CoreLink Cervical Spacer	
Instructions for Use	
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CoreLink
The Source for Spine™

READ CAREFULLY PRIOR TO USE.

FEDERAL LAW RESTRICTS THE USE OF THIS ALLOGRAFT FOR USE BY A LICENSED CLINICIAN ONLY.

DESCRIPTION AND INDICATION FOR USE

The contents of this package were donated from human tissue generously gifted with consent.
Allografts are provided to medical practitioners, directly responsible for the use of tissue within their designated discipline.
Tissue identifying information and expiry dates are printed on the container label and packaging.
Allografts that are indicated as sterile on the label are sterilized via low-dose electron beam irradiation and achieve a sterility assurance level (SAL) of 10^{-6}.
This implant is regulated as a 361 human cell and tissue product (HCT/P) as defined in FDA 21 CFR 1271 and is restricted to homologous use for in the repair or reconstruction of the musculoskeletal system.

CONTRAINDICATIONS

The contraindications include, but are not limited to:

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

WARNINGS AND PRECAUTIONS

Medical/surgical conditions and/or complications that apply during or after any surgical procedure are the same for implanting allografts.
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 implant, the potential for transmission of infectious agents exists.
This allograft may contain residuals of gentamycin antibiotic, alcohol and/or surfactants. A small number of patients may experience localized immunological reactions to the implant. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents.

Do not resterilize the implant. Use standard practices for handling and disposal of human tissue.

Promptly report any implant defect to CoreLink.

POTENTIAL ADVERSE EVENTS

Potential adverse events or outcomes include, but are not limited to;

- Infection
- Allograft tissue rejection
- Allergic reaction to residual processing reagents

Adverse outcomes attributable to the tissue must be promptly reported to CoreLink. (See COMPLAINTS AND RETURNS section below).

PROCESSING

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 5 environment.
Tissue is aseptically recovered, processed and terminally sterilized via radiation (i.e. electron beam or Cobalt 60).

DONOR SCREENING

The completed donor chart for the enclosed tissue, including but not limited to: serology results, recovery culture results, medical and social history evaluation and serodilution calculation, has been reviewed and approved for transplantation by an appropriately qualified Medical Director.
All donor history has been screened for the presence of active infectious disease, malignancy, degenerative neurological disease and diseases of unknown etiology.
Origin Biologics utilizes strict donor screening procedures to avoid the collection and use of tissues from donors who may carry infectious or toxic agents.
The manufacture and release of this allograft is in accordance with the Origin Biologics Regulatory Framework and Origin Biologics procedures.

Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and FDA licensed.
The donor blood samples were tested for:

- Hepatitis B Surface Antigen
- Hepatitis C Antibody
- Syphilis
- HCV
- HTLV 1/2*
- Hepatitis B Core Antibody
- HIV-1/2 Antibody
- HIV -1
- HBV
- WNV*

*Where applicable
All infectious disease tests returned negative/non-reactive.
This allograft tissue has been determined to be suitable for transplantation by a qualified Medical Director.

STORAGE REQUIREMENTS

Maintain tissue for transplantation at appropriate storage conditions prior to further distribution or transplant and recipient records must be maintained for the purpose of tracing tissue post transplantation.

Unused/ unopened allografts must be stored as follows:

Preservation Method	Storage Temperature	Special Conditions
Freeze Dried	Ambient Temperature 15-30°C.	Do not freeze.

If storage conditions or container seal have been compromised before intended use, the tissue should be **discarded**.

GENERAL INSTRUCTIONS

Use on a single occasion for a single patient only.

- Once the packaging is opened, allograft must be used for the current procedure or discarded.
- Inspect the allograft, inner and outer packaging, and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the allograft is damaged or the packaging integrity is compromised.
  - Do not use if there are any discrepancies in label information.
  - Do not use if the allograft has not been used within 6 hours of rehydration or has been stored at temperatures that exceed recommended storage temperatures.
- Use aseptic technique at all times.
- Keep the allograft stored according to recommended storage instructions until preparing it for implantation.

OPENING INSTRUCTIONS

This allograft has been aseptically packaged into sterilized packaging components.

Use standard aseptic/sterile techniques to open the package ready for use.

NOTE: Once the outer pouch is opened, the allograft should be used promptly. The inner packaging alone, is not intended for storage of allograft, as it may not provide an adequate moisture barrier.

Pouch Packaging:

1. Peel open the outer pouch.
2. Aseptically pass inner pouch to sterile field/scrub.
3. Sterile individual is to peel open or cut the inner pouch.
4. Sterile individual is to remove tissue into a sterile bowl and rehydrate.
5. Implant as per surgeon's preference.

Jar Packaging:

1. Peel open the outer pouch.
2. Aseptically pass inner jar to sterile field/scrub.
3. Sterile individual is to open the jar.
4. Sterile individual can remove tissue or rehydrate within the container.
5. Implant as per surgeon's preference.

Syringe Packaging:

1. Peel open the outer pouch.
2. Aseptically pass inner syringe to sterile field/scrub.
3. Sterile individual is to remove the red luer lock cap and rehydrate as required.
4. Sterile individual is to remove screw cap lid, push plunger to expel allograft.
5. Implant as per surgeon's preference.

PREPARATION

Refer to the table below for the recommended rehydration time.

It is the clinician's preferred surgical technique to use a specific solution soak technique for rehydration, such as the following: antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other blood products.

Allograft Type	Room Temperature / Warmed Solution (15-42°C)
Traditional Bone	15-30 minutes
Demineralized Bone	Rehydrate until required consistency and handling are achieved as per surgeon's preference.

TRACEABILITY

In order to maintain tissue traceability regulated by the FDA and AATB, we ask that you please complete the form attached at the time of surgery and return to Origin Biologics at the earliest convenience. To simplify this procedure, please peel off the labels provided with the allograft and attach to the Allograft Tracking Form.

WARRANTY

This implantable graft is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects in biologics which cannot be detected, removed, or prevented by reasonable use of available scientific techniques. ALL EXPRESSED OR IMPLIED WARRANTIES ARE DISCLAIMED.

COMPLAINTS AND RETURNS

For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or CoreLink Customer Service at 888.349.7808 or customerservice@CoreLink.com.

SYMBOL DEFINITIONS

	Single Use
	Caution
	See Instructions for Use
	Sterilized using irradiation
	Expiration Date
	Manufacture
	For Use by a Licensed Clinician Only
	Store in a dry, ambient environment (15-30°C) Until Use
	Minimize excessive exposure to light and protect from excessive heat.

Manufactured By:

ORIGIN BIOLOGICS Life Enhancing Allografts

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