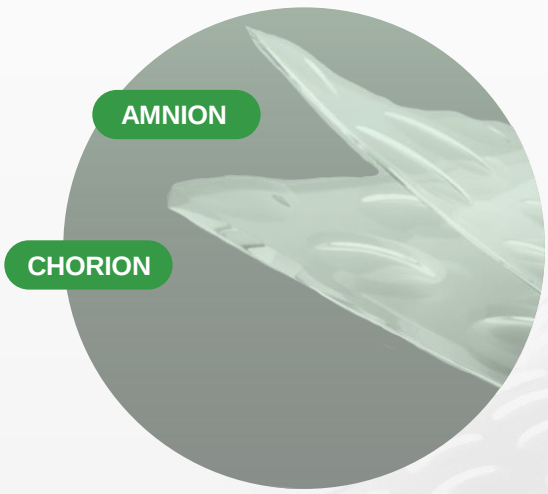
surgiGRAFT™ AC

MAXIMIZING OUTCOMES, MINIMIZING COSTS



DESCRIPTION:

surgiGRAFT™ AC is a dehydrated dual layer (amnion/chorion) 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™ AC Ordering Information

Product Code	Description (size)	Total Sq Cm
ORSGDAC -202	2cm x 2cm	$4cm^2$
ORSGDAC-203	2cm x 3cm	$6cm^2$
ORSGDAC-204	2cm x 4cm	$8cm^2$
ORSGDAC-206	2cm x 6cm	$12cm^2$
ORSGDAC-208	2cm x 8cm	$16cm^2$
ORSGDAC-404	4cm x 4cm	$16cm^2$
ORSGDAC-408	4cm x 8cm	$32cm^2$
ORSGDAC-316	3cm x 16cm	$48cm^2$
ORSGDAC-810	8cm x 10cm	$80cm^2$
ORSGDAC-715	7cm x 15cm	$105cm^2$
ORSGDAC-915	9cm x 15cm	135cm2
ORSGDAC-820	8cm x 20cm	160cm2
ORSGDAC-1016	10cm x 16cm	160cm2

FDA Regulations:

surgiGRAFT™ AC 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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