Distributed By:

SeaSpine

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Manufactured By:

rti surgical®

TEL: 386.418.8888 □ 800.624.7238 □ www.rtix.com

CAPISTRANO™ CERVICAL SPACER

Read this entire package insert carefully prior to use.

Single patient use only, on a single occasion.

Restricted to sale by or on the order of a physician.

DESCRIPTION

The *Capistrano* cervical spacer is comprised of cancellous bone held between cortical bone using press-fit cortical bone pins. After assembly, the construct is precision machined, processed through the BioCleanse® sterilization process, lyophilized and terminally sterilized. The implant is provided sterile and requires rehydration prior to use. The implant is regulated as a 361 human cell and tissue product (HCT/P) as defined in USFDA 21 CFR 1271 and is restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects by a qualified healthcare professional (e.g., physician).

DONOR SCREENING AND TESTING

LOT This symbol on the outer label indicates the unique number assigned to the tissue donor.

The donated human tissue utilized for this implant was recovered from a donor screened for risk factors associated with infectious diseases and medical conditions that rule out donation. The donor's blood was tested for relevant communicable diseases in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) or equivalent and registered with the U.S. Food and Drug Administration (FDA) for donor testing. The following test criteria were met for this donor:

REQUIRED INFECTIOUS DISEASE TESTING	
BLOOD TEST	**ACCEPTABLE RESULT**
HIV-1 / HIV-2 Antibody	Negative/ Non-Reactive
Hepatitis C Virus Antibody	Negative/ Non-Reactive
Hepatitis B Surface Antigen	Negative/ Non-Reactive
Hepatitis B Core Antibody (Total)	Negative/ Non-Reactive
Treponema pallidum (Syphilis)	Negative/ Non-Reactive
Human T-Cell Lymphotropic Virus I/II Antibody	Negative/ Non-Reactive
HIV-1 / HCV / HBV* NAT-TMA	Negative/ Non-Reactive

*For donors received after January 01, 2014.

If additional testing was performed (e.g., West Nile Virus), all available test results were reviewed as part of the donor eligibility determination.

A licensed physician for RTI Surgical, Inc. determined that the donor met eligibility requirements. The physician utilized available relevant information which may have included, but was not limited to: donor risk assessment interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology reports, death certificate and autopsy report (if performed).

PROCESSING

SN This symbol on the outer label indicates a unique serial number used for traceability.

The implant was processed in a controlled environment from a single donor. Microbial testing was performed where appropriate and results met a documented acceptance criterion. The implant was released for transplantation based on the donor eligibility determination and a review of processing records.

Trace amounts of the following manufacturing residuals may remain after processing; ascorbic acid, detergents, hydrogen peroxide, hydrochloric acid, isopropyl alcohol and povidone-iodine.

STERILIZATION

This implant was processed using the following methods:

BIOCLEANSE® TISSUE STERILIZATION PROCESS

The *BioCleanse* process is a validated sterilization process that inactivates or removes potential pathogens through a complex, proprietary combination of chemical treatments and mechanical processes.

STERILE R

Low dose gamma irradiation is applied terminally to the implant to achieve a sterility assurance level (SAL) of 10^{-6}.

STORAGE AND SHIPPING

This symbol on the outer label indicates the storage temperature range for the implant.

This symbol on the outer label indicates the expiration date of the implant.

Store at the temperature range specified on the product label.

SHIPPING CONDITIONS

Implant was shipped at ambient temperature via expedited shipping methods.

WARNINGS

The same potential 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 human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant.

Successful treatment is dependent upon the patient's host tissue response. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function. Fragmentation, displacement and/or disintegration of the implant at the surgical site may compromise its integrity and/or function.

PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Where provided, use surgical instrumentation, accessories, and/ or surgical technique guide with this implant.

Do not resize or manipulate the implant. Manipulation or alteration of an assembled implant may cause implant failure.

Impaction tools should distribute pressure evenly across cortical areas of implant. Do not apply any concentrated pressure to the cancellous bone area of the implant.

Inadequate rehydration may result in implant failure upon impaction.

WARRANTY STATEMENT

This biologic graft, processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws in most states. 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 procedures or techniques. Furthermore, ***ALL WARRANTIES ARE DISCLAIMED, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN ADDITION, ALL CONSEQUENTIAL DAMAGES, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THESE GRAFTS ARE HEREBY DISCLAIMED.***

INSTRUCTIONS FOR USE

It is important to read and understand the following instructions and precautions prior to clinical use. Improper preparation technique may adversely affect the success of the surgical procedure.

GENERAL PRECAUTIONS:

- Use on a single occasion for a single patient only. Once the package is opened, the implant must be used for the current procedure or discarded.
- The box is non-sterile and is used to protect the implant during shipping and storage.
- Remove the double-barrier packaged product, the package insert, implant stickers and Tissue Utilization Record from the box.
- Inspect the product, including all packaging and labeling materials carefully:
  - Do not use past expiration date.
  - Do not use if the implant or packaging is damaged.
  - Do not use if there are discrepancies in label information.
- The sterile barrier packaging is comprised of two sealed pouches. To prevent contamination of the implant, use sterile technique for preparation and implantation.
- Additional product should be available in case of unexpected need during the procedure.
- This implant and all packaging materials used by RTI are latex-free.
- Do not re-sterilize the implant.
- Use standard practices for handling and disposal of human tissue.
- Promptly report all complaints and patient adverse events to SeaSpine Orthopedics Corporation (Customer Returns and Complaints).

DIRECTIONS FOR TISSUE PREPARATION:

1. Open outer package and pass inner package onto sterile field.
2. Open inner package within sterile field.
3. Place implant in sterile container and cover with sterile water, physiological saline or the patient's blood.
4. Hydrate for a minimum of 30 seconds before use.

TISSUE UTILIZATION RECORD (TUR CARD)

Complete and return the enclosed Tissue Utilization Record (TUR) to RTI Surgical, Inc. This information is kept confidential and used only for implant traceability. The TUR card should be filled out and returned for all implants, even if the implant was discarded. Refer to the enclosed TUR card for additional information.

CUSTOMER RETURNS AND COMPLAINTS

For further information or to report a complaint or adverse event, please contact:

SeaSpine Orthopedics Corporation
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Carlsbad, CA 92008, USA
Telephone: +1-760-727-8399
Fax: +1-760-727-8809
Complaints: complaints@seaspine.com
Customer Service: customerservice@seaspine.com
Website: www.seaspine.com

A complete symbols glossary is located at
http://www.rtix.com/en_us/healthcare-professionals/labeling

DEFINITION OF LABEL SYMBOLS		
Caution, consult instructions for use	Use-by date	Storage temperature limits
For prescription use only	Single use Do not re-use	Manufacturer
Catalogue number	Serial Number	Lot number (Donor number)
Sterilized using Irradiation	**FD** Freeze Dried	Do not use if package is damaged
Do not resterilize		

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