BioCleanse® Processed Meniscus

HOSPITAL INNOVATIONS

Meniscal allograft with both bone and meniscus sterilised through the BioCleanse® Tissue Sterilisation Process.

A PROVEN STANDARD FOR TISSUE SAFETY

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

FEATURES AND BENEFITS

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

RTI's BioCleanse processed meniscus is:

- Sterilised 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. RTI's BioCleanse Tissue Sterilisation 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 U.S. FDA Q5A Guidance.1

STERILIZATION WITHOUT IRRADIATION

The BioCleanse Tissue Sterilisation Process

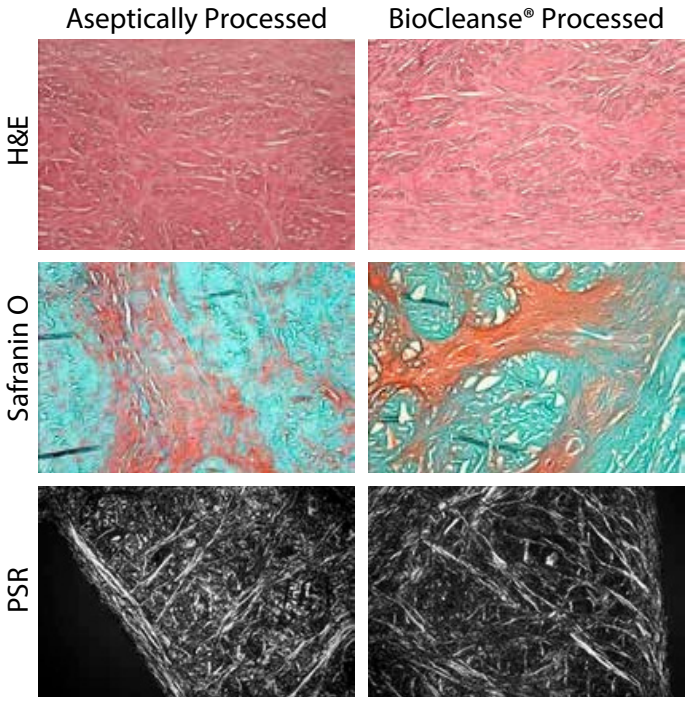
- Is an automated chemical and mechanical sterilisation
- process that achieves a SAL of 10-6 WITHOUT the use of irradiation for allograft tendons and meniscus.
- Uses mild detergents and sterilants common to the tissue banking industry to inactivate or remove bacteria, fungi, spores and viruses.
- Addresses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

BIOCLEANSE® TISSUE STERILIZATION PROCESS

MECHANICAL AND BIOCHEMICAL EVALUATION OF CHEMICALLY STERILISED HUMAN MENISCAL ALLOGRAFTS IN VITRO1*

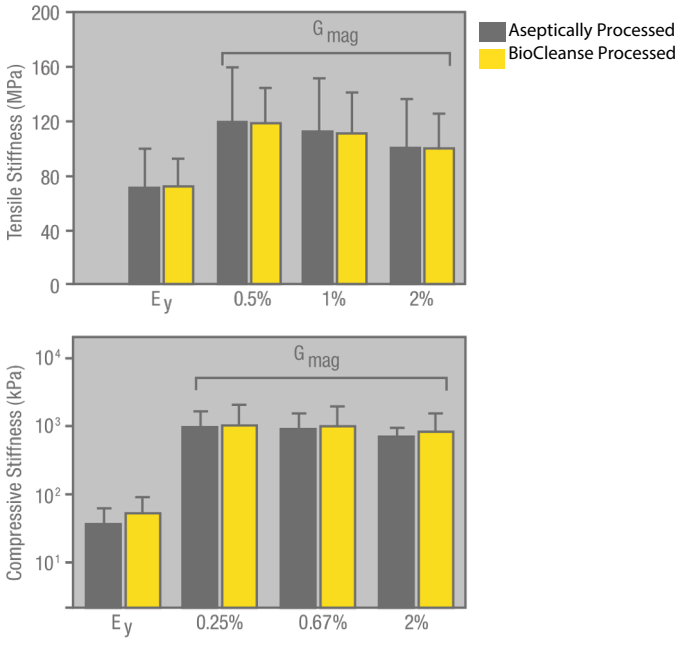
The results indicate that both grafts contain:

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



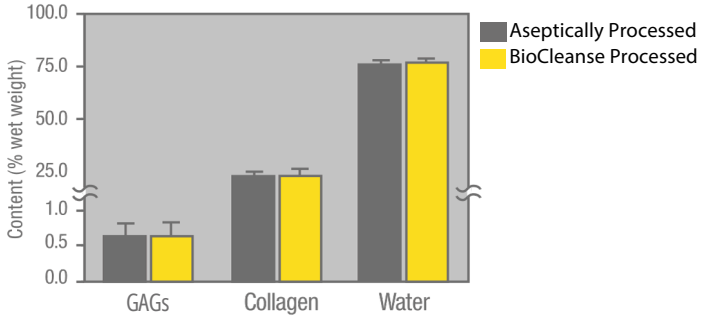
Comparison of histology for aseptically processed and BioCleanse® processed human meniscus. Multiple sections were stained with H&E, safranin-O and picrosirius red. 100x magnification.

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 Ey of the BioCleanse processed group was larger on average.

IN VITRO BIOCHEMICAL ANALYSIS1*

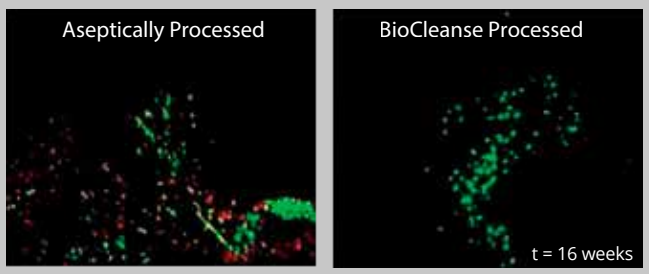


Glycosaminoglycans (GAGs), collagen and water content, which are three key components of the meniscus, were evaluated between BioCleanse processed and aseptically processed meniscus allografts.

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; $p<0.001$).

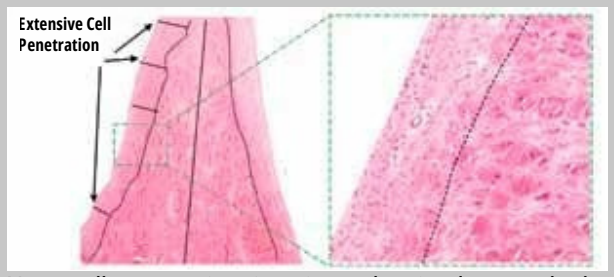
LARGE ANIMAL STUDY1*

Living Cell Staining

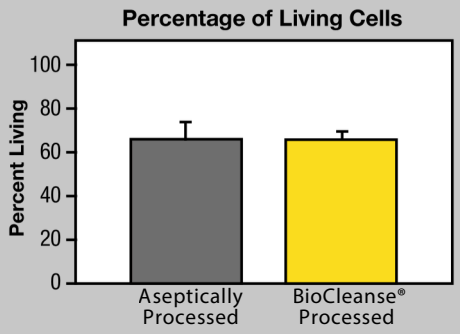


Green stain shows new cells migrating into the area. Both aseptic and BioCleanse® processed groups are on normal path to remodelling.

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.

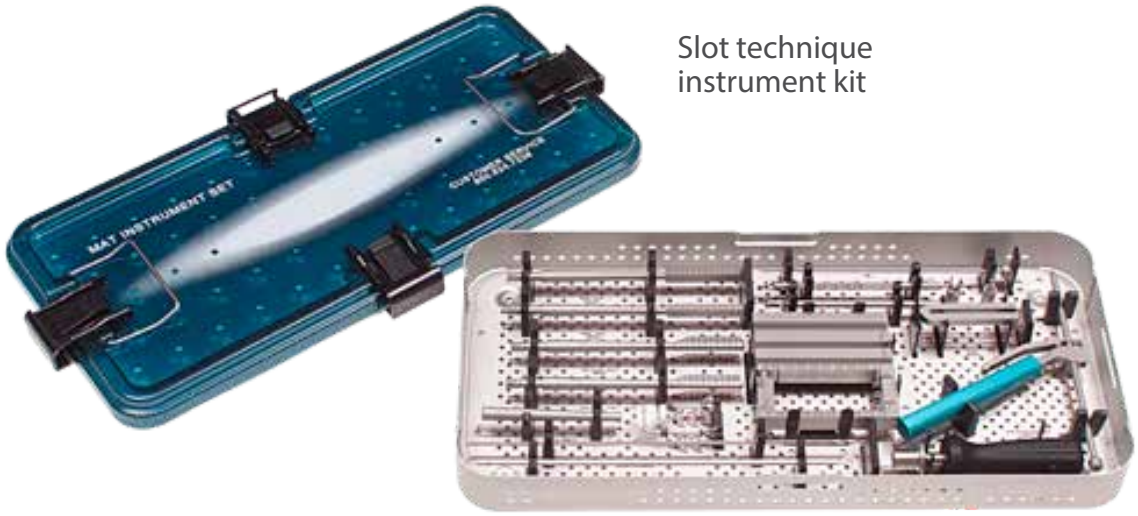


*Performance data from animal studies and lab data may not be representative of performance in humans.

HOSPITAL INNOVATIONS

BioCleanse® Processed Meniscus

Item No.	Item Description
453101	Meniscus Lateral: Left
453102	Meniscus Lateral: Right
453201	Meniscus Medial: Left
453202	Meniscus Medial: Right



Slot technique instrument kit

Speak to your local Business Development Manager for further information or contact us using the details below:

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