



BioCleanse® Processed Meniscus Overview



The only meniscal allograft with both bone and meniscus sterilized through the **BioCleanse® Tissue Sterilization Process.**



BIOCLEANSE®
TISSUE STERILIZATION PROCESS

A PROVEN STANDARD FOR TISSUE SAFETY

RTI has distributed more than five million biologic implants processed through its proprietary, validated sterilization processes with zero confirmed incidence of implant-associated infection.

FEATURES AND BENEFITS

The BioCleanse processed meniscus graft provides a sterilized alternative to traditional aseptically processed meniscus allografts and sets the standard for safety and reliability.

RTI's BioCleanse processed meniscus is:

- Sterilized to a Sterility Assurance Level (SAL) of 10^{-6} through the BioCleanse Process.
- Equivalent to aseptically processed meniscus allografts in biomechanics and is biocompatible (shown in animal and in vitro studies).¹
- Provided with custom graft sizing and patient matching using the Pollard et al. technique.²
- Available with loaner instrumentation for lateral meniscus (slot technique).

ADVANCING BEYOND ASEPTIC PROCESSING

Aseptic processing does not address existing organisms or completely remove cellular elements from donor tissue.

Risk of disease transmission remains for all donated human tissue but sterilization adds a measure of safety above screening and testing alone.

RTI's BioCleanse Tissue Sterilization Process, however, has been validated to achieve a 12 log reduction of bacteria, fungi, and spores, using spores as the "most difficult case" marker per ISO 14161.¹ The BioCleanse Process has been validated to inactivate or remove a panel of viruses such as HIV and hepatitis per USP <1050>.¹

STERILIZATION WITHOUT IRRADIATION

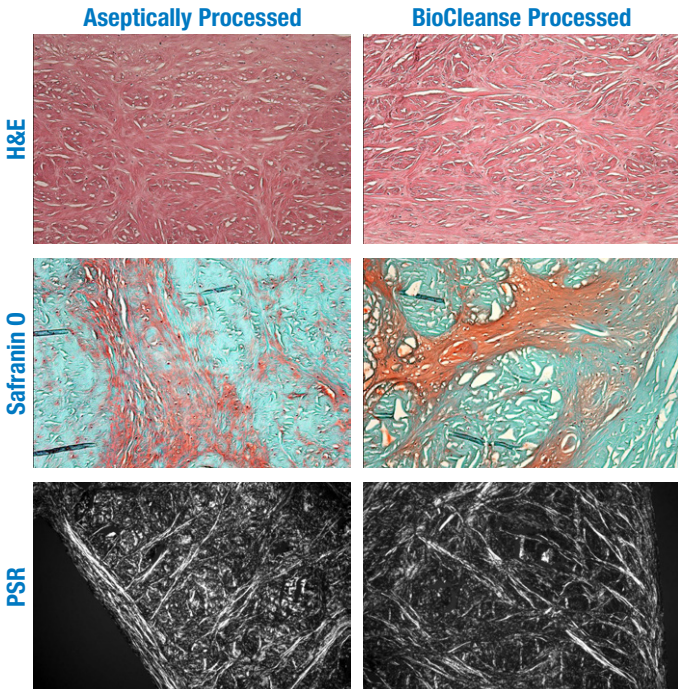
The BioCleanse Tissue Sterilization Process

- Is an automated chemical and mechanical sterilization process that achieves a SAL of 10^{-6} WITHOUT the use of irradiation for allograft tendons and meniscus.
- Uses mild detergents and sterilants common to the tissue banking industry to inactivate or remove bacteria, fungi, spores and viruses.
- Addresses donor to recipient disease transmission risk and retains the tissue's biomechanical integrity.¹

MECHANICAL AND BIOCHEMICAL EVALUATION OF CHEMICALLY STERILIZED HUMAN MENISCAL ALLOGRAFTS IN VITRO¹

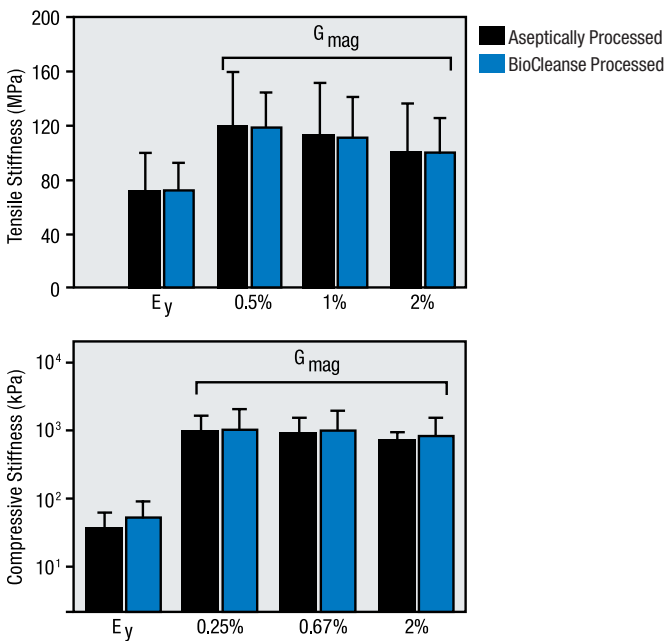
The results indicate that both grafts contain:

- Normal overall matrix appearance
- Normal proteoglycan content
- Normal collagen organization



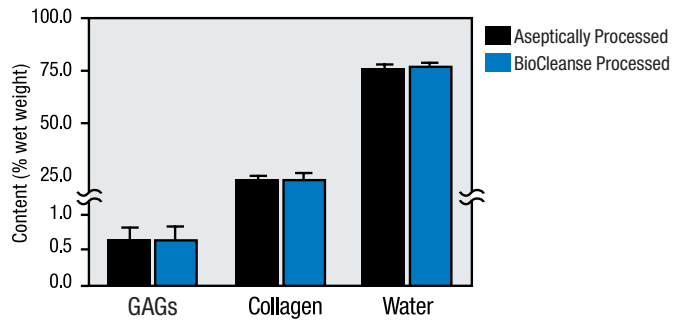
Comparison of histology for aseptically processed and BioCleanse processed human meniscus. Multiple sections were stained with H&E, safranin-O and picosirius red. 100x magnification.

IN VITRO BIOMECHANICAL TESTING¹



Tensile stiffness and compressive stiffness were evaluated between BioCleanse processed and aseptically processed meniscus allografts. The results indicate that there was no statistically significant difference in tensile stiffness between the two groups. Compressive E_y of the BioCleanse processed group was larger on average.

IN VITRO BIOCHEMICAL ANALYSIS¹

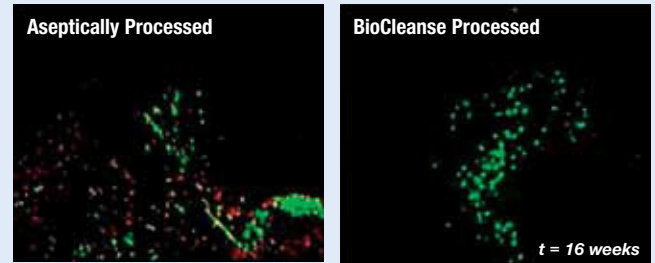


Glycosaminoglycans (GAGs), collagen and water content, which are three key components of the meniscus, were evaluated between BioCleanse processed and aseptically processed meniscus allografts.

The results indicate that there was no statistically significant difference in GAGs, or collagen content between the two groups. Water content of BioCleanse processed menisci was slightly higher (77.2 vs. 76.4% of wet weight; $p < 0.001$).

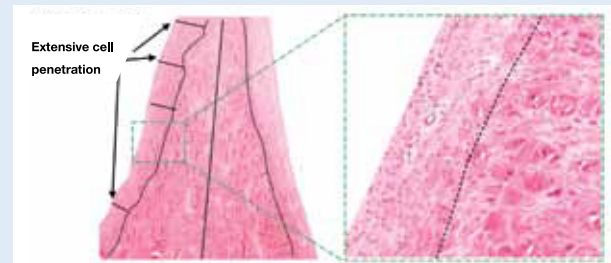
LARGE ANIMAL STUDY*¹

Living Cell Staining

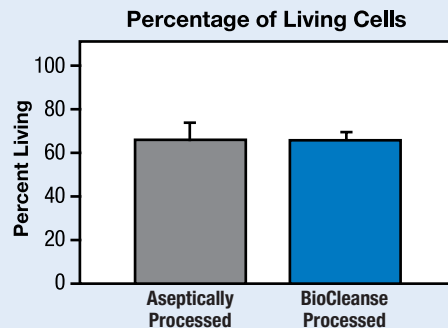


Green stain shows new cells migrating into the area. Both aseptic and BioCleanse processed groups are on normal path to remodeling.

Cell Penetration in BioCleanse Processed Meniscus



New cells are migrating into the implant and deeply penetrating the collagen matrices. The BioCleanse Process did not alter the normal remodeling of meniscal allografts in this model.



*Performance data from animal studies may not be representative of performance in humans.

ORDERING INFORMATION

BioCleanse Processed Meniscus

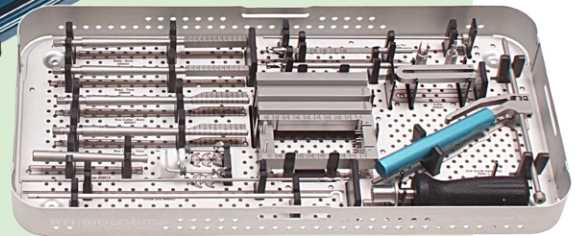
CODE	DESCRIPTION
453101	Meniscus lateral (left)
453102	Meniscus lateral (right)
453201	Meniscus medial (left)
453202	Meniscus medial (right)

To order, call RTI directly: 800.624.7238

For reimbursement information, please call: 877.839.7152
or e-mail: RTIReimbursementSupport@rtix.com



Slot technique
instrument kit



REFERENCES

1. Data on file at RTI Surgical, Inc.
2. Pollard ME, Kang Q, Berg EE: Radiographic sizing for meniscal transplantation. *Arthroscopy*, 1995. Dec;11(6):684-7.



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RTI Surgical, Inc.
11621 Research Circle
Alachua, Florida 32615
t: 877.343.6832
www.rtisurgical.com