ZIMMER BIOMET

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Cervical Solutions

Trinnect®

Hydrated Anterior Cervical Spacer System

Surgical Technique Guide

Trinnect Cervical Allograft Spacers are pre-hydrated in Preservon® technology to provide safety, strength and performance.

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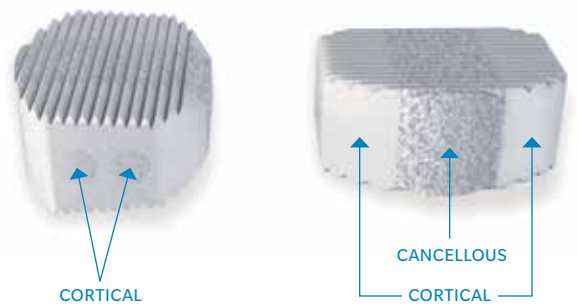
Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

PRODUCT OVERVIEW

The Trinnect Hydrated Anterior Cervical Spacer System is a line of precision-machined cervical allograft spacers. Trinnect Allograft Spacers are processed by LifeNet Health®, which is accredited by the American Association of Tissue Banks (AATB). Trinnect Allograft Spacers are packaged using Preservon®, a glycerol-based preservation technology, allowing the spacer to be stored in a fully hydrated state at ambient temperature, eliminating the need to freeze or freeze-dry the spacers.

- *Preservon retains mechanical strength by eliminating the potential brittleness associated with freeze drying*
- *Load-bearing cortical edges provide structural integrity while the large cancellous center allows for osteointegration*
- *Ready for use in under 30 seconds without the need for rehydration*



Trinnect Allograft Spacers are composed of cortical bone for structural integrity and dense cancellous bone for integration. The graft features two pieces of cortical bone to form the lateral aspects of the graft with cancellous bone in the center.

The footprint of the Trinnect Spacer measures 14.5 mm wide with a depth of 11.5 mm. Available heights range from 5 mm to 12 mm in 1 mm increments. The spacer features 7° of lordosis to closely approximate the curvature of the cervical spine. In addition, each graft is machined with horizontal ridges to provide expulsion resistance.

PATIENT PREPARATION AND VERTEBRAL BODY DISTRACTION

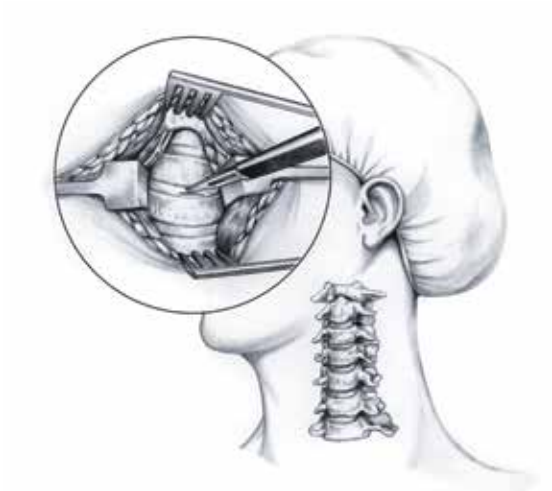


Figure 1a
Expose vertebral bodies to be fused

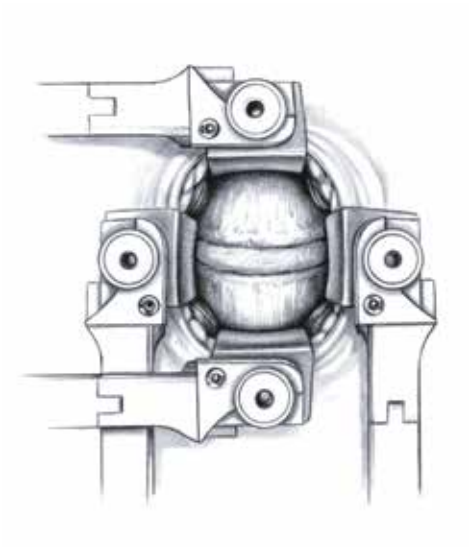


Figure 1b
Prepare fusion site

STEP 1

- 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 1a, 1b).
- 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.

DISCECTOMY AND END-PLATE PREPARATION

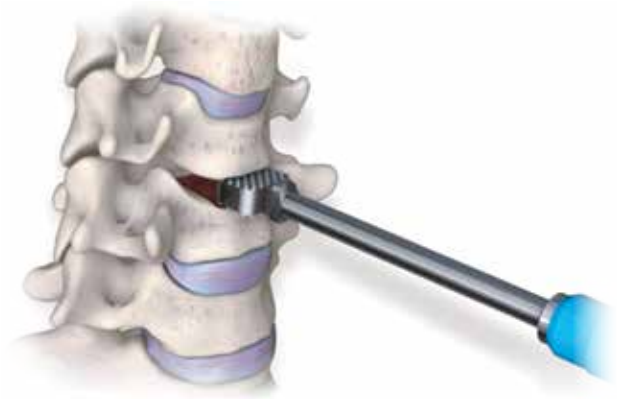


Figure 2
Discectomy and end-plate prepartion

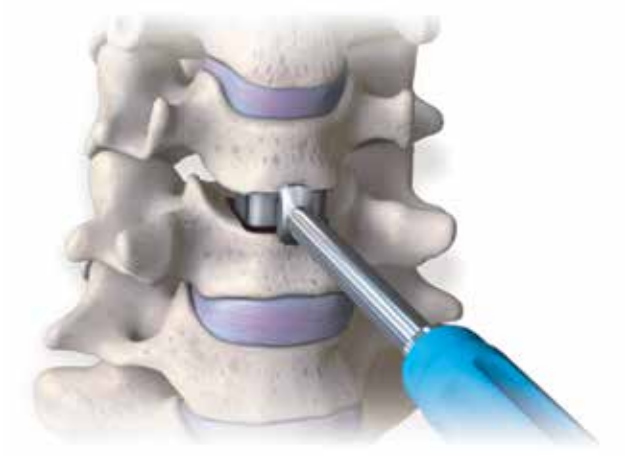


Figure 3
Determine implant sizing

STEP 2

- 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 (Figure 2).
- The trials and rasps are double-sided for efficiency. These instruments correspond to the implant footprints and are available in 5 mm – 12 mm heights in 1 mm increments similar to the implants.
- The rasps are designed so that the teeth cut on the backstroke as the instrument is being pulled away from the spinal cord.

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

STEP 3

- Using the double-sided rasps or trials, determine the appropriate implant size by sizing the disc space (Figure 3).
- 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.
- There should be no gaps between the prepared size and trial or rasp.
- The trials and rasps are both available with or without stops. The stops allow for a maximum of 2 mm of countersink into the disc space.
- Once the desired disc height is determined, select the appropriate Trinnect implant.

IMPLANT INSERTION

Figure 4
Implant insertion

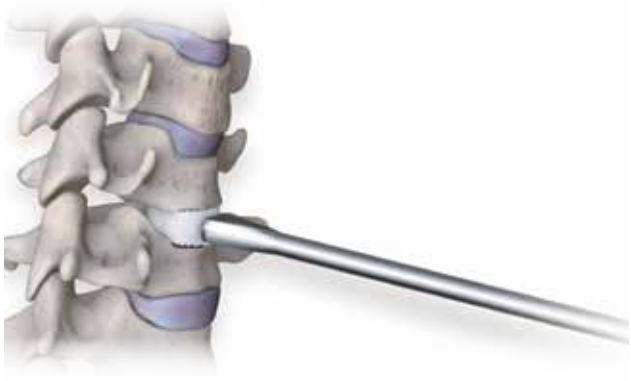


Figure 5
Adjust the implant using the tamp, if necessary

STEP 4

- Load the graft onto the inserter by placing it between the tines and turn the knob at the proximal end of the inserter clockwise to fully engage the implant.
- Introduce the implant into the vertebral disc space using the inserter. The implant should be the same height as the size determined by the trial and should be seated securely within the disc space (Figure 4).
- Tap the proximal strike plate of the inserter with a mallet to gently seat the implant.
- The implant may be inserted flush with the anterior rim of the adjacent vertebral bodies or may be countersunk past the anterior rim at the physician's discretion.

STEP 5

- Disengage the implant from the inserter and remove the instrument.
- The tamp may be utilized to further advance the implant into the disc space if desired (Figure 5).

CLOSURE

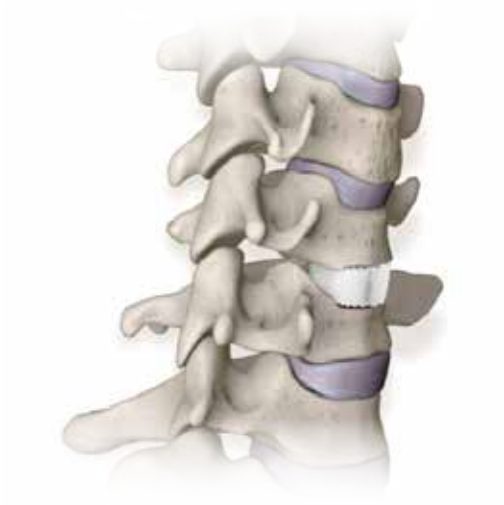


Figure 6
Closure

STEP 6

- Repeat steps to insert additional Trinnect Spacer System implants at additional intervertebral levels.
- Proceed with the application of anterior cervical instrumentation and closure (Figure 6).

IMPLANT KIT

Trinnect Hydrated Anterior Cervical Allograft Implants Kit Number: 14-531209

SIZE	QTY	PART NUMBER
Lordotic Graft, 5mm	2	LNHC05
Lordotic Graft, 6mm	3	LNHC06
Lordotic Graft, 7mm	4	LNHC07
Lordotic Graft, 8mm	4	LNHC08
Lordotic Graft, 9mm	4	LNHC09
Lordotic Graft, 10mm	3	LNHC10
Lordotic Graft, 11mm	3	LNHC11
Lordotic Graft, 12mm	3	LNHC12

Trinnect Hydrated Anterior Cervical Allograft Instruments Kit Number: 14-531208

SIZE	QTY	PART NUMBER
Trial with Stops, 5/6H x 14W x 12D	1	14-531640
Trial with Stops, 7/8H x 14W x 12D	1	14-531641
Trial with Stops, 9/10H x 14W x 12D	1	14-531642
Trial with Stops, 11 1/2H x 14W x 12D	1	14-531643
Trial without Stops, 5/6H x 14W x 12D	1	14-531750
Trial without Stops, 7/8H x 14W x 12D	1	14-531751
Trial without Stops, 9/10H x 14W x 12D	1	14-531752
Trial without Stops, 11 1/2H x 14W x 12D	1	14-531753
Rasp with Stops, 5/6H x 14W x 12D	1	14-531830
Rasp with Stops, 7/8H x 14W x 12D	1	14-531831
Rasp with Stops, 9/10H x 14W x 12D	1	14-531832
Rasp with Stops, 11 1/2H x 14W x 12D	1	14-531833
Rasp without Stops, 5/6H x 14W x 12D	1	14-531890
Rasp without Stops, 7/8H x 14W x 12D	1	14-531891
Rasp without Stops, 9/10H x 14W x 12D	1	14-531892
Rasp without Stops, 11 1/2H x 14W x 12D	1	14-531893
Cervical Spacer Inserter	2	14-531141
Tamp, 5mm	1	14-531142
Slotted Mallet Head	1	14-531563

INSTRUMENTS

The Trinnect Hydrated Allograft implant set offers a unique set of instrumentation that is simple to use and designed with the intent of making a direct contribution to successful clinical results.

SLOTTED MALLET HEAD	PART NUMBER
	14-531563

RASP WITH STOPS	PART NUMBER
5/6H x 14W x 12D	14-531830
7/8H x 14W x 12D	14-531831
9/10H x 14W x 12D	14-531832
11 1/12H x 14W x 12D	14-531833

TRIAL WITH STOPS	PART NUMBER
5/6H x 14W x 12D	14-531640
7/8H x 14W x 12D	14-531641
9/10H x 14W x 12D	14-531642
11 1/12H x 14W x 12D	14-531643

RASP WITHOUT STOPS	PART NUMBER
5/6H x 14W x 12D	14-531890
7/8H x 14W x 12D	14-531891
9/10H x 14W x 12D	14-531892
11 1/12H x 14W x 12D	14-531893

TRIAL WITHOUT STOPS	PART NUMBER
5/6H x 14W x 12D	14-531750
7/8H x 14W x 12D	14-531751
9/10H x 14W x 12D	14-531752
11 1/12H x 14W x 12D	15-531753

CERVICAL SPACER INSERTER	PART NUMBER
5/6H x 14W x 12D	14-531141

TAMP	PART NUMBER
5mm	14-531142

IMPORTANT INFORMATION ON THE TRINNECT HYDRATED ANTERIOR CERVICAL SPACER SYSTEM

Device Description

The Trinnect Hydrated Anterior Cervical allograft spacer was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. The spacer was cleaned and disinfected through a proprietary process and terminally sterilized via gamma irradiation.

There are two preservation methods included in these instructions: Freeze-Dried, and packaged with Preservon. Please refer to the label to identify which preservation method was utilized for this spacer.

Indications for Use

This allograft spacer is intended for implantation.

Contraindications

The contraindications include, but are not limited to:

- Use in any patient who has a known or suspected allergy to any of the antibiotics and/or processing reagents listed in this package insert.

Warnings and Precautions

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any allograft spacer, the transmission of infectious agents exists. This spacer may contain residuals of antibiotics (Bacitracin, Gentamicin, and/or Polymyxin B Sulfate), alcohol, surfactants, and/or glycerol. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents.

Potential Adverse Events

Potential adverse events or outcomes include, but are not limited to, disease transmission, infection, allograft tissue rejection, allergic reaction to residual processing reagents, reoperation and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to the allograft spacer.

Safety Information

All donors have been screened and tissues recovered, processed, stored, tested and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270 and 1271, current Standards for Tissue Banking set forth by the AATB and international laws and regulations as required. More information can be found in the donor screening and testing section of the package insert.

Product Complaints

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to Zimmer Biomet Spine.

Disclaimer: *This document 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.*

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

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