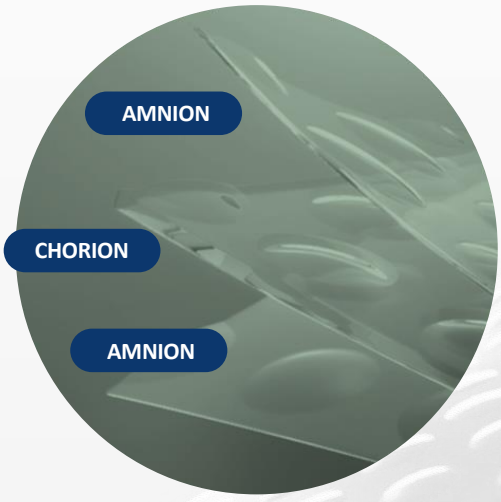
surgiGRAFT™ DUAL

MAXIMIZING OUTCOMES, MINIMIZING COSTS



DESCRIPTION:

surgiGRAFT™ Dual is a dehydrated tri-layer (amnion/chorion/amnion) allograft. The tissue acts as a shielding barrier that promotes the progression of healing while providing improved handling properties for surgical applications.

PRODUCT ADVANTAGES

- Protective Barrier
- Ambient storage
- Natural Regenerative Healing
- Flexible ease of use

POTENTIAL CLINICAL APPLICATIONS

- Spine and Neurosurgery
- Wound and Burn Care
- Orthopedics
- Urology
- Foot and Ankle
- OB/GYN
- General Surgery
- Vascular Surgery
- Ophthalmology

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surgiGRAFT™ Dual Ordering Information

Product Code	Description (size)	Total Sq Cm	HCPCS Code
ORSGDL -202	2cm x 2cm	$4cm^2$	Q4219
ORSGDL-203	2cm x 3cm	$6cm^2$	Q4219
ORSGDL-204	2cm x 4cm	$8cm^2$	Q4219
ORSGDL-208	2cm x 8cm	$16cm^2$	Q4219
ORSGDL-404	4cm x 4cm	$16cm^2$	Q4219
ORSGDL-505	5cm x 5cm	$25cm^2$	Q4219
ORSGDL-408	4cm x 8cm	$32cm^2$	Q4219
ORSGDL-707	7cm x 7cm	$49cm^2$	Q4219

FDA Regulations:

surgiGRAFT™ Dual products are regulated by the FDA under 21 CFR part 1271 and section 361 of the public health service act.

In 21 CFR 1271.10, the regulations identify the criteria for regulation solely under section 361 of the PHS Act and 21 CFR Part 1271. An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 if it meets all of the following criteria (21 CFR 1271.10(a)):

1. The HCT/P is minimally manipulated;
2. The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
3. The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
4. Either:
    i. The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
    ii. The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        a. Is for autologous use;
        b. Is for allogeneic use in a first-degree or second-degree blood relative; or
        c. Is for reproductive use.

If an HCT/P does not meet the criteria set out in 21 CFR1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any of the exceptions in 21 CFR 1271.156 , the HCT/P will be regulated as a drug, device, and/or biological product under the FD&C Act, and/or section 351 of the PHS Act (42 U.S.C. 262), and applicable regulations, including 21 CFR Part 1271, and premarket review will be required.

For more information, please contact:

850-328-0340

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www.synergybiologics.net

APPROVED FDA REGISTERED FACILITY

ACCREDITED AATB INSTITUTION

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