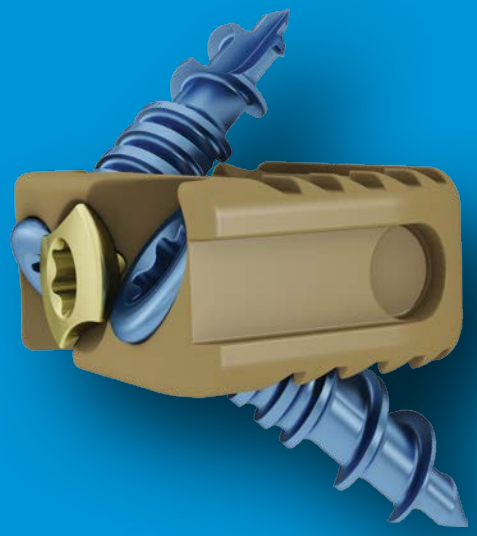
DIVERGENCE™
CARING ABOUT SURROUNDING STRUCTURES



Preoperative planning guide
and surgical technique

Medtronic
Further, Together

MICHELSON TECHNOLOGY AT WORK

DIVERGENCE™ STAND-ALONE INTERBODY CAGE

Preoperative Planning
- Implant Overview
- Instrument Overview
- Interbody Cage Graft Volumes
- Inserter Options
- Guided and Freehand Assembly

Surgical Technique
- Patient Positioning, Exposure and Decompression
- Interbody Cage Trialing
- Inserter Loading
- Awling and Drilling the Bone Screw Holes
- Bone Screw Loading
- Bone Screw Insertion
- Locking Bone Screws
- Device Removal

Product Information and Labeling
- Product Ordering Information
- Important Product Information

Medtronic

Implant Overview

Interbody Cage Options

15mm × 12mm | 17mm × 14mm | 20mm × 14mm

6° Lordotic

Interbody Cage Footprint Options

5mm Height | 8mm Height

Bone Screw Options

- Cortical cancellous thread design
- 3.5mm/4.0mm diameters
- 11mm, 13mm, 15mm lengths
- Self-drillng

Self-Drilling Bone Screw

Instrument Overview

Trials

SA Lordotic Interbody Trial

Drill Guide and Inserters

Guided Inserter

Freehand Inserter

Universal Handle

Universal Handle, G850000

Awl

Spring-Loaded Awl for pilot holes up to 9.6mm deep
11mm Awl, 6630908

Drills

Spring-Loaded Straight Drill Option
Drill Sterile 11mm, 6630911

Angled Drill Option to Accommodate Varying Anatomic Angles
Angled Drill, 6630902

Screwdrivers

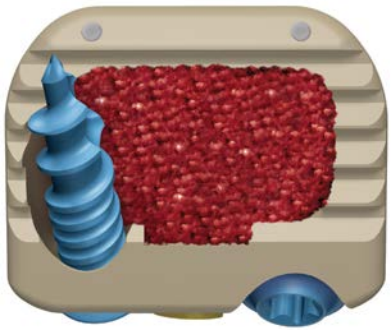
Straight Driver, 6630904

Angled Driver, 6630905

Interbody Cage Graft Volumes

Divergence™ Stand-Alone Interbody Cage Graft Volume Summary

	15mm wide x 12mm deep volume	17mm wide x 14mm deep volume	20mm wide x 14mm deep volume
Size	**Graft volume (cc)**	**Graft volume (cc)**	**Graft volume (cc)**
5mm	0,31	0,5	0,5
6mm	0,37	0,59	0,59
7mm	0,43	0,68	0,69
8mm	0,48	0,78	0,78



Guided and Freehand Inserter Options

The Guided Inserter **(OPTION 1**) and Freehand Inserter (**OPTION 2**) are provided in the set to accommodate surgeon needs or preferences for the bone screw insertion angles for varying patient anatomy.

OPTION 1: Guided Inserter with Guide

Cranial Caudal Angulation = 40°

Lateral Divergence = 8°

The Guided Inserter is designed for loading and inserting the Interbody Cage and it also serves as an Awl, Drill, and Screw Guide that sets the Bone Screw trajectories at 40° cranial/ caudal divergent angles and 8° laterally divergent angles.

OPTION 2: Freehand Inserter without Guide

Cranial Caudal Angulation = 27° - 47°

Lateral Divergence = 1.0° - 10.0°

The Freehand Inserter is designed for loading and inserting the Interbody Cage and does not have an integrated Awl, Drill and Screw Guide. This design allows the surgeon to place screws at variable angles as needed. The Freehand inserter is designed to allow 27° - 47° cranial/ caudal divergent angles and 1.0° - 10.0° laterally divergent angles.

Inserter Assembly

Tips on Inserter Assembly

When assembling any of the DIVERGENCE™ Inserters, if the Inserter component will not pass through the Inserter Sleeve, rotate the Inserter until it passes through the Inserter Sleeve.

Place the Inserter Knob into the Guide Shaft with the slots between the tabs on the tip of the Inserter Knob facing towards the opening in the Guide Shaft as shown in the picture.

Inserter Assembly *continued*

Guided Inserter Assembly

Assemble the Inserter Knob, SA Guide Sleeve, and SA Guide by sliding the SA Guide into the SA Guide Sleeve until the threaded end makes contact with the Inserter Knob. Provisionally tighten the Inserter assembly by rotating the Inserter Knob clockwise until it engages the threads on the Guide Sleeve. See **Figure A** for Guided Inserter Assembly.

Figure A) Guided Inserter Components and Assembly

SA Inserter Knob

SA Guide Sleeve

SA Guide

1. Insert the Inserter Knob, then insert the Guide Sleeve into the Guide

2. Turn the Inserter Knob clockwise thread onto the Guide Sleeve.

3. Guide Sleeve, Inserter Knob & Guide in assembled condition

Freehand Inserter Assembly

Assemble the Inserter Knob, Freehand Inserter Sleeve, and SA Freehand Inserter by inserting the Inserter Knob sliding the SA Freehand Inserter into the Freehand Inserter Sleeve until the threaded end makes contact with the inserter knob. Provisionally tighten the Inserter assembly by rotating the Inserter Knob clockwise until it engages the threads on the Freehand Inserter. See Figure B for Freehand Inserter Assembly.

Figure B Freehand Inserter Components and Assembly

SA Inserter Knob

SA Freehand Inserter Sleeve

SA Freehand Inserter

1. Insert the Inserter Knob, then insert the Freehand Inserter into the Freehand Inserter Sleeve.

2. Turn the Inserter Knob clockwise.to thread onto the Freehand Inserter Sleeve

3. Freehand Inserter, Inserter Knob & Freehand Inserter Sleeve in assembled condition

DIVERGENCE™ STAND-ALONE INTERBODY CAGE

Surgical Technique

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Patient Positioning and Exposure

The patient is placed in the supine position with the neck supported posteriorly to achieve normal segmental lordosis (Figure A).

A standard transverse incision is used to acess the cervical spine, and the longus colli muscles are elevated with medial/lateral retractor blades. Cranial/caudal retractors may be also used (Figure B). Distract the disc space as needed to complete the decompression.

Figure A

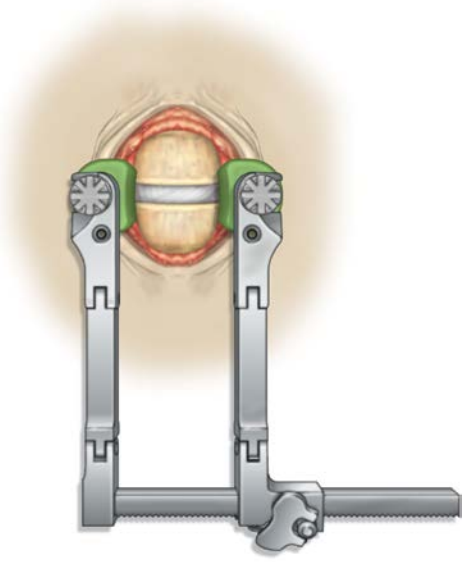


Figure B

Interbody Cage Trialing

Each Divergence™ Stand-Alone Interbody Cage has a corresponding Trial that is used to approximate the height, width, depth, and lordosis of the disc space.

The size of the interbody device to be implanted is determined by selecting the Trial height, witdth and depth that provides the most satisfactory fit in the prepared disc space **(Figure A)**.

Note

The Trials are designed to account for the height. Smooth out the edges of the Vertebral Body for correct fit and depth measurments

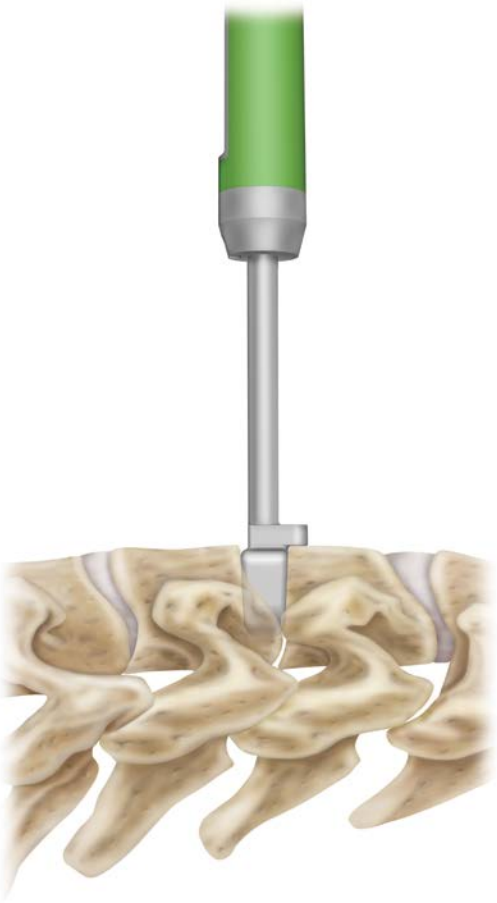


Figure A

Inserter Loading

Place the appropriately sized Interbody Cage selected in the trialing step in the the designated size slot in the Loading Block and load it onto the Inserter **(Figure A)**.

Figure A

To load the implant from the Loading Block onto the Guided or Freehand Inserter, slide the prongs on the Inserter along the lateral, outer edges of the Interbody Cage **(Figures B and C)**. Rotate the Inserter Knob clockwise and engage the second set of threads on the Inner Sleeve until a positive stop is felt. Remove the implant and Inserter from the Loading Block and ensure the Interbody Cage is firmly secured to the inserter **(Figures D and E)**.

Place the Interbody Cage in the graft loading block and pack it with autograft **(Figures F and G)**. Insert in Disc Space.

Guided Inserter Option

Figure B

Figure D

Figure F

Freehand Inserter Option

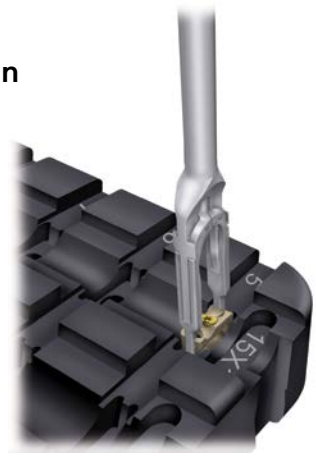


Figure C

Figure E

Figure G

Awling and Drilling Screw Holes

The SA Guided or Freehand Inserters can be left in place when preparing the screw holes. The Inserters can accommodate the Awls, Drills and Drivers. The 11mm Spring-Loaded Awl is designed to create a pilot hole up to 9.6mm deep. Straight and Angled Awls and Drills are available to accommodate varying patient anatomy and insertion angles. (**Figure A,B**)

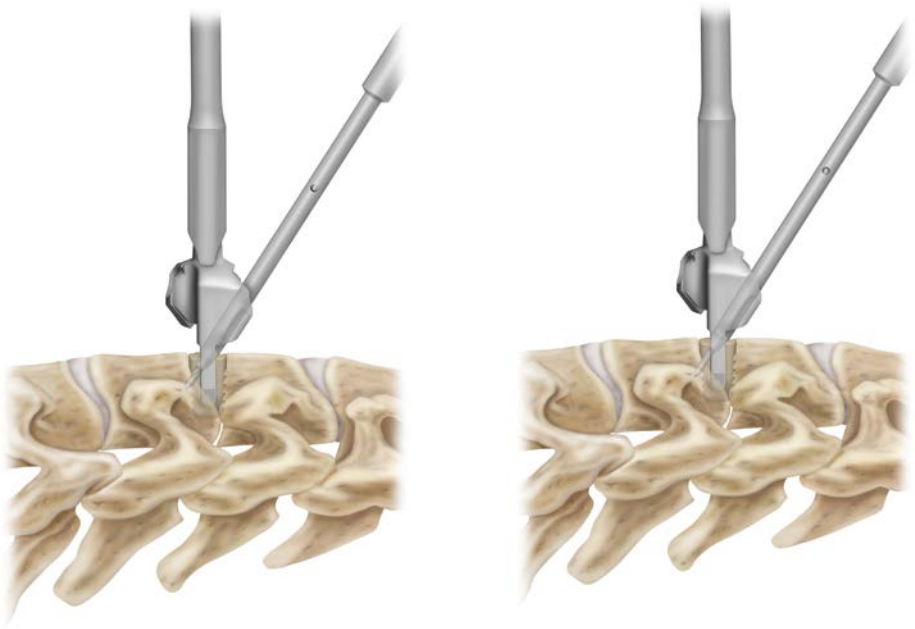


Figure A) Guided Inserter

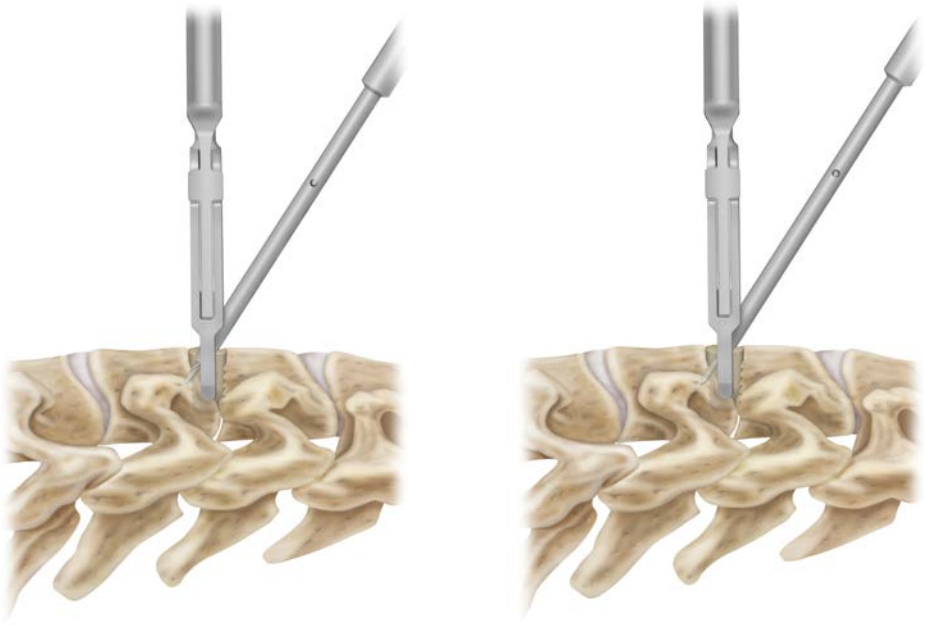


Figure B) Freehand Inserter

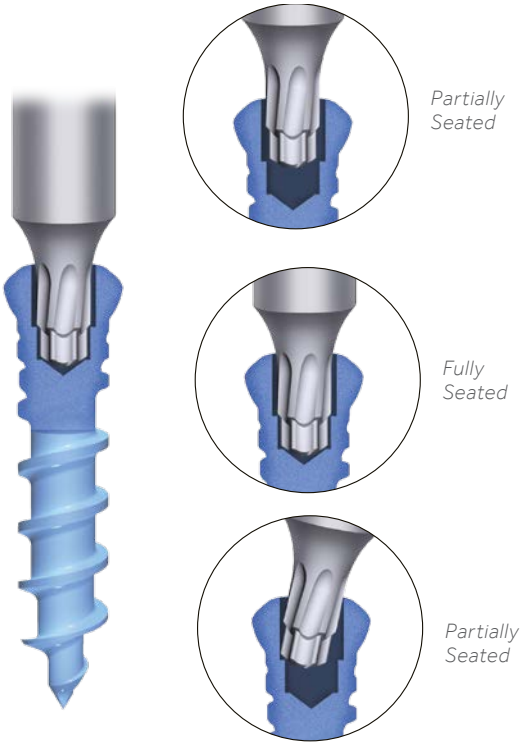
Bone Screw Loading

The Loading Block contains a single 3.5mm diameter hole that can be used to ensure the screw diameter is no larger than 3.5mm. If using a 3.5mm diameter Bone Screw, place it inside the 3.5mm hole in the Loading Block to ensure the screw fully seats. If the screw will not fully seat, double check the screw diameter.

There are eight 4.0mm screw holes in the Loading Block which can accommodate all of the screw lengths and screw diameters. Place the selected diameter and length screws in the 4.0mm holes in the Loading Block. Use the Driver to stab and grab the Screw from the Loading Block **(Figure A)**.

Note

Make sure the T8 and T10 tips of the Driver are fully seated inside the Bone Screw head before tightening. Failure to fully seat both the T8 tip and the T10 tip before rotating the Driver to advance the screw may result in stripping.



Bone Screw Insertion

Insert the first Bone Screw into the prepared hole (**Figures A and C**). Applying light to moderate pressure, provisionally tighten the Bone Screws by rotating the Driver clockwise (**Figures B and D**). When using the Guided Inserter, stop rotating the Driver when the beginning of the laser mark on the Driver shaft meets with the edge of the Guide. Repeat this step with the second Bone Screw.

Separate the Inserter from the implant by turning the Inserter Knob counterclockwise.
A final tightening of the screws may be performed. Only a quarter to a half turn is recommended.

Guided Screw Insertion

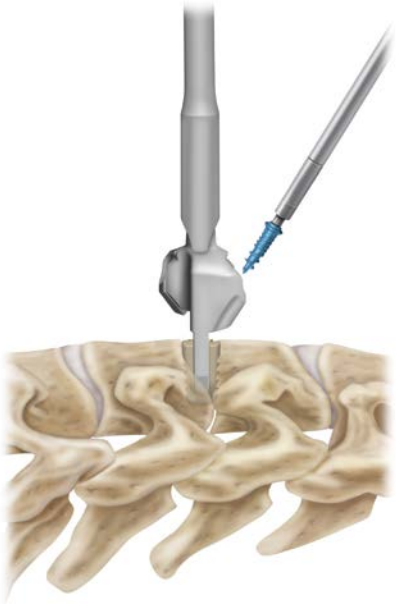


Figure A

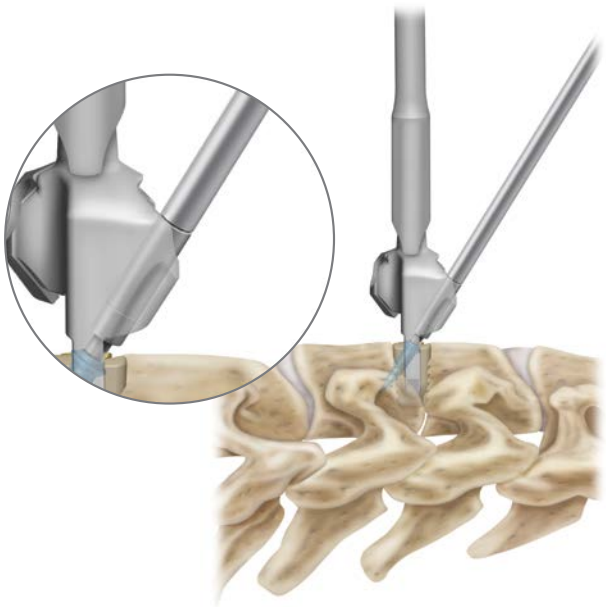


Figure B

Freehand Screw Insertion

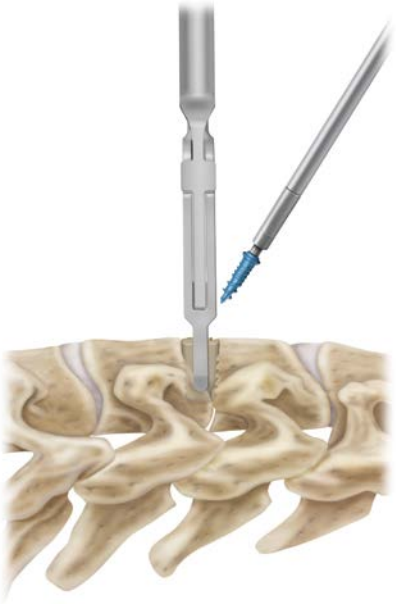


Figure C

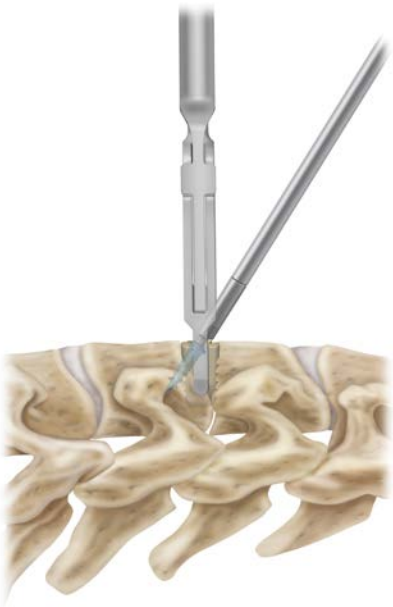


Figure D

Locking the Bone Screws

The Interbody Cage contains a built-in locking mechanism. The same Driver used for screw insertion is used to engage the locking cap. Insert the Driver into the head of the locking cap and rotate it clockwise **(Figure A)** until the cap covers all of the screw heads and a light positive stop is felt. You will have visual and tactile confirmation that the cap is fully engaged and covering all of the screw heads **(Figure B)**. Only finger-tip tightening of the locking cap is necessary and over-tightening of the lock may damage the implant. If the locking cap does not rotate with finger-tip pressure, check to make sure that the screws are fully seated.

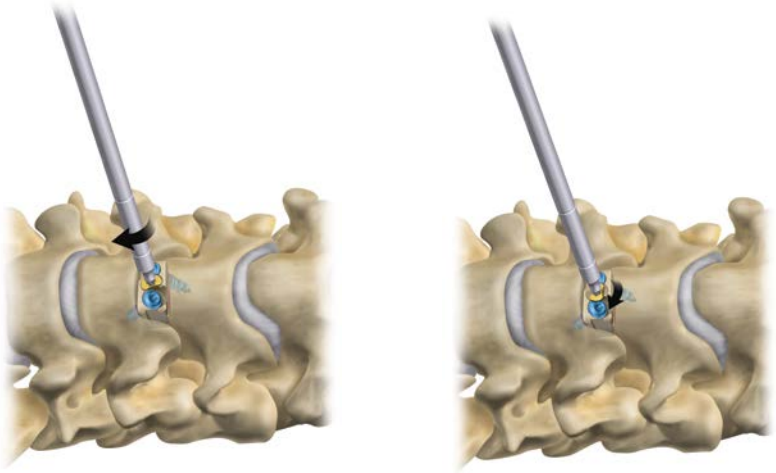


Figure A

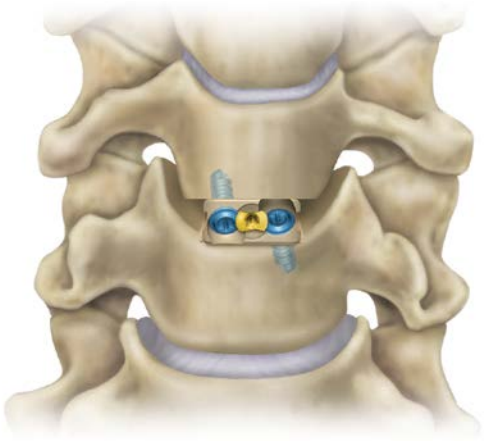


Figure B

Final AP and Lateral Fluoros

Final A/P and lateral fluoroscopy can be used to verify final position of the implant.

Device Removal

Using the Screw Driver, rotate the locking cap counterclockwise to uncover the screw heads. Using the same Driver, loosen and extract the screws and remove the implant **(Figure A)**.

A 2.0mm screw removal tool can also be used to explant the screws if necessary. The tip of the Screw Removal Tool is inserted into the head of the screw and rotated counterclockwise (**Figure B**).

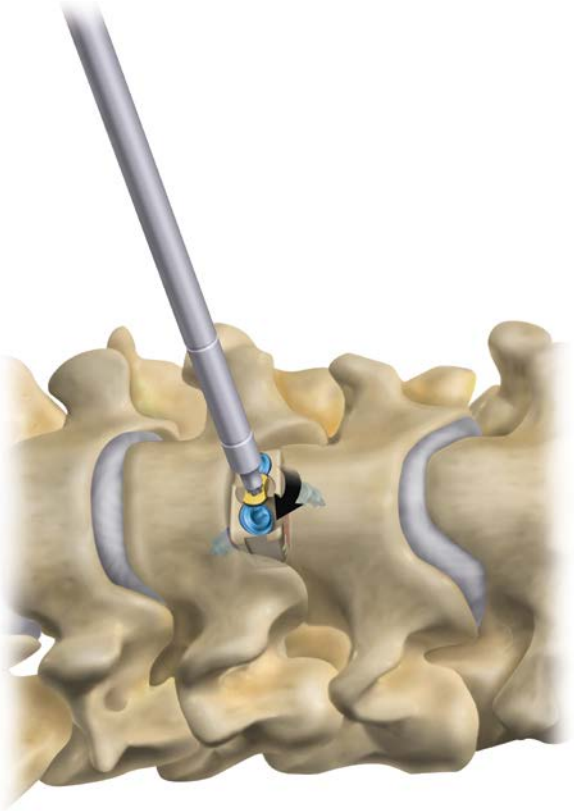


Figure A

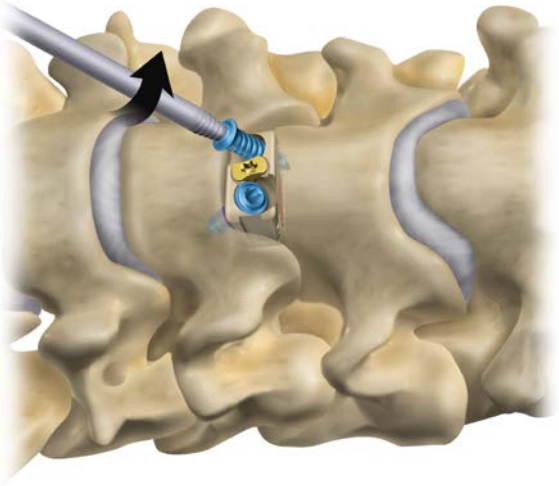


Figure B

Product Ordering Information

DIVERGENCE™ SPS01720 Implants (mandatory)

	ITEM	Description	Qty
Implants	G6623511	SCREW G6623511 DIVERG NP 35 SDS 11MM	2
	G6623513	SCREW G6623513 DIVERG NP 35 SDS 13MM	2
	G6623515	SCREW G6623515 DIVERG NP 35 SDS 15MM	2
	G6624011	SCREW G6624011 DIVERG NP 40 SDS 11MM	1
	G6624013	SCREW G6624013 DIVERG NP 40 SDS 13MM	1
	G6624015	SCREW G6624015 DIVERG NP 40 SDS 15MM	1
	G6626525	NO-P LORDOTIC PEEK IB,15mmx12mmx5mm	2
	G6626526	NO-P LORDOTIC PEEK IB,15mmx12mmx6mm	2
	G6626527	NO-P LORDOTIC PEEK IB,15mmx12mmx7mm	1
	G6626528	NO-P LORDOTIC PEEK IB,15mmx12mmx8mm	1
	G6626745	NO-P LORDOTIC PEEK IB,17mmx14mmx5mm	2
	G6626746	NO-P LORDOTIC PEEK IB,17mmx14mmx6mm	2
	G6626747	NO-P LORDOTIC PEEK IB,17mmx14mmx7mm	1
	G6626748	NO-P LORDOTIC PEEK IB,17mmx14mmx8mm	1
Case / Tray	77300000	Generic Modular Suitcase	1
	77300024	Generic Modular Tray 1	2
Instruments	6630911	11MM DRILL STERILE	1

Product Ordering Information *continued*

SPS01721 General Instruments (mandatory)

	ITEM	Description	Qty
Instruments	3036024	TOOL 3036024 2.0MM SCREW REMOVAL TOOL	1
	6620800	SA Guide Sleeve	1
	6620810	Freehand Inserter Sleeve	1
	6620811	No-P Freehand Inserter 15 Wide	1
	6620812	No-P Freehand Inserter 17 Wide	1
	6628155	No-P 5mm x 15 Guide	1
	6628156	No-P 6mm x 15 Guide	1
	6628157	No-P 7mm x 15 Guide	1
	6628158	No-P 8mm x 15 Guide	1
	6628175	No-P 5mm x 17 Guide	1
	6628176	No-P 6mm x 17 Guide	1
	6628177	No-P 7mm x 17 Guide	1
	6628178	No-P 8mm x 17 Guide	1
	6630902	DIVERGENCE™ ANGLED DRILL	1
	6630904	T8/T10 DRIVER	2
	6630905	ANGLED DRIVER	1
	6630908	11MM AWL	1
	6630909	Inserter Knob	2
	66265256	NO-P LORDOTIC IB TRIAL,5-6x15x12	1
	66265278	NO-P LORDOTIC IB TRIAL,7-8x15x12	1
	66267456	NO-P LORDOTIC IB TRIAL,5-6x17x14	1
	66267478	NO-P LORDOTIC IB TRIAL,7-8x17x14	1
	G850000	Tri-Flat Quick Connect Fixed Inline Hand	2
Case / Tray	6620011	LOADING BLOCK	1
	7742000	Divergence™ SA outer case label	2
	7742004	Divergence™ Top Instrument Tray	1
	7742005	Divergence™ SA Bottom Instrument Tray	1
	1850077	CASE 1850077 DOUBLE GENERIC OUTER CASE	1
	1850079	LID 1850079 GENERIC OUTER LID	1

DIVERGENCE™ SPS01722 20MM WIDE TRIALS (optional)

	ITEM	Description	Qty
Instruments	66262456	NO-P LORDOTIC IB TRIAL,5-6x20x14	1
	66262478	NO-P LORDOTIC IB TRIAL,7-8x20x14	1
Case / Tray	7742016	Divergence™ Wide Trial Module	1
	7742019	Divergence™ Lordotic 20mm SA Trial Lid	1

Product Ordering Information *continued*

SPS01723 RASP (optional)

	ITEM	Description	Qty
Instru-ments	6630922	LORDOTIC 5MM X 15MM X 12MM RASP	1
	6630923	DIVERGENCE™ LORDOTIC 6MM X 15MM X 12MM RASP	1
	6630924	LORDOTIC 7MM X 15MM X 12MM RASP	1
	6630925	LORDOTIC 8MM X 15MM X 12MM RASP	1
Case / Tray	7742018	Anterior Cervical RASP Tray	1
	1850096	Generic Metal Implant Lid	1

DIVERGENCE™ ADD ON (optional)

	ITEM	Description
Implants	G6626245	NO-P LORDOTIC PEEK IB,20mmx14mmx5mm
	G6626246	NO-P LORDOTIC PEEK IB,20mmx14mmx6mm
	G6626247	NO-P LORDOTIC PEEK IB,20mmx14mmx7mm
	G6626248	NO-P LORDOTIC PEEK IB,20mmx14mmx8mm

Important Product Information

SUMMARY OF IMPORTANT PRODUCT INFORMATION FOR THE DIVERGENCE™ ANETRIOR CERIVCAL FUSION SYSTEM (For Stand-Alone Interbody Device Only)

PURPOSE

The DIVERGENCE™ Anterior Cervical Fusion System consists of a stand-alone interbody fusion device with internal screw fixation. The DIVERGENCE™ Anterior Cervical Fusion System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. This system is indicated for single-level use only in the C2-T1 anterior spine.

DESCRIPTION

The DIVERGENCE™ Anterior Cervical Fusion System is an intervertebral body fusion device with internal screw fixation. The system is comprised of an interbody cage and bone screws. These implants are for single use only.

The DIVERGENCE™ anterior cervical cages are provided in 0 and 6 degrees of lordosis, 5-12mm heights, 15-20mm widths and 12-16mm depths. This device is intended to be radiolucent, and the interior space of the product is to be used with autogenous bone graft. The DIVERGENCE™ stand-alone cervical interbody device is manufactured from medical grade polyetheretherketone (PEEK) and contains radiopaque markers made from medical grade titanium alloy. The PEEK interbody cage also comes preassembled with a titanium alloy, built-in rotary locking mechanism.

The bone screws used with this device are provided in self-drilling and self-tapping options and are manufactured from medical grade titanium alloy. The bone screws are provided in 3.5mm and 4.0mm diameters and 9-17mm lengths.

The PEEK material used conforms to ASTM F2026 and the titanium alloy material used conforms to ASTM F136.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Medical grade titanium implants and medical grade PEEK implants may be used together. **Never use stainless steel and titanium implant components in the same construct.**

To achieve best results, do not use any of the DIVERGENCE™ Anterior Cervical Fusion System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the DIVERGENCE™ Anterior Cervical Fusion System components should ever be reused under any circumstances.

INDICATIONS

The DIVERGENCE™ Anterior Cervical Fusion System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The DIVERGENCE™ stand-alone cervical interbody device must be used with internal screw fixation. The DIVERGENCE™ stand-alone cervical interbody device is also required to be used with autogenous bone graft and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

CONTRAINDICATIONS

The DIVERGENCE™ Anterior Cervical Fusion System is not intended for posterior surgical implantation.

Contraindications include, but are not limited to:

- Any case needing to mix metals from different components.
- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or 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.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Any condition not described in the indications for use.
- Fever or leukocytosis.
- Infection local to the operative site.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Prior fusion at the level(s) to be treated.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Signs of local inflammation.
- Suspected or documented metal allergy or intolerance.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Cessation of any potential growth of the operated portion of the spine.
- Change in mental status.

Important Product Information *continued*

- Death.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Disassembly, bending, and/or breakage of any or all of the components.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
- Early or late loosening of the components and implant migration.
- Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation, and/or autoimmune disease.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone of the autograft, or at the bone graft harvest site at, above, and/or below the level of surgery.
- Gastrointestinal complications.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Wound necrosis or wound dehiscence.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Infection.
- Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Subsidence of the device into vertebral body(ies).
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery. The DIVERGENCE™ stand-alone cervical interbody device must be used along with the provided bone screws to augment stability. Use of this product in cervical interbody fusion procedures without autogenous bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery.

Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

A device that has been implanted should never be reused, reprocessed, or resterilized under any circumstances. Implants which have come in contact with the patient are designed for single patient use only. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

Based on fatigue testing results, when using the DIVERGENCE™ Anterior Cervical Fusion System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

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CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Please contact Customer Service or your Sales Representative for the most up-to-date revision of the package insert for current indications, warnings, precautions and other important medical information.

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.