veyron-C Implant Kit

07.02217.401

Catalog Number	Description	Kit Quantity
07.02217.001	Integrated Assy, 16 x 13 x 7 5mm PC	2
07.02217.002	Integrated Assy, 16 x 13 x 0 5mm PC	2
07.02217.003	Integrated Assy, 16 X 13 X 7°, 6mm, PC	2
07.02217.004	Integrated Assy, 16 X 13 X 0°, 6mm PC	2
07.02217.005	Integrated Assy, 16 X 13 X 7°, 7mm PC	3
07.02217.006	Integrated Assy 16 X 13 X 0°, 7mm, PC	3
07.02217.007	Integrated Assy, 16 X 13 X 7°, 8mm, PC	3
07.02217.008	Integrated Assy, 16 X 13 X 0°, 8mm, PC	3
07.02217.009	Integrated Assy, 16 X 13 X 7°, 9mm, PC	3
07.02217.010	Integrated Assy, 16 X 13 X 0°, 9mm, PC	3
07.02217.011	Integrated Assy, 16 X 13 X 7°, 10mm, PC	2
07.02217.012	Integrated Assy, 16 X 13 X 0°, 10mm, PC	2
07.02217.013	Integrated Assy, 16 X 13 X 7°, 11mm, PC	2
07.02217.014	Integrated Assy, 16 X 13 X 0°, 11mm, PC	1
07.02217.015	Integrated Assy, 16 X 13 X 7°, 12mm, PC	1
07.02217.016	Integrated Assy, 16 X 13 X 0°, 12mm, PC	1
07.02217.017	Integrated Assy, 18 X 14 X 7°, 5mm, PC	2
07.02217.018	Integrated Assy, 18 X 14 X 7°, 6mm, PC	2
07.02217.019	Integrated Assy, 18 X 14 X 7°, 7mm, PC	3
07.02217.020	Integrated Assy, 18 X 14 X 7°, 8mm, PC	3
07.02217.021	Integrated Assy, 18 X 14 X 7°, 9mm, PC	3
07.02217.022	Integrated Assy, 18 X 14 X 7°, 10mm, PC	2
07.02217.023	Integrated Assy, 18 X 14 X 7°, 11mm, PC	1
07.02217.024	Integrated Assy, 18 X 14 X 7°, 12mm, PC	1
07.02217.025	3.5 X 12mm, Self-Drilling Screw	8
07.02217.026	3.5 X 12mm, Self-Tapping Screw	6
07.02217.027	3.5 X 14mm, Self-Drilling Screw	8
07.02217.028	3.5 X 14mm, Self-Tapping Screw	6
07.02217.029	3.5 X 16mm, Self-Drilling Screw	8
07.02217.030	3.5 X 16mm, Self-Tapping Screw	6
07.02217.031	3.5 X 18mm, Self-Drilling Screw	4
07.02217.032	3.5 X 18mm, Self-Tapping Screw	4
07.02217.033	3.5 X 20mm, Self-Drilling Screw	4
07.02217.034	3.5 X 20mm, Self-Tapping Screw	4
07.02217.035	3.7 X 13mm, Self-Tapping Rescue Screw	4
07.02217.036	3.7 X 15mm, Self-Tapping Rescue Screw	4
07.02217.037	3.7 X 17mm, Self-Tapping Rescue Screw	4
07.02217.038	3.7 X 19mm, Self-Tapping Rescue Screw	4
07.02217.039	3.7 X 21mm, Self-Tapping Rescue Screw	4
07.02218.002	16 x 13 Lordotic Caddy, PC	1
07.02218.003	18 X 14 Lordotic Caddy, PC	1
07.02218.004	16 X 13 Parallel Caddy, PC	1
07.02218.005	Screw Caddy	1

Veyron-C Instrument Kit

07.02217.402

Catalog Number	Description	Kit Quantity
07.02218.001	Sterilization Case, Implant	1
07.02218.006	Modular Inserter Tip Caddy	1
07.02218.007	Sterilization Case, Instrument	1
07.02218.008	Freehand Awl	1
07.02218.009	Angled Sleeve, Fixed Angle Driver	2
07.02218.010	Shaft, Fixed Angle Driver	2
07.02218.011	Straight Driver	2
07.02218.012	Fixed Angle Driver Tip	2
07.02218.013	12mm Fixed Angle Drill Tip	2
07.02218.014	14mm Fixed Angle Drill Tip	2
07.02218.015	16mm Fixed Angle Drill Tip	2
07.02218.016	18mm Fixed Angle Drill Tip	1
07.02218.017	12mm Drill, Straight	2
07.02218.018	14mm Drill, Straight	2
07.02218.019	16mm Drill, Straight	2
07.02218.020	18mm Drill, Straight	1
07.02218.021	Guide Handle	2
07.02218.022	Fixed Angle Tap Tip	1
07.02218.023	Straight Tap	1
07.02218.024	Tamp	1
07.02218.025	Mallet	1
07.02218.026	Guided Straight Awl	1
07.02218.027	Guided Angled Awl	1
07.02218.028	Screw Removal Instrument	1
07.02218.029	Graft Packer	1
07.02218.030	Graft Packing Block	1
07.02218.031	Non-Ratcheting Handle, Hand Twist, A/O	2
07.02218.032	5mm Parallel Rasp, 16 X 13	1
07.02218.033	7mm Parallel Rasp, 16 X 13	1
07.02218.034	9mm Parallel Rasp, 16 X 13	1
07.02218.035	11mm Parallel Rasp, 16 X 13	1
07.02218.036	5/6mm Lordotic Trial, 16 X 13	1
07.02218.037	7/8mm Lordotic Trial, 16 X 13	1
07.02218.038	9/10mm Lordotic Trial, 16 X 13	1
07.02218.039	11/12mm Lordotic Trial, 16 X 13	1
07.02218.040	5/6mm Parallel Trial, 16 X 13	1
07.02218.041	7/8mm Parallel Trial, 16 X 13	1
07.02218.042	9/10mm Parallel Trial, 16 X 13	1
07.02218.043	11/12mm Parallel Trial, 16 X 13	1
07.02218.044	5/6mm Lordotic Trial, 18 X 14	1

Veyron-C Instrument Kit, continued

Catalog Number	Description	Kit Quantity
07.02218.045	7/8mm Lordotic Trial, 18 X 14	1
07.02218.046	9/10mm Lordotic Trial, 18 X 14	1
07.02218.047	11/12mm Lordotic Trial, 18 X 14	1
07.02218.048	Guided Modular Inserter Tip, 5mm	1
07.02218.049	Guided Modular Inserter Tip, 6mm	1
07.02218.050	Guided Modular Inserter Tip, 7mm	1
07.02218.051	Guided Modular Inserter Tip, 8mm	1
07.02218.052	Guided Modular Inserter Tip, 9mm	1
07.02218.053	Guided Modular Inserter Tip, 10mm	1
07.02218.054	Guided Modular Inserter Tip, 11mm	1
07.02218.055	Guided Modular Inserter Tip, 12mm	1
07.02218.056	Freehand Modular Inserter Tip	1
07.02218.057	Implant Inserter Assy	2
07.02218.058	Instructions For Use	1

Warnings and Precautions

As with any surgical system, the *Veyron-C* Anterior Cervical System should only be used by experienced surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient

Knowledge of surgical techniques, proper selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Mixing Metal; some degree of corrosion occurs on all implanted metal alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, etc. which come in contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing parameters, the components of *Veyron-C* should not be used in conjunction with components from any other manufacturer's spinal system.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic and neurosurgical implants, none of the *Veyron-C* Anterior Cervical System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The *Veyron-C* Anterior Cervical System has not been evaluated for safety and compatibility in the MR environment. The *Veyron-C* Anterior Cervical System has not been tested for heating or migration in the MR environment. The materials used in the manufacture of the *Veyron-C* Anterior Cervical System have an established safety profile with respect to compatibility, heating and migration in the MR environment. However, it must be noted that there are several different manufacturers and generations of MRI systems available, and Zimmer Spine cannot make any claims regarding the safety of Zimmer Spine implants and devices with any specific MR system.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

Disclaimer:

This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.

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