Surgical Technique

Solitaire™-C Cervical Spacer System

A Zero Profile Anterior Cervical Fusion Device

Large Graft Cavity and Multiple Footprint Options

- Large autograft cavity encourages optimal healing environment
- Comprehensive offerings with three spacer footprints

Unique Spacer Band

- Assists device placement with accurate radiographic visualization
- Color-coded with screws to identify appropriate screw depth

Sophisticated Instruments Simplify Implantation

- Unique inserter guide provides clear visualization of hole preparation for screw insertion
- Multiple screw inserter options

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Contents

Introduction

The Solitaire™-C Cervical Spacer System is used for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients. It offers several unique features including a large graft cavity, three footprint sizes (in both lordotic and parallel), a unique color-coded band around the implant for easier screw identification, and a sophisticated yet simple instrumentation system. The Solitaire™-C System also offers two locking screws (3.5mm and 3.75mm) and zero profile in the anterior cervical spine.

This technique guide describes a surgical technique used by:

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The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Product Overview

Solitaire™-C Spacers

The Solitaire™-C Spacers are composed of a Titanium alloy faceplate, PEEK-OPTIMA® body, tantalum markers, and a Titanium alloy band. The Titanium faceplates are color-coded to denote height (see chart below). The Titanium bands are color-coded to denote depth.

Spacer Height	Color
6mm	Dark Green
7mm	Light Magenta
8mm	Dark Blue
9mm	Gold
10mm	Bronze

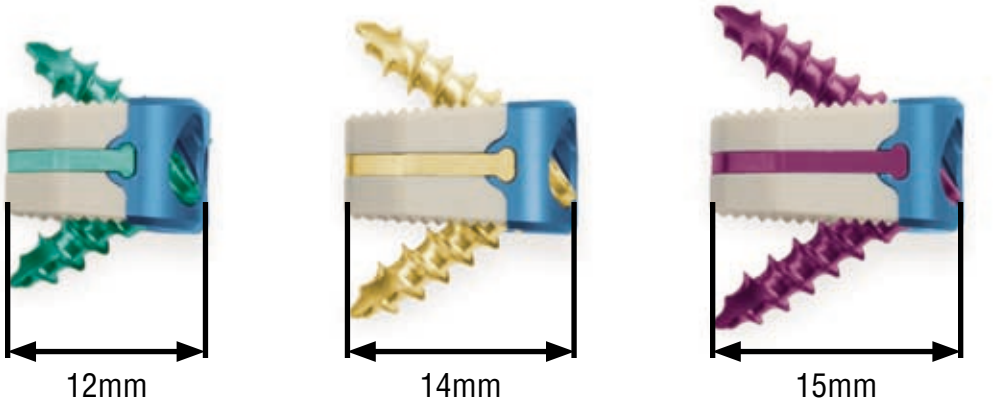
Spacer Depth	Screw Length	Color
12mm	12mm	Light Green
14mm	14mm	Gold
15mm	15mm	Light Magenta

Screws

Screws are placed at a fixed trajectory of 35° cephalad/caudal and 7° medial/lateral. The screw length is defined as the distance (in the lateral view) from the anterior face of the spacer to the tip of the screw. Screws are also color-coded by length which is designed to match spacer depth and the color of the implant band. Two screws are intended to be placed into each spacer such that one screw attaches the spacer to the superior vertebral body of the affected level and the other screw attaches the spacer to the inferior vertebral body of the affected level. Screws lock to the titanium faceplate by way of a threaded, cam-style locking mechanism that is torqued with a minimum of 14 in.-lbs. to lock the screws in place. Screws are manufactured from Titanium alloy.

Screws are offered in 3.5mm and 3.75mm diameters. The 3.5mm screws are fully colored, while the 3.75mm screws have only their heads colored (while the threads are silver).

Features and Benefits



Large Graft Cavity and Multiple Footprint Options

- Large autograft cavity encourages optimal healing environment
- Comprehensive offerings with three spacer footprints

Unique Spacer Band

- Assists device placement with accurate radiographic visualization
- Color-coded with screws to identify appropriate screw depth

Sophisticated Instruments Simplify Implantation

- Unique inserter guide provides clear visualization of hole preparation for screw insertion
- Multiple screw inserter options

Implants

Spacers:

Footprint: 14mm (wide) x 12mm (deep)
Heights: 6.0mm – 10mm (1.0mm increments)
Shapes: Parallel and Lordotic (7°)

Footprint: 16mm (wide) x 14mm (deep)
Heights: 6.0mm – 10mm (1.0mm increments)
Shapes: Parallel and Lordotic (7°)

Footprint: 18mm (wide) x 15mm (deep)
Heights: 6.0mm – 10mm (1.0mm increments)
Shapes: Parallel and Lordotic (7°)

Screws:

Length: 12mm, 14mm, 15mm
Diameter: 3.5mm

Length: 12mm, 14mm, 15mm
Diameter: 3.75mm

NOTE: Screw length is defined as the distance in the lateral view from the anterior face of the spacer to the tip of the screw. This means screw depth will be equivalent to spacer depth when corresponding sizes are used.

Instruments

Trials

Rasps

Slim Inserter Guide

Open Inserter Guide

Inserter Handle

12mm Angled Awl

Fixed Angled Driver (45°)

Includes:

- Angled Screw Driver Bit
- Angled Drill Bit
- Fixed Angled Driver

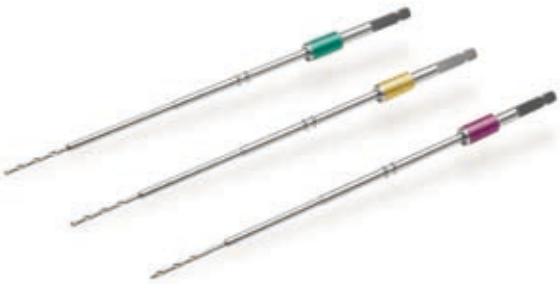
Instruments (Continued)

Tip with Malleable Shaft

Fixed Angle Bit Remover

Drill/Awl Sleeve

Spring-Loaded Drill/Awl Sleeve



Straight Drills

Straight Awls

Quick Connect Handle

Driver Sleeve Family

Includes:

- Driver Sleeve
- Driver for Sleeves
- Driver Spring Sleeve

Auto-Centering Driver

Non-Retaining Driver

Flexible Driver

Non-Retaining Flexible Driver

Threaded Screw Inserter

Torque Wrench Handle

Slide Hammer

Includes:

- Slide Hammer Adapter

Instruments (Continued)

Slotted Mallet

Graft Packing Caddy

Implant Remover

Includes:

- Inner Shaft
- Implant Remover

Using a standard surgical approach, expose the vertebral bodies to be fused. Traditional cervical retractors may be used. Prepare the fusion site following the appropriate technique for the specific indication.

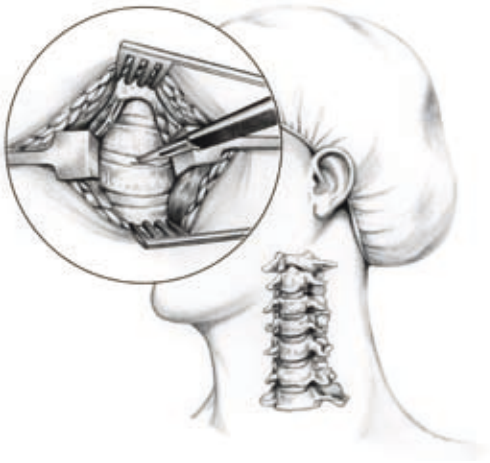


Figure 1

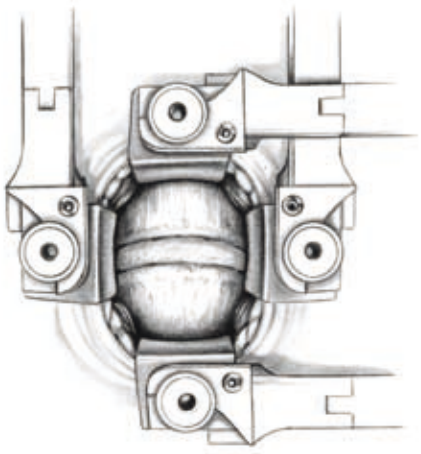


Figure 2

Step 1: Vertebral Body Distraction

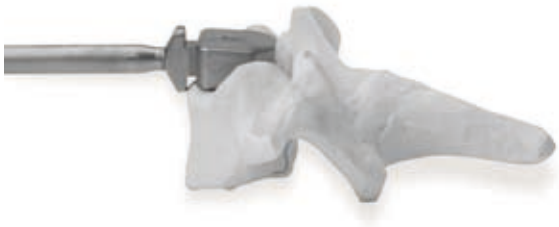
If using distraction pins, place one distraction pin in the vertebral body superior to the affected level and the other distraction pin in the vertebral body inferior to the affected level. The Pin Distractor is placed over the pins and opened as needed to distract the vertebral bodies (being careful not to over-distract the segment).

Step 2: Discectomy and End-Plate Preparation

Using rongeurs, pituitaries and curettes, remove the intervertebral disc and osteophytes as needed. Rasps can also be used to prepare the endplates and expose bleeding bone.

The Solitaire™-C trials and rasps are double-sided for efficiency. These instruments correspond to the implant footprints and are available in 5.0mm – 10mm heights in 1.0mm increments similar to the implants. (Please note that there is a 5.0mm trial and rasp, but that height is not available in an implant).

Also, the rasps are designed so that the teeth cut on the backstroke as the instrument is being pulled away from the spinal cord.



NOTE: Aggressive preparation of the endplate may remove excessive bone and weaken the endplate.

Step 3: Implant Sizing

Using the double-sided rasps or trials, determine the appropriate implant size by sizing the disc space. When sizing, use incrementally larger sizes until a tight fit is achieved. A secure fit is desirable to maintain disc height and stabilize the segment, so there should be no gaps between the prepared site and trial or rasp.

The trials and rasps are both available with or without stops. The stops allow for a maximum of 2.0mm of countersink into the disc space.

Once the desired disc height is determined, select the appropriate Solitaire™-C implant. Rasps and trials have sleeves that are color-coded to match the height of the corresponding spacer.

NOTE: The trial, rasp and implant heights for each particular size are all equal. Implant height is measured to the superior/inferior surfaces of the Titanium faceplate and peaks of the PEEK-OPTIMA® body macro-texture. Rasps are measured to the peaks of the teeth.

Step 4: Inserter Guide Assembly and Implant Attachment

The Solitaire™-C system offers two inserter guide options, slim and open, that thread onto the inserter handle and facilitate screw hole preparation and screw insertion through the same instrument. Both guide options allow for visualization of the implant/endplate interface and screw insertion.

Slim Inserter Guide

The slim inserter guide provides visualization to the front of the spacer on a lateral x-ray. This inserter guide can be used to place screws with or without hole preparation. Drill/Awl and Screw sleeves can be used with this guide.

Open Inserter Guide

The open inserter guide provides more visualization than the slim inserter guide. All drivers, awls and drills must be in contact with the guide arc during use.

NOTE: Biomet Spine does not recommend free handing Solitaire™-C screws.

Select the inserter guide (open or slim) that corresponds to the final implant size to be used. Each implant width and height has a corresponding guide tip which is color-coded to match a particular spacer height. There is a stop on one side of the inserter guide to facilitate placing the spacer at a 2.0mm countersink relative to the anterior face of the vertebral body. The stop can be oriented in a superior or inferior direction based on surgeon preference.

Attach the inserter guide to the inserter handle by threading the distal tip of the inserter handle completely through the threaded hole of the inserter guide. The inserter guide will be loose on the inserter handle until the spacer is attached.

Align the spacer to the inserter guide. Since the implant and the inserter guide are both rotationally symmetric, the superior and inferior surfaces of both devices are interchangeable. Turn the inserter handle to thread the inner shaft into the threaded hole in the center of the spacer until the assembly is rigid.

O.R. Tip: Confirm proper orientation of guide to implant by inserting a driver with a centering sleeve option down one of the inserter guide tubes. The instrument should easily seat into the guide with no manipulation.

Autograft Packing

Once the implant is attached to the inserter, fill the cavity with autograft. The graft packing caddy can be used.

Step 5: Implant Insertion

Impact the implant into the fusion site by striking the proximal end of the inserter handle. The slide hammer with adapter can also be used for insertion.

Each implant contains two Tantalum markers 1.0mm from the posterior wall of the implant that can be used as a reference when using fluoroscopy.

Additionally, the Solitaire™-C Spacer incorporates a uniquely designed titanium band around the spacer which assists with radiographic visualization at the fusion site.

Release any distractors in use to ensure that the implant is fully engaged with endplates.

Step 6: Screw Hole Preparation

A variety of drills, awls and centering sleeves are available to aid in screw hole preparation in order to meet anatomical challenges.

Awl and Drill Options

Straight awls and straight drills are available in 12mm, 14mm and 15mm lengths and correspond to equivalent screw lengths. Like the screws, drill depth is measured in the lateral view from the anterior face of the spacer to the tip of the drill or awl. Several guide sleeve options are available for drills as well as awls. Additionally, drills and awls are color-coded to aid in instrument identification and ensure proper depth. Straight drills and awls are color-coded to match screw length. Angled drill bits have their own color-coding scheme.

	12mm	14mm	15mm
Screws	Light Green	Gold	Light Magenta
Straight Drill	Light Green	Gold	Light Magenta
Straight Awl	Light Green	Gold	Light Magenta
Angled Drill Bit	Silver	Gold	Dark Gray

The straight drill, straight awl and angled awl (45°) are designed to connect directly to the quick connect handle. The angled drill bit must be attached to the fixed angle driver (45°). This driver mates with the quick connect handle.

To attach the angled drill bit to the fixed angle driver (45°), line up the male square of the driver with the female square within the bit. When the squares are aligned, the male square on the driver will sit deeper in the bit. Once the squares are aligned, apply force to seat the cantilever springs on the bit over the retention bump on the driver. The angled drill bit will be retained on the fixed angle driver (45°) until it is removed with the fixed angled bit remover as described later in the technique.

Angled Drill Bit **Fixed Angled Driver (45°)**

NOTE: The outer sleeve must be assembled on to the inner shaft of the fixed angle driver (45°). Slide the outer sleeve over the inner shaft and seat the female hex over the male hex prior to attaching the handle.

Angled Awl

An angled awl is available in a 12mm length and is not color-coded. It does not require an additional guide sleeve.

There is a hard stop between the awl and the inside of the faceplate on the spacer.

The angled awl has a laser etched marking that disappears inside the inserter guide when the awl is fully seated in the spacer and at the correct depth.

Centering Sleeve Options

The following combinations of drills, awls, and sleeves are available:

	Straight Awl	Straight Drill	Angled Drill Bit which attaches to the Fixed Angle Driver
Drill/Awl Sleeve 	X	X	
Spring-Loaded Drill/Awl Sleeve 	X	X	
Tip with Malleable Shaft (For Angled Drill. Must be used with Slim Inserter Guide.) 			X
Short Centering Tip* (For Angled Drill. Must be used with slim inserter guide.) 			X

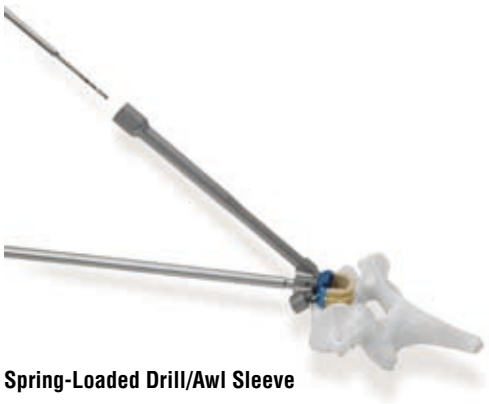
NOTE: All guide tubes or tips must be removed before screw insertion.

NOTE: Drill and awl options are used with centering sleeves to aid in screw hole preparation.

* Special order instrument

Drill/Awl Sleeve

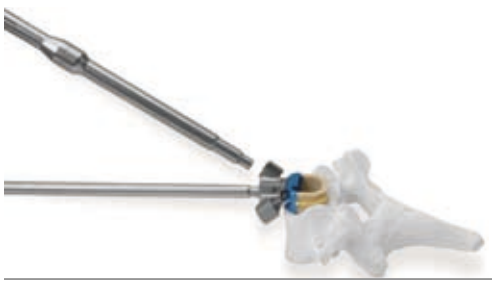
This sleeve is placed directly into either style inserter guide after implant insertion. Straight awls and drills can be used with this instrument. Both have a positive hard stop just below the color-coded boss that contacts the top of this sleeve. This sleeve has a laser etched marking that disappears inside the inserter guide when it is fully seated in the spacer and at the correct depth.



Spring-Loaded Drill/Awl Sleeve

This sleeve is intended to be pre-attached to straight drills and awls prior to insertion into the inserter guide. Both straight drills and awls have a bump mid-way along the shaft. To properly attach the spring sleeve, slide the sleeve onto the straight drill or awl until the cantilever springs on the spring sleeve slide over the bump. Now the spring sleeve is retained on the straight drill or awl. To remove the sleeve, slide it over the bump in the opposite direction.

Standard drills and awls have a positive hard stop just below the color-coded boss that interacts with this guide tube. This sleeve has a laser etched marking that disappears inside the inserter guide when it is fully seated in the spacer and at the correct depth.



Tip with Malleable Shaft for Angled Drill

The tip with malleable shaft can be used with any straight awl or drill option but is primarily used with the angled drill bits. It is intended to be placed directly into the inserter guide prior to inserting a drill. It has a malleable nitinol handle that can be positioned to help avoid anatomical challenges. Angled drills have a visible hard stop that contacts the top of this guide. Straight drills and awls have an internal stop.

O.R. Tip: When using the tip with malleable shaft, it may be helpful to place it into the inserter guide prior to implant insertion.

Short Centering Tip for Angled Drill

The centering tip is used with the angled drill bits. It is intended to be placed directly into the slim inserter guide prior to inserting a drill. The angled drills have a visible hard stop that contacts the top of this guide. The centering tip also has a small hole at the proximal end of the tip to accept a suture which will aid in removal after use. A suture should be placed in the loop of the short centering tip prior to use.

NOTE: The short centering tip is not a part of the kit, but is available as a special order item only.

Screw Driver Options

Multiple screw driver options are available to aid in screw placement and help meet surgeon needs and preferences. All drivers have a hexalobe interface at the distal tip and a quick connect geometry at the proximal end which engages with a quick connect handle or torque limiting handle. All drivers are compatible with both the open and slim inserter guides.

NOTE: When using the open inserter guide, ensure the driver is in contact with the arc of the guide as the screw is advanced.

The following driver options are available:

Threaded Screw Inserter

The threaded screw inserter allows for a rigid screw attachment to the inserter. The internal thread at the distal end of the inserter mates with the external thread on the head of the screw. The threaded screw inserter is self-centering when used with the slim guides. If using the open guide, the screw inserter should contact the guide arc as the screw is advanced to ensure proper screw placement.

Auto-centering Driver

This is a stab-and-grab driver. It has an increased shaft diameter at the distal end of the Driver. This increased diameter works with the slim inserter guide to help ensure that the screw head is properly centered as it enters into the titanium faceplate of the spacer. If using the open guide, the auto-centering driver should contact the guide arc as the screw is advanced to ensure proper screw placement.

Driver for Sleeves

This driver is a stab-and-grab driver that is used with sleeves to help ensure that the screw is entering the titanium faceplate of the spacer centered and at the proper trajectory. Both the driver and the sleeves have dark gray color-coding to help differentiate them from the drill/awl sleeves and denote that they should be used together. Like the drill and awl sleeves, this driver can be used with the driver sleeve or the driver spring sleeve. The driver sleeve is placed directly into the inserter guide. The driver for sleeves can then be passed down this sleeve to insert the screw. Alternatively, the driver spring sleeve is intended to be pre-attached to the driver for sleeves prior to insertion into the inserter guide. The straight driver for sleeves has a bump mid-way along the shaft. To properly attach the driver spring sleeve, slide the sleeve onto the driver until the cantilever springs on the spring sleeve slide over the bump. Now the spring sleeve is retained on the driver. To remove the sleeve, slide it over the bump in the opposite direction.

Driver Sleeve Family

Includes:

- Driver Sleeve
- Driver for Sleeves
- Driver Spring Sleeve

Driver Sleeve

Driver Spring Sleeve

Non-Retaining Driver

This driver does not frictionally lock to the screws and has a gold tip to help denote that it is not intended to be stab-and-grab. Because it is not a stab-and-grab, this driver sits deeper into the screw's hexalobe drive giving the driver-to-screw interface more strength. It also has a decreased shaft diameter at the distal end of the driver. This allows for additional versatility which may be necessary during screw removal or revision cases.

O.R. Tip: All gold-tip drivers are not intended to be stab-and-grab, and will not retain the screw. The gold-tip drivers are intended for final tightening or removal.

O.R. Tip: Using a non-retaining driver during final tightening and screw removal can reduce the chance of stripping the screw or the driver.

Fixed Angle Driver (45°) and Angled Driver Bits

This angled driver option has a stab-and-grab screw interface as well as a rigid fixed angle to aid in screw placement and help address anatomical challenges which can be found in the upper and lower regions of the cervical spine. Driver bits are intended to attach to the fixed angled driver. To do so, line up the male square of the driver with the female square within the bit. When the squares are aligned the male square on the driver will sit deeper in the bit. Once the squares are aligned apply force to seat the cantilever springs on the bit over the retention bump on the driver. The bit will be retained on the driver until it is removed using the bit remover described later in this technique.

Flexible Driver

This alternate angled driver option has a stab-and-grab screw interface as well as robust flexible links. This instrument contours to the anatomy and helps address anatomical challenges which can be found in the upper and lower regions of the cervical spine.

Non-Retaining Flexible Driver

This driver combines the benefits of the flexible driver with the versatility of the non-retaining driver. It is not intended to be a stab-and-grab driver (gold tip), as it does not frictionally engage with the screw.

Step 7: Screw Insertion

Reminder: Screws are placed at a fixed trajectory of 35° cephalad/caudal and have a 7° medial convergence. The slim guides will facilitate this trajectory. When using the open guides, ensure the inserter shaft remains in contact with the guide arc to ensure the proper trajectory.

Attach the quick connect handle to the desired driver or threaded screw inserter.

When using a stab-and-grab driver, affix the desired size screw to the driver by seating the distal tip of the driver into the hexalobe on the screw head. Place the screw into the appropriate screw hole through the inserter guide. Insert each screw until solid engagement of the cancellous thread occurs. Repeat for the contralateral hole.

When using the threaded screw inserter

Affix the desired size screw to the threaded screw inserter by turning the screw clockwise to mate the external thread on the screw head with the internal thread of the screw inserter until the screw bottoms out. Insert the hexalobe on the distal tip of the inserter into the head of the screw.

Place the screw into the appropriate screw hole through the inserter guide. While holding the T-handle of the screw inserter steady, turn the straight quick-connect handle clockwise to advance the screw out of the sleeve and into the faceplate of the spacer until solid engagement of the cancellous thread occurs. Repeat for the contralateral hole.

Step 8: Final Tightening

Attach the torque wrench handle to the desired driver and insert the tip of the driver into the hexalobe drive of the screw. Turn the handle until an audible “click” is heard at (a minimum of) 14 in.-lbs. of torque.

O.R. Tip: The inserter guide should remain engaged during screw insertion and final tightening to serve as a counter torque.

O.R. Tip: Torque wrench can be attached to the driver at the beginning of the screw insertion process, if preferred, so there is no need to switch handles.

NOTE: Biomet does not recommend using the fixed angle driver for final tightening. Any other driver option (including the flexible driver) can be used for final torquing.

Step 9: Inserter Guide Removal

Turn the inserter guide handle counterclockwise until it disengages from the spacer. The tip will be loose on the shaft but will be retained on the shaft.

Removal

Implant Removal

Should it become necessary to remove the Solitaire™-C Spacer, the following guidelines should be observed:

- Removal follows the reverse order of implantation
- Soft tissue on the anterior surface of the implant should be removed
- Assemble the implant remover by placing the inner shaft into the implant remover
- Attach the implant remover to the implant by turning the knob clockwise to thread the inner shaft into the center fixation hole on the spacer. The flats on the remover are to be parallel to the inferior and superior surfaces of the implant.
- Remove the screws using a screw driver
- Once screws are removed, remove implant from wound site. The slotted mallet or slide hammer with adapter can be used to aid in implant removal if necessary. If using the slide hammer, thread the adapter to the distal end of the slide hammer. Then slide the adapter over the proximal end of the remover.

Angled Driver Bit Removal

The driver bit and/or drill bits placed on the fixed angle driver should be removed using the angled driver bit remover. To remove a bit, line up the laser etched lines on the bit remover and fixed angle driver housing. Then, place the bit through the custom tips of the remover until the face of the tips contact the housing of the fixed angle driver. Squeeze the handles of the remover to disengage the bit.

Ordering Information

Solitaire™-C Small-Medium Lordotic Implant Kit

(Catalog No. 14-531504)

Catalog #	Description	Qty/Set
14-520506	6H x 14W x 12D Lordotic Spacer	2
14-520507	7H x 14W x 12D Lordotic Spacer	2
14-520508	8H x 14W x 12D Lordotic Spacer	2
14-520509	9H x 14W x 12D Lordotic Spacer	2
14-520510	10H x 14W x 12D Lordotic Spacer	2
14-520536	6H x 16W x 14D Lordotic Spacer	2
14-520537	7H x 16W x 14D Lordotic Spacer	2
14-520538	8H x 16W x 14D Lordotic Spacer	2
14-520539	9H x 16W x 14D Lordotic Spacer	2
14-520540	10H x 16W x 14D Lordotic Spacer	2

Solitaire™-C Small-Medium Parallel Implant Kit

(Catalog No. 14-531505)

Catalog #	Description	Qty/Set
14-520706	6H x 14W x 12D Parallel Spacer	2
14-520707	7H x 14W x 12D Parallel Spacer	2
14-520708	8H x 14W x 12D Parallel Spacer	2
14-520709	9H x 14W x 12D Parallel Spacer	2
14-520710	10H x 14W x 12D Parallel Spacer	2
14-520736	6H x 16W x 14D Parallel Spacer	2
14-520737	7H x 16W x 14D Parallel Spacer	2
14-520738	8H x 16W x 14D Parallel Spacer	2
14-520739	9H x 16W x 14D Parallel Spacer	2
14-520740	10H x 16W x 14D Parallel Spacer	2

Solitaire™-C Large Lordotic and Parallel Implant Kit

(Catalog No. 14-531506)

Catalog #	Description	Qty/Set
14-520586	6H x 18W x 15D Lordotic Spacer	2
14-520587	7H x 18W x 15D Lordotic Spacer	2
14-520588	8H x 18W x 15D Lordotic Spacer	2
14-520589	9H x 18W x 15D Lordotic Spacer	2
14-520590	10H x 18W x 15D Lordotic Spacer	2
14-520786	6H x 18W x 15D Parallel Spacer	2
14-520787	7H x 18W x 15D Parallel Spacer	2
14-520788	8H x 18W x 15D Parallel Spacer	2
14-520789	9H x 18W x 15D Parallel Spacer	2
14-520790	10H x 18W x 15D Parallel Spacer	2

Solitaire™-C Screws (Catalog No. 14-531500)

Included in Standard Instrument and Screw Kit

Catalog #	Description	Qty/Set
14-531712	3.5mm x 12mm Screw	6
14-531714	3.5mm x 14mm Screw	6
14-531715	3.5mm x 15mm Screw	6
14-531722	3.75mm x 12mm Screw	6
14-531724	3.75mm x 14mm Screw	6
14-531725	3.75mm x 15mm Screw	6

Solitaire™-C Standard Instrument and Screw Kit
(Catalog No. 14-531500)

Catalog #	Description	Qty/Set
14-520635	Inserter Handle	2
14-531563	Mallet	1
14-531565	Quick Connect Handle	2
14-531593	Drill/Awl Sleeve	2
14-531594	Spring-Loaded Drill/Awl Sleeve	2
14-531602	12mm Awl**	2
14-531604	14mm Awl**	2
14-531605	15mm Awl**	2
14-531612	12mm Drill**	2
14-531614	14mm Drill**	2
14-531615	15mm Drill**	2
14-531571	Driver Sleeve	2
14-531572	Drive Spring Sleeve	2
14-531574	Driver for Sleeves	2
14-531575	Auto-Centering Driver	1
14-531576	Non-Retaining Driver	1
14-531577	Threaded Screw Inserter	1
14-531578	Tip with Malleable Shaft	2
14-531579	Short Centering Tip*	0
14-531581	Fixed Angle Driver (45°)	2
14-531582	Angled Driver Bit	2
14-531632	12mm Angled Drill Bit**	2
14-531634	14mm Angled Drill Bit**	2
14-531635	15mm Angled Drill Bit**	2
14-531583	Fixed Angled Bit Remover	1
14-531702	12mm Angled Awl**	2
14-531585	Flexible Driver	1
14-531586	Non-Retaining Flexible Driver	1
14-531588	Torque Wrench	1
14-531590	Implant Remover	1
14-531561	Inner Shaft	1
14-531591	Slide Hammer	1
14-531592	Slide Hammer Adapter	1
14-531595	Graft Packing Caddy	1

* Denotes Special Order Item

** Denotes Single Use Only

Solitaire™-C Standard Instrument and Screw Kit
(Catalog No. 14-531500) (Continued)

Catalog #	Description	Qty/Set
14-520636	14W x 6H Slim Guide Tip	1
14-520637	14W x 7H Slim Guide Tip	1
14-520638	14W x 8H Slim Guide Tip	1
14-520639	14W x 9H Slim Guide Tip	1
14-520640	14W x 10H Slim Guide Tip	1
14-520646	16W x 6H Slim Guide Tip	1
14-520647	16W x 7H Slim Guide Tip	1
14-520648	16W x 8H Slim Guide Tip	1
14-520649	16W x 9H Slim Guide Tip	1
14-520650	16W x 10H Slim Guide Tip	1
14-520651	18W x 6H Slim Guide Tip	1
14-520652	18W x 7H Slim Guide Tip	1
14-520653	18W x 8H Slim Guide Tip	1
14-520654	18W x 9H Slim Guide Tip	1
14-520655	18W x 10H Slim Guide Tip	1
14-520666	14W x 6H Open Guide Tip	1
14-520667	14W x 7H Open Guide Tip	1
14-520668	14W x 8H Open Guide Tip	1
14-520669	14W x 9H Open Guide Tip	1
14-520670	14W x 10H Open Guide Tip	1
14-520676	16W x 6H Open Guide Tip	1
14-520677	16W x 7H Open Guide Tip	1
14-520678	16W x 8H Open Guide Tip	1
14-520679	16W x 9H Open Guide Tip	1
14-520680	16W x 10H Open Guide Tip	1
14-520681	18W x 6H Open Guide Tip	1
14-520682	18W x 7H Open Guide Tip	1
14-520683	18W x 8H Open Guide Tip	1
14-520684	18W x 9H Open Guide Tip	1
14-520685	18W x 10H Open Guide Tip	1

Solitaire™-C Small-Medium Lordotic Rasp and Trial Kit

(Catalog No. 14-531501)

Catalog #	Description	Qty/Set
14-531890	5/6H x 14W x 12D Lordotic Rasp (w/o Stops)	1
14-531891	7/8H x 14W x 12D Lordotic Rasp (w/o Stops)	1
14-531892	9/10H x 14W x 12D Lordotic Rasp (w/o Stops)	1
14-531905	5/6H x 16W x 14D Lordotic Rasp (w/o Stops)	1
14-531906	7/8H x 16W x 14D Lordotic Rasp (w/o Stops)	1
14-531907	9/10H x 16W x 14D Lordotic Rasp (w/o Stops)	1
14-531750	5/6H x 14W x 12D Lordotic Trial (w/o Stops)	1
14-531751	7/8H x 14W x 12D Lordotic Trial (w/o Stops)	1
14-531752	9/10H x 14W x 12D Lordotic Trial (w/o Stops)	1
14-531765	5/6H x 16W x 14D Lordotic Trial (w/o Stops)	1
14-531766	7/8H x 16W x 14D Lordotic Trial (w/o Stops)	1
14-531767	9/10H x 16W x 14D Lordotic Trial (w/o Stops)	1
14-531830	5/6H x 14W x 12D Lordotic Rasp (with Stops)	1
14-531831	7/8H x 14W x 12D Lordotic Rasp (with Stops)	1
14-531832	9/10H x 14W x 12D Lordotic Rasp (with Stops)	1
14-531845	5/6H x 16W x 14D Lordotic Rasp (with Stops)	1
14-531846	7/8H x 16W x 14D Lordotic Rasp (with Stops)	1
14-531847	9/10H x 16W x 14D Lordotic Rasp (with Stops)	1
14-531640	5/6H x 14W x 12D Lordotic Trial (with Stops)	1
14-531641	7/8H x 14W x 12D Lordotic Trial (with Stops)	1
14-531642	9/10H x 14W x 12D Lordotic Trial (with Stops)	1
14-531655	5/6H x 16W x 14D Lordotic Trial (with Stops)	1
14-531656	7/8H x 16W x 14D Lordotic Trial (with Stops)	1
14-531657	9/10H x 16W x 14D Lordotic Trial (with Stops)	1

Ordering Information (Continued)

Solitaire™-C Small-Medium Parallel Rasp and Trial Kit

(Catalog No. 14-531502)

Catalog #	Description	Qty/Set
14-532140	5/6H x 14W x 12D Parallel Rasp (w/o Stops)	1
14-532141	7/8H x 14W x 12D Parallel Rasp (w/o Stops)	1
14-532142	9/10H x 14W x 12D Parallel Rasp (w/o Stops)	1
14-532155	5/6H x 16W x 14D Parallel Rasp (w/o Stops)	1
14-532156	7/8H x 16W x 14D Parallel Rasp (w/o Stops)	1
14-532157	9/10H x 16W x 14D Parallel Rasp (w/o Stops)	1
14-532020	5/6H x 14W x 12D Parallel Trial (w/o Stops)	1
14-532021	7/8H x 14W x 12D Parallel Trial (w/o Stops)	1
14-532022	9/10H x 14W x 12D Parallel Trial (w/o Stops)	1
14-532035	5/6H x 16W x 14D Parallel Trial (w/o Stops)	1
14-532036	7/8H x 16W x 14D Parallel Trial (w/o Stops)	1
14-532037	9/10H x 16W x 14D Parallel Trial (w/o Stops)	1
14-532080	5/6H x 14W x 12D Parallel Rasp (with Stops)	1
14-532081	7/8H x 14W x 12D Parallel Rasp (with Stops)	1
14-532082	9/10H x 14W x 12D Parallel Rasp (with Stops)	1
14-532095	5/6H x 16W x 14D Parallel Rasp (with Stops)	1
14-532096	7/8H x 16W x 14D Parallel Rasp (with Stops)	1
14-532097	9/10H x 16W x 14D Parallel Rasp (with Stops)	1
14-531960	5/6H x 14W x 12D Parallel Trial (with Stops)	1
14-531961	7/8H x 14W x 12D Parallel Trial (with Stops)	1
14-531962	9/10H x 14W x 12D Parallel Trial (with Stops)	1
14-531975	5/6H x 16W x 14D Parallel Trial (with Stops)	1
14-531976	7/8H x 16W x 14D Parallel Trial (with Stops)	1
14-531977	9/10H x 16W x 14D Parallel Trial (with Stops)	1

Solitaire™-C Large Lordotic, Parallel Rasp and Trial Kit

(Catalog No. 14-531503)

Catalog #	Description	Qty/Set
14-531925	5/6H x 18W x 15D Lordotic Rasp (w/o Stops)	1
14-531926	7/8H x 18W x 15D Lordotic Rasp (w/o Stops)	1
14-531927	9/10H x 18W x 15D Lordotic Rasp (w/o Stops)	1
14-531785	5/6H x 18W x 15D Lordotic Trial (w/o Stops)	1
14-531786	7/8H x 18W x 15D Lordotic Trial (w/o Stops)	1
14-531787	9/10H x 18W x 15D Lordotic Trial (w/o Stops)	1
14-531865	5/6H x 18W x 15D Lordotic Rasp (with Stops)	1
14-531866	7/8H x 18W x 15D Lordotic Rasp (with Stops)	1
14-531867	9/10H x 18W x 15D Lordotic Rasp (with Stops)	1
14-531675	5/6H x 18W x 15D Lordotic Trial (with Stops)	1
14-531676	7/8H x 18W x 15D Lordotic Trial (with Stops)	1
14-531677	9/10H x 18W x 15D Lordotic Trial (with Stops)	1
14-532175	5/6H x 18W x 15D Parallel Rasp (w/o Stops)	1
14-532176	7/8H x 18W x 15D Parallel Rasp (w/o Stops)	1
14-532177	9/10H x 18W x 15D Parallel Rasp (w/o Stops)	1
14-532055	5/6H x 18W x 15D Parallel Trial (w/o Stops)	1
14-532056	7/8H x 18W x 15D Parallel Trial (w/o Stops)	1
14-532057	9/10H x 18W x 15D Parallel Trial (w/o Stops)	1
14-532115	5/6H x 18W x 15D Parallel Rasp (with Stops)	1
14-532116	7/8H x 18W x 15D Parallel Rasp (with Stops)	1
14-532117	9/10H x 18W x 15D Parallel Rasp (with Stops)	1
14-531995	5/6H x 18W x 15D Parallel Trial (with Stops)	1
14-531996	7/8H x 18W x 15D Parallel Trial (with Stops)	1
14-531997	9/10H x 18W x 15D Parallel Trial (with Stops)	1

Indications and Contraindications

Indications for Use

The Solitaire™-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative 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 Solitaire™-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. The Solitaire™-C Cervical Spacer must be implanted with the Solitaire™-C Titanium Screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Contraindications

Contraindications include, but are not limited to:

1. Infection, systemic, spinal or localized
2. Morbid obesity
3. Signs of local inflammation
4. Fever or leukocytosis
5. Metal sensitivity/allergies to the implant materials
6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Grossly distorted anatomy due to congenital abnormalities
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
9. Any case not needing a bone graft and fusion or where fracture healing is not required
10. Any patient having inadequate tissue coverage over the operative site
11. Any patient unwilling to cooperate with the postoperative instructions
12. Prior fusion at the level(s) to be treated.

Warnings

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device.
5. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.
6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.
8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
9. The Solitaire™-C Spacer must be implanted with the Solitaire™-C Titanium screws that are part of the system.
10. The Solitaire™-C Cervical Spacer System has not been evaluated for safety and Compatibility in the MR environment. The Solitaire™-C Cervical Spacer System has not been tested for heating or migration in the MR environment.

Precautions

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
3. Biomet Spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions. Bone grafts must be placed in the area to be fused.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone can result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Solitaire-C Cervical Spacer System components should ever be reused under any circumstances.

Potential Adverse Effects and Complications

Possible adverse effects include, but are not limited to:

1. Bending, loosening, migration or fracture of the implants or instruments
2. Loss of fixation
3. Sensitivity to a metallic foreign body, including possible tumor formation
4. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
5. Nonunion or delayed union
6. Infection
7. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage
8. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
9. Pain or discomfort at the operative and/or bone graft donor site
10. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra)
11. Hemorrhage of blood vessels and/or hematomas
12. Misalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
13. Bursitis
14. Inability to resume activities of normal daily living
15. Reoperation
16. Death

Sterilization

Unless supplied sterile, devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. Re-sterilization is not recommended.

For product supplied non-sterile, all packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended:

U.S. Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 270°F/132°C
Time: 4 minutes
Drying Time: 30 minutes
NOTE: Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

Sterilization Parameters for Use Outside of U.S.:
Cycle: Pre-vacuum Steam
Temperature: 275°F/135°C
Time: 3 minutes
Drying Time: 30 minutes
NOTE: Allow for cooling

Further Information

Biomet does not recommend stacking of trays during the sterilization process.

Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Additional information about instrumentation (including assembly/disassembly) may be found in the system surgical technique, reference guide and/or associated package inserts.

Refer to the Biomet Non-sterile Instrument IFU for full processing instructions for instruments.

For further information, please contact the Customer Service Department at:

Biomet Spine
310 Interlocken Parkway, Suite 120,
Broomfield, CO 80021
303.443.7500 • 800.447.3625
biometspine.com

Notes:

At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

Solitaire™-C Cervical Spacer System
A Zero Profile Anterior Fusion Cervical Device

To learn more about this product,
contact your local Biomet Sales Representative today.

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