OrthoNovis GUARD Amniotic Allograft
Instructions For Use (IFU)

READ THIS ENTIRE INSERT PRIOR TO USE.

Federal (USA) law restricts the use of this allograft to licensed clinician only.

Indications for Use
This allograft is intended for homologous use in one patient on a single occasion for a variety of orthopedic, surgical, spinal, wound, and ophthalmic covering applications.

Contraindications
Active or latent infection at the site.

Warnings and Precautions
Even though the allograft was sterilized using a validated dose of radiation, the possibility of transmitting infectious agents still exists.
Do not re-sterilize.

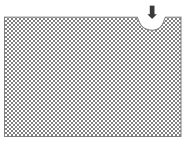
Complaints or Adverse Events
Potential adverse events include, but are not limited to, infection.
Immediately report any complaints or adverse events that are potentially attributable to the allograft to OrthoNovis, Inc. by contacting cs@orthonovis.com. Please have the product identification number available.

Storage
This allograft is supplied dry and intended to be stored at room temperature (10°C-30°C). Do not freeze.
It is the responsibility of the intermediary, distributor, or end-user clinician to store the allograft appropriately prior to further distribution or use.

Preparation for Use
Remove the product pouch from the cardboard sleeve, peel open the outer pouch, and aseptically present the inner pouch to the scrubbed team member.
After opening the package, the allograft must be used for the current procedure or discarded.
Do not use if the packaging integrity is compromised or if there are discrepancies between the labels.
Do not use past the expiration date.

Application
While the allograft is in a dry state, it can be easily cut to the desired shape or size for the application.
Place the allograft directly on the defect, and if needed, apply adhesive strips or suture it in place.
The allograft may be rehydrated using sterile isotonic solution, as required.

Orientation
If the allograft includes a notch, position it so that the notch is in the upper right (as shown here). In this orientation the epithelial side is facing up.



If there is no notch, the allograft is dual-layer and omnidirectional.

Donor Screening and Testing
This allograft was derived from donated, healthy human birth tissue, and was retrieved, processed, and distributed in accordance with FDA regulations (21 CFR 1271), American Association of Tissue Banks' standards, and applicable State regulations. The allograft was processed using minimal manipulation and terminally sterilized to a Sterility Assurance Level of 10^{-6}. The allograft was deemed suitable for implantation by the manufacturer. The tissue donor was determined to be eligible by a physician medical director, and this determination was based on a review of all relevant medical records, including infectious disease test results, donor medical history, behavioral risk assessment interview, and laboratory test results. Infectious disease testing was performed by a CLIA certified laboratory registered with FDA to perform donor testing. Test methods that are FDA licensed, approved, or cleared are used, as available. The following criteria were met for the donor of this allograft:

Infectious Disease Testing	
HIV-1/HIV-2 Antibody	Negative/Non-Reactive
Hepatitis B Surface Antigen	Negative/Non-Reactive
Hepatitis C Antibody	Negative/Non-Reactive
Hepatitis B Core Antibody (Total)	Negative/Non-Reactive
Human T-Lymphotropic Virus Types I/II Antibody	Negative/Non-Reactive
Syphilis RPR or Treponemal Specific Assay	Confirmatory Negative/Non-Reactive
Hepatitis B Nucleic Acid Test	Negative/Non-Reactive
Hepatitis C Nucleic Acid Test	Negative/Non-Reactive
HIV-1 Nucleic Acid Test	Negative/Non-Reactive
West Nile Virus Nucleic Acid Test*	Negative/Non-Reactive

*Required only for donors recovered between June 1 and October 31.

Traceability
It is the responsibility of the end-user to maintain recipient records for the purpose of tracing tissue post-transplantation. To facilitate this, an allograft implant card is included as well as additional allograft identification labels.

Please complete and return the card.

Donor Eligibility and Processing By:
C5 Biomedical, 6452 E Rogers Cir, Boca Raton, FL 33487.
FDA FEI: 3021867303.

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