NeoMTX™ Viable Bone Matrix

Frequently Asked Questions

What makes NeoMTX™ different?

NeoMTX represents the latest innovation in viable cellular allograft-it provides the building blocks necessary for tissue repair and is a forward-thinking approach to the power of biology. Allograft, re—imagined.

Although autograft is the gold standard, it can be unreliable-especially from older patients.[1] NeoMTX is processed from an age-restricted group (≤55 ys): the median age is approimately 35 years old.

Why is that important? Clinicians have long recognized that the osteogenic capacity of a bone graft declines with patient age.[1] Younger donors provide potentially higher bone density and osteogenic capacity.[1]

NeoMTX supplies physiologic levels of growth factors and proteins, as well as approximately 2 million vertebral bone adherent (VBA) cells/cc of graft material. The graft is approximately 80% cancellous, which is an optimal scaffold for bone cells to attach to, proliferate and remodel.[1]

What is the backtable time?

The graft should be thawed in a warm water bath, but no decanting is required. NeoMTX must be used within 2 hours from when the pouch was removed from the water bath.*

What are the shipping and storage details?

Shippers have an expiration date of 4 days (96 hours). NeoMTX™ must be stored immediately in its original packaging at -60°C or colder. NeoMTX™ may incur temperature excursions above -60°C up to 5 minutes due to cycling or opening of freezer doors.

Transport the graft to the OR using a preferred method that maintains the temperature at -60°C or below without excursions above -60°C for longer than 5 minutes.*

What is the processing time?

Recovery and donor screening begins within 8 hours and processing is initiated within the first 72 hours of recovery to minimize loss in cell viability. The product is then put into cryopreservation within 82 hours of recovery, which inhibits any enzymatic and chemical activities that may cause cell damage.

What is the donor screening process?

Ossium Health is not a typical tissue processor—they're a biotech company focused on developing a bone marrow bank for treating blood cancers. This leads to an organ donor pool—not tissue donors, and the screening process is extremely stringent.

All donors are screened according to FDA requirements for HCT/Ps, AATB requirements for tissue, and additionally, for OPTN requirements for organ donors. Please see chart on next page for specific screening criteria.

*See IFU for complete instructions.

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SCREENING CRITERIA	FDA	INDUSTRY	OSSIUM
HEPATITIS B VIRUS	●	●	●
HEPATITIS C VIRUS	●	●	●
HIV 1/2	●	●	●
ILLICIT DRUG USE, INJECTION DRUGS	●	●	●
MALARIA	●	●	●
SEPSIS	●	●	●
SYPHILIS	●	●	●
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE)	●	●	●
VACCINIA	●	●	●
WEST NILE VIRUS (WNV)	●	●	●
CLINICALLY SIGNIFICANT METABOLIC BONE DISEASE		●	●
GONORRHEA (CLINICALLY ACTIVE)		●	●
LEPROSY (HANSEN'S DISEASE)		●	●
POLYARTERITIS NODOSA		●	●
RABIES		●	●
RHEUMATOID ARTHRITIS		●	●
SARCOIDOSIS		●	●
SYSTEMIC LUPUS ERYTHEMATOSUS		●	●
SYSTEMIC MYCOSES		●	●
TUBERCULOSIS		●	●
ANKYLOSING SPONDYLITIS			●
AUTOIMMUNE HEMOLYTIC ANEMIA			●
AUTOIMMUNE HEPATITIS			●
BACTERMIA/SYSTEMIC INFECTION			●
CANCER			●
CHAGAS DISEASE			●
ENCEPHALITIS (CLINICALLY ACTIVE)			●
END STAGE RENAL DISEASE/CHRONIC DIALYSIS			●
ENDOCARDITIS (CLINICALLY ACTIVE)			●
EPSTEIN BARR VIRUS (CLINICALLY SYMPTOMATIC MONONUCLEOSIS)			●
GUILLAIN-BARRE SYNDROME (CLINICALLY ACTIVE)			●
HEMATOLOGIC MALIGNANCIES			●
MELANOMA			●
MENINGITIS (CLINICALLY ACTIVE)			●
METASTATIC DISEASE (ANY HISTORY)			●
MIXED CONNECTIVE TISSUE DISEASE			●
MULTIPLE SCLEROSIS			●
MYASTHENIA GRAVIS			●
OSTEOPOROSIS			●
PERITONITIS			●
POLIOMYELITIS			●
PROGRESSIVE SYSTEMIC SCLEROSIS (SCLERODERMA)			●
PYELONEPHRITIS			●
REACTIVE ARTHRITIS (REITER'S SYNDROME)			●
RHEUMATIC FEVER			●
STEROID TREATMENT (CHRONIC)			●
VARICELLA ZOSTER			●
VASCULITIS			●
WEGENER'S GRANULOMATOSIS			●
ANTIPHOSPHOLIPID SYNDROME			●
BLOOD TRANSFUSION IN UK OR FRANCE SINCE 1980			●
CREUTZFELDT-JAKOB DISEASE			●
DEMENTIA (ALZHEIMER'S OR UNKNOWN ETIOLOGY)			●
HEPATITIS A (ACTIVE)			●
HTLV 1/2			●
JAIL TIME (3 CONSECUTIVE DAYS IN LAST YEAR)			●
OSTEOGENESIS IMPERFECTA			●
OSTEOMYELITIS (ACTIVE)			●
TOXOPLASMOSIS (ACTIVE)			●
XENOGRAFT RECIPIENT			●

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Footnotes:

1. *A WNT protein therapeutic improves the bone-forming capacity of autografts from aged animals. Tao Chen, et al. Sci Rep. 2018; Jan 8;8:119*

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