

Primus Product Portfolio

SurGraft XT (Q4269)



Disclaimer

- This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 2023 and is based upon publicly available source information.
- Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third-party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record.
- When making coding decisions, we encourage you to seek input from The American Medical Association (AMA), relevant medical societies, Centers for Medicare & Medicaid Services (CMS), your local Medicare Administrative Contractor (MAC) and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation.
- It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors. The following is not legal advice and should not be taken as legal advice.
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Primus Product Portfolio

Surgraft XT

All 3 products received FDA issued Tissue Reference Group (TRG) confirmations.

Applications may include:

- Acute and chronic wounds
- Diabetic foot ulcers
- Venous leg ulcers
- Traumatic wounds
- Pressure ulcers
- Burns wounds

Features:

- Easily cut and shaped
- No specific orientation required
- Resorbable barrier
- Sterile
- Room temperature storage
- 5-year shelf life

FDA Regulated Human Tissue 21 CFR 1271 & Section 361

- The combination of federal regulations that cover the use of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).
- HCT/Ps are defined in 21 CFR 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.
- Section 361 of the PHS Act explain the types of HCT/Ps that do not require premarket approval (510k)

Minimal Manipulation

- For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement;
- For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

Homologous Use

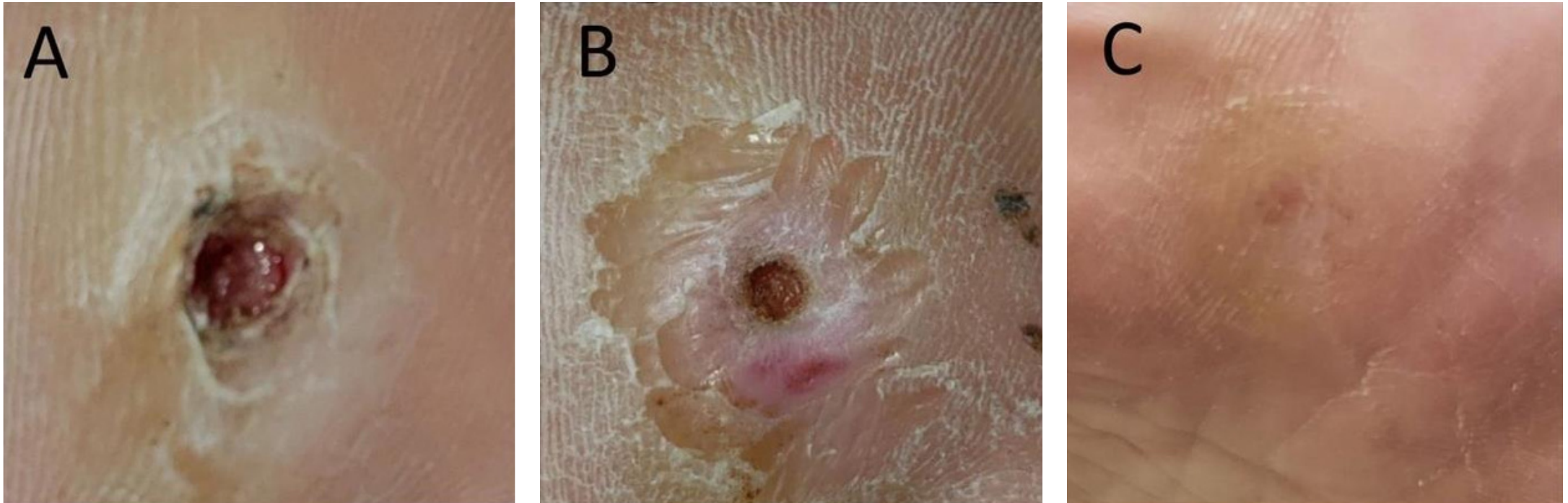
- The repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor

Case Study: Post-BKA Trauma



92 sq cm post BKA wound: Healed with 7 applications of Zenith

Case Study: DFU



Chronic DFU failed to heal after 4 weeks of conservative therapy.
Healed with 4 applications.

SURGRAFT XT



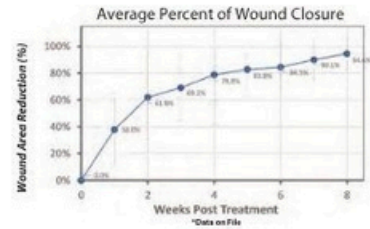
allografts

SurGraft XT® Product Details

SurGraft XT® is a cutting-edge dual layer allograft sourced from amnion, expertly crafted to optimize healing.

SurGraft XT® contributes to healing by serving as a barrier and protection for the patient's wound, reducing complications during the healing process. It has a five-year shelf life.

SurGraft XT® Product Details – HCPCS Code Q4269



Why SurGraft XT®?

SurGraft XT® is processed in compliance with the United States Food and Drug Administration current Good Tissue Practices (cGTP) Regulations and the American Association of Tissue Banks Standards. We pride ourselves on quality and testing that meet or exceed industry standards.

SurGraft XT® has been shown to be effective as a protective covering in the management of chronic non-healing ulcers including diabetic, pressure, and venous ulcers. Our allografts support enhanced tissue adherence along with heightened strength and effortless handling. SurGraft XT® is regulated under Section 361 of the PHS Act and 21 CFR Part 1271 and is intended for homologous use.

- Human Extracellular Matrix (ECM)**
The membrane sheet provides a protective covering that may aid in wound management
- Barrier**
The extracellular matrix acts as a barrier and may potentiate the migration and adhesion of resident cells²
- Immunogenicity**
The amniotic membrane has unique non-immunological properties
- Growth Factors**
The membrane is a natural source of cytokines and growth factors³

¹ Park A, J, Parkerson S, Dyer L, Gombick RP, J, Chouk B S. *Amniotic Membrane Transplantation for Wound Healing*. *Wound Care*. 2018;18(1):11-17. doi:10.1016/j.woc.2017.07.001

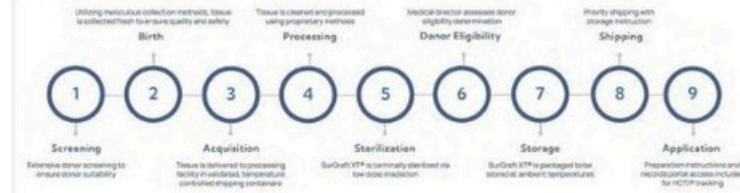
² The presence of extracellular matrix cells with their own cell-to-cell interactions, including cell-to-cell, cell-to-matrix and cell-to-matrix interactions, is essential for cell-to-cell interactions.

³ The presence of growth factors is essential for cell-to-cell interactions, including cell-to-cell, cell-to-matrix and cell-to-matrix interactions.

Excellion® Process Differentiators

- Fresh Tissue Processing**
Tissue is collected promptly and delivered fresh for processing to achieve optimal results
- No Harsh Chemicals or Antibiotics**
Our proprietary Excellion® process precisely eliminates contaminants with minimal manipulation
- Meticulous Quality Assurance**
Surgenex® takes pride in assuring the highest technical quality and rigorous testing to ensure safety without compromise
- Fully Optimized Process**
The Excellion® process is tailored to retain key extracellular matrix and regulatory proteins

Our Process



SURGRAFT XT Sheet Sizes

SIZES	SKU	Billing Units
1 X 1 CM	0611	1 CM ²
2 X 2 CM	0622	4 CM ²
2 X 3 CM	0623	6 CM ²
2 X 4 CM	0624	8 CM ²
4 X 4 CM	0644	16 CM ²
4 X 6 CM	0646	24 CM ²
4 X 8 CM	0648	32 CM ²
12 X 15 CM	0650	180 CM ²

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SURGENEX

10-2018 (REV 1)

Updated IVR: 3 Products

Patient Insurance Verification and Prior Authorization Request Form

New patient
 Re-verification
 Additional applications
 New insurance

Sales representative name _____

Patient and Insurance Information

Patient name _____ Date of birth _____
 Address _____ City _____ State _____ Zip _____

Is the patient currently residing in a skilled nursing facility? Yes No
 If yes, is the patient covered under a Part A stay? Yes No

If patient is currently under a surgical global period, please indicate date and procedure completed

Procedure (CPT) code(s) _____ Date of procedure _____

Primary insurance	Policy # _____	Payer phone _____
Secondary insurance	Policy # _____	Payer phone _____
Tertiary insurance	Policy # _____	Payer phone _____
Workers comp claim #	Adjuster name _____	Adjuster phone _____

Physician and Facility Information

Physician name _____ Physician specialty _____
 NPI # _____ Medicare (PTAN) provider # _____
 Tax ID _____ Medicaid provider # _____
 Office contact _____ Phone _____ Fax _____

Treating facility place of service (POS)
 Hospital-based outpatient wound department (HOPD – POS 22)
 Ambulatory surgery center (ASC – POS 24)
 Physician office (POS 11)
 Other (please specify, e.g. critical access hospital or POS 19 off-campus) _____

Facility name _____

Facility address _____ City _____ State _____ Zip _____
 NPI # _____ Tax ID _____
 Medicare contractor (MAC) and Provider ID (PTAN) for claims processing _____

Product and Treatment Information

Product: (Q4253) Zenith
 (Q4262) Impax
 (Q4268) SurGraft FT

Application codes: 15271 – 15274 for wounds on the trunks, arms, and/or legs
 15275 – 15278 for wounds on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits

Anticipated treatment start date _____ Number of applications _____ Frequency _____
 Total surface area of all wounds _____

Diabetic foot ulcer	Venous leg ulcer	Pressure ulcer or chronic wound	Other
E code _____	I code _____	L code _____	_____
L code _____	L code _____		

I certify I have obtained a valid authorization under applicable law from the patient listed on this form (a) permitting me to release the patient's protected health information to Legacy Medical and its contractors to research insurance coverage regarding Legacy Medical products, and to provide me with reimbursement assistance services regarding such products; and (b) authorizing the payer to disclose PHI to Legacy Medical and its contractors for the purposes of determining benefit coverage.

Provider signature _____ Date _____

Please send form along with a copy of the front and back of patient's insurance card to sunderwood@prodatamgmt.com or fax to (866) 205-0732.

If further assistance is needed, please contact IVR Support Team at (919) 249-7293 for additional support.

Disclaimer: Legacy Medical offers insurance verification as an information service only. Information gathered during the requested research will be provided by the insurer or third-party payer. Results of this research are not a guarantee of coverage or reimbursement in the future. Legacy Medical disclaims liability for payment of any claims, benefits, or costs.



Insurance Verification Request (IVR) form

- Patient Name
- Patient Date of Birth
- Patient Insurance Plan(s) Policy number(s)
- Physician and Facility NPI, Tax ID, Payer IDs, PTANs
- Physician and Facility Network Status
- Benefit verification turn-around-time within 48 hours

Verified patient status includes:

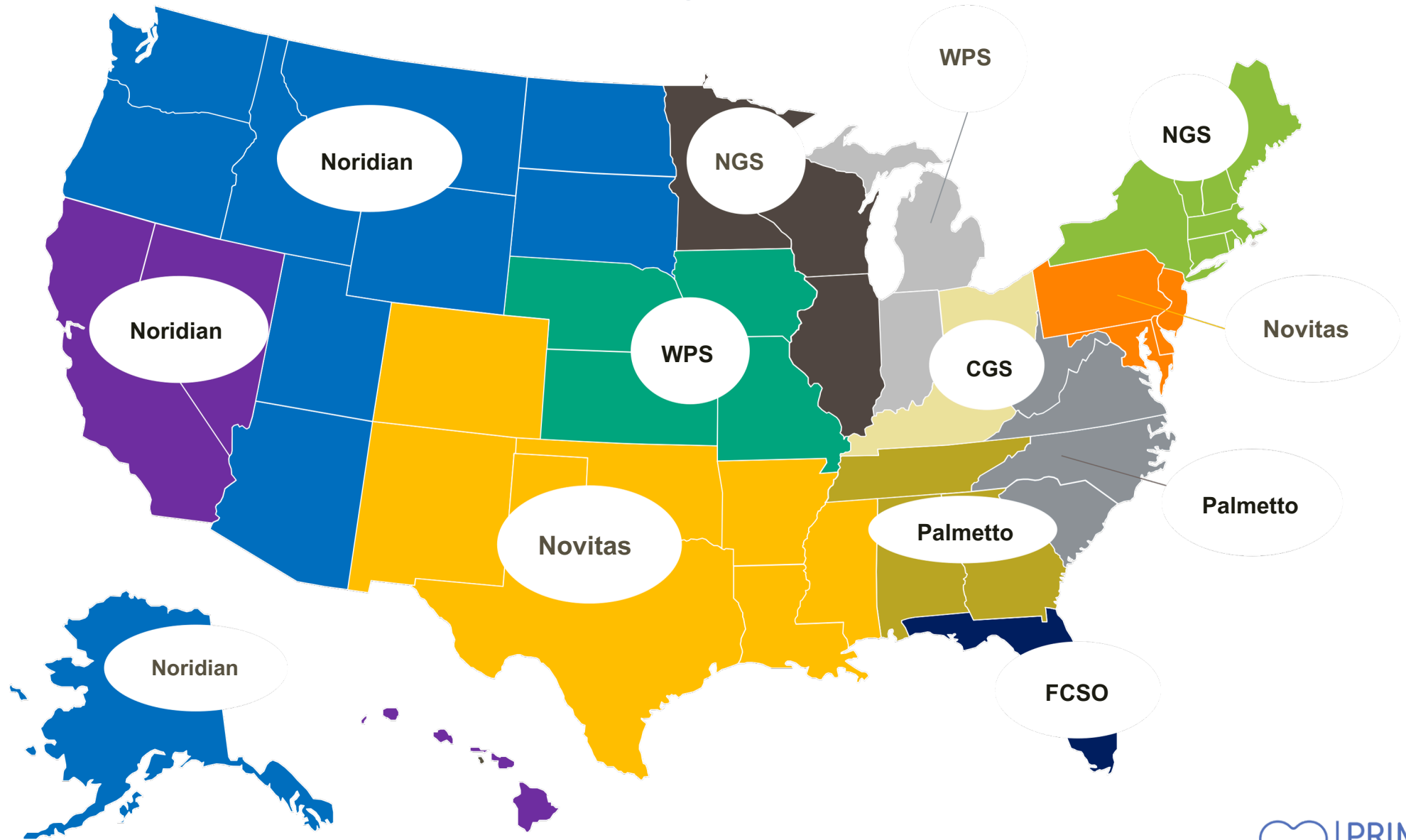
- Effective date with the plan
- Deductible/Deductible met
- Copay Coinsurance Out of
- Pocket/Out of Pocket Met

Verified with the submitted:

- ICD-10/CPT code(s)
- HCPCS code



MAC MAP



Compliance Knowledge: Fraud, Waste, Abuse

Criminal Fraud

- Knowingly and willfully executing or attempting to execute a scheme to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program.

Waste

- Overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare or Medicaid Program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

Abuse

- Includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare or Medicaid program. Abuse involves payment for items or services when there is not legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

Safety and Sterility

Placentas are acquisitioned from planned C-sections in the OR. Donor eligibility determined by licensed Medical Director.

- Serology testing completed on mother's blood (Hepatitis B surface antigen, Hepatitis B core and Hepatitis C, HIV 1 & 2 and group O, syphilis, HTLV (human t-cell lymphatic virus), Nucleic acid testing (NAT) for HIV/HCV/HBV/WNV).
- Review the physical assessment made at the time of admit.
- Review the DRAI, containing questions regarding high-risk behavior, travel, and medical history which screens for possible relative communicable diseases.
- Review of prenatal medical records.

Tissue is processed in an ISO Class 6 Cleanroom

- Pre-processing cultures of the transport media.
- Terminally irradiated via E-beam.

Tissue is stored at 15-30 degrees Celsius and shipped over night or couriered same-day to the end user.

References

<https://idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html>

Setacci C, Benevento D, De Donato G, Viviani E, Bracale UM, Del Guercio L, Palasciano G, Setacci F. Focusing on Diabetic Ulcers. *Transl Med UniSa*.2020 Feb 20;21:7-9. PMID: 32123673; PMCID: PMC7039261.

Sheehan P, Jones P, Caselli A, Giurini JM. Percent Change in Wound Area of Diabetic Foot Ulcers Over a 4-Week Period Is a Robust Predictor of Complete Healing in a 12-Week Prospective Trial. *Diabetes Care*26(6):1879-82. DOI: 10.2337/diacare.26.6.1879

Raghav A, Kahn ZA, Labala RK, et al. Financial burden of diabetic foot ulcers to world: a progressive topic to discuss always. *Ther Adv Endocrinol Metab*.2018 Jan; 9(1): 29–31. DOI: 10.1177/2042018817744513

Guest JF, Atkin L, Aitkins C. Potential cost-effectiveness of using adjunctive dehydrated human amnion/chorion membrane allograft in the management of non-healing diabetic foot ulcers in the United Kingdom. *Int Wound J*.2021 Dec;18(6):889-901.DOI: 10.1111/iwj.13591

Contact Primus HealthCare



Any Questions?

Please Contact Us

info@specialtywoundcare.com

(844) 299-9499