OSSIUM HEALTH®
THE GREATEST WEALTH IS HEALTH

OSSIGRAFT ™ SAFETY

What distinguishes OssiGraft™ on safety?

Distributed by:

EXTREMITY MEDICAL
Real change *starts* here™

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TISSUE SOURCE

OssiGraft™ is derived from the vertebral bones of organ donors, a source with more stringent recovery requirements than tissue donors – the source of all other bone allografts on the market. OssiGraft™ is made from vertebral bone, without the addition of bone from other sources, which reduces the potential for cross-contamination from other parts of the body.

ISCHEMIA TIME

Bones used to produce OssiGraft™ are recovered and placed on ice within 8 hours of asystole, compared to up to 24 hours for bones used to produce other allografts on the market.

DONOR AGE

OssiGraft™ donors have an average age of 35 with a range of 7 to 55 years, which is much younger than industry standards. Older age has been linked to recent TB outbreaks associated with the viable bone allograft products made by a legacy manufacturer.

DONOR SCREENING

All OssiGraft™ donors undergo screening against stringent requirements including OPTN criteria for organ donation, FDA criteria for HCT/Ps, and AATB criteria for tissue donation.

DECONTAMINATION

OssiGraft™ is decontaminated twice to ensure the highest level of product safety. Before production starts, bones used to produce OssiGraft™ are surface decontaminated through a proprietary process. Prior to packaging, OssiGraft™ is decontaminated using a best-in-class cocktail of three antibiotics and one antimycotic:

- Vancomycin targets gram-positive bacteria
- Gentamicin targets gram-negative bacteria
- Polymyxin B destabilizes bacterial cell walls for resistant bacterial strains
- Voriconazole prevents fungal cell membrane synthesis

STORAGE

OssiGraft™ is stored in hermetically sealed, cryo-suitable double pouches, reducing the potential for contamination. Prior to shipment, OssiGraft™ is stored at true cryopreservation temperature (< -150°C), the standard for cell therapies. Hospitals may store OssiGraft™ in -80°C freezers.

STERILITY

Every OssiGraft™ lot is tested for sterility under USP <71>.

IMMUNOGENICITY

Non-immunogenicity is confirmed by a mixed lymphocytes reaction assay.