

SAFETY PROFILE

SUMMARY

PriMatrix is made from collagen, the material that makes up the majority of all human and animal tissues. The collagen used in these and many other collagen medical devices is derived from cows. As such, there is a theoretical possibility that these collagen devices could transmit viruses or variant Creutzfeldt-Jakob disease (vCJD), the human form of mad cow disease (a transmissible spongiform encephalopathy or TSE).

Per regulatory requirements, the manufacturing process for PriMatrix has been rigorously validated to assure product sterility and inactivation of any potentially contaminating viruses. Additionally, the product has been specifically designed to safeguard against the possibility of transmitting vCJD as it is derived from fetal bovine dermis. Fetal tissue, which is naturally protected against infectious agents, is a source known to be free of TSE infectivity.¹

STERILITY ASSURANCE²

PriMatrix is terminally sterilized via exposure to ethylene oxide gas. The cycle has been validated to provide a sterility assurance level of 10⁻⁶ with undetectable levels (<0.01 mg per device) of harmful ethylene oxide chemical residuals.

VIRAL INACTIVATION²

The PriMatrix manufacturing process includes a chemical viral inactivation step validated to ensure inactivation of potentially contaminating virus classes:

- Enveloped RNA virus
- Enveloped DNA virus
- Non-enveloped RNA virus
- Non-enveloped DNA virus

PRI-MATRIX TSE SAFETY

- PriMatrix is derived from **dermal** bovine tissue, which, per WHO designation, has no known detectable TSE infectivity.¹
- PriMatrix is derived from **fetal** bovine tissue which is designated safe by WHO, US and EU scientific committees as no detectable levels of TSE infectivity have been identified in fetal tissues.¹
- The source tissues for PriMatrix are selected and processed in accordance with strict US and European regulatory requirements; tissue is obtained only from animals certified fit for human consumption.²
- PriMatrix has passed the rigorous criteria for TSE safety certification by the European Directorate for the Quality of Medicines.³

WORLD HEALTH ORGANIZATION (WHO) CATEGORIES OF INFECTIVITY IN BOVINE TISSUES AND BODY FLUID¹

Category	Designation	Tissues
I	High infectivity	Brain, spinal cord, eye
II	Medium infectivity	Spleen, tonsil, lymph nodes, CSF, dura mater
III	Low infectivity	Peripheral nerves, nasal mucosa, thymus, bone marrow, liver, lung, pancreas
IV	No detectable infectivity	Skin , connective tissues, fetal tissues , striated muscle, milk, serum, feces, saliva

1- Report of a WHO (World Health Organization) Consultation on Medicinal and Other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies—With the Participation of the Office International des Epizooties (OIE)—Geneva, Switzerland, 24-26 March (1997)

2- Data on file, TEI Biosciences Inc.

3- EDQM Certificate No. RO-CEP 2004-116 Rev. 00 for Collagen Matrix, Strasbourg, 23 November 2004.

PriMatrix™ is a trademark of TEI Biosciences Inc.



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