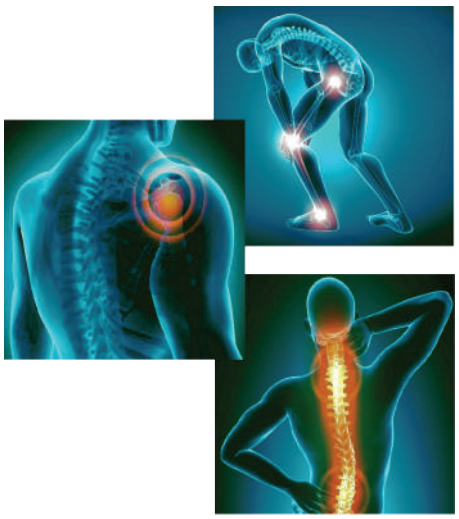
Nouvelle GROWTH FACTOR-RICH MATRIX

Alliant Biotech introduces nascent components for tissue repair, including collagens, elastins, embryonic signaling molecules, and hyaluronic acids.

Nouvelle delivers a myriad of tissue repair cytokines including Fibroblast Growth Factor (FGF), Epidermal Growth Factor (EGF), Platelet-Derived Growth Factor (PDGF-AA and -BB), Transforming Growth Factor beta (TBG beta 1& 3), and Vascular Endothelial Growth Factor (VEGF).

These cytokines support tissue progenitors promoting constructive remodeling of tendon, ligament, bone, and integument tissue. Importantly, Nouvelle reduces inflammatory and pain mediators implicated in arthritis and joint injury.



Nouvelle down regulates trauma-induced inflammation and Prostaglandin E2 levels in vivo.

ORDERING INFORMATION

Item number	Description
NV-1215	1.5 mL matrix
NV-2230	3.0 mL matrix

Contact Customer Service at: orders@alliantbiotech.com

Alliant Biotech,LLC. 2140 Oak Industrial Drive NE Grand Rapids, MI 49505. 888-307-1144

Nouvelle is sourced exclusively through IntegoGen LLC, an AATB Accredited and FDA Approved Lab. Nouvelle is an HCT/P 361 approved product indicated for homologous use in the USA. For any questions please email: orders@alliantbiotech.com

FDA Classification

Gratitude Therapeutics 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 cells or tissues with another article, except for water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCTP; and
4. Either:
   A. HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
   B. The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
      I. Is for autologous use;
      II. Is for allogeneic use in the first-degree or second-degree blood relative; or
      III. 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.

APPROVED FDA REGISTERED FACILITY

CERTIFIED AATB CTBS TISSUE BANK SPECIALIST

ALLIANT™ BIOTECH

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