

SYNKROSCAFF

Indigenous

SYNKROSCAFF

Technological

SYNKROSCAFF

Classic



SYNKROSCAFF

(Tissue Engineered Pericardial Patch)



Flexible
Ultra-Thin
Saves Time
Suturability

Ease of Operation
Long Term Durability

Strong & Exceptional Features

Well Preserved Extra Cellular Matrix



SYNKROSCAFF

(Tissue Engineered Pericardial Patch)

ISO 13485:2016 & CE Certified

Device Description

SynkroScaff is comprised of a rectangular or square of Tissue engineered Bovine Pericardium that has been preserved in a buffered solution.

SynkroScaff may be tailored during surgery to meet the specific configuration according to the site of usage. It integrates with the body. Extensive quality control procedures assure a reproducible, consistent & high quality product. Stringent sterility practice with vigilance

Packing materials

SynkroScaff is supplied in a sterile and non-pyrogenic, sealed container and is designed to facilitate convenient, aseptic transfer of the pericardium to the sterile field.

Available Sizes

Not less than 4cm X 4cm, 6cm X 6cm, 8cm X 8cm

Clinical Benefits

SynkroScaff, our Tissue Engineered Pericardial Patch offers unquestionable Bio-compatibility and reliable handling for various Surgical repairs.

It has got versatile use to fill the gap and achieve anatomical correction of the biological system as and when necessary.

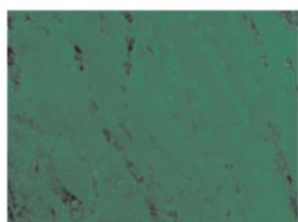
Time can be saved during procedures through the rinseless and ready to use preparation as it is non glutaraldehyde treated.

Our processing methodology incorporates an anti-calcification treatment of a proprietary nature.

Compared to other synthetic patches, suturability and reliable handling are provided.

Cytotoxicity and antigenicity are absent through the proprietary technology. Aneurysm formation and patch shrinkage have not been reported so far.

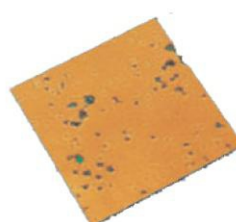
SynkroScaff can be sutured or stapled to the host tissue/blood vessel.



Homogenous appearance of SynkroScaff - by Laser Confocal Microscopy (LCM)



H&E Stain of the Indigenously Processed & Completely Acellular - SynkroScaff



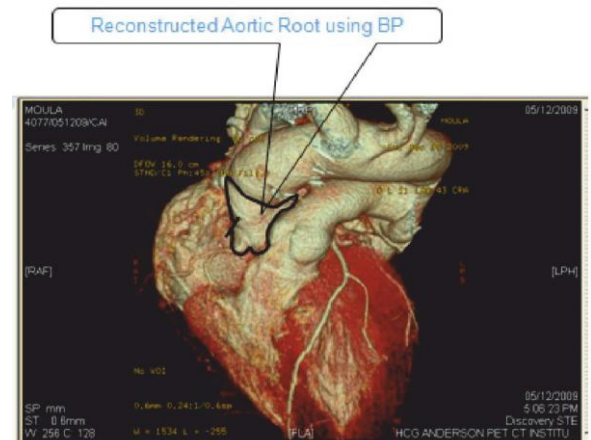
SynkroScaff- Smooth luminal surface with less light penetration - by Laser confocal Microscopy



Shows the processed pericardium, SynkroScaff

MORE INFORMATION ABOUT SYNKROSCAFF

- More than 18 Mega Pascal is the tensile strength(SCTIMST)
- More than 80°C is the Tm (melting temperature), by DSC and it remains the same after 2yrs of storage.
- For versatile usage different sizes have been produced, and all protection for the patient's use has been designed
- Excellent non thrombogenic properties
- Open carboxyhydroxyl moiety is absent which creates calcification; over and above Glutaraldehyde treatment which is 100% cytotoxic, is never used during processing. THUS WE PREVENT CALCIFICATION
- No rinsing is necessary; for enhancement of bio-activity certain suggestions have been made in the insert. It has to be taken in a kidney tray preferably in heparinised saline for bioactivity, not for prevention of clotting. That part has been taken care of by the process.

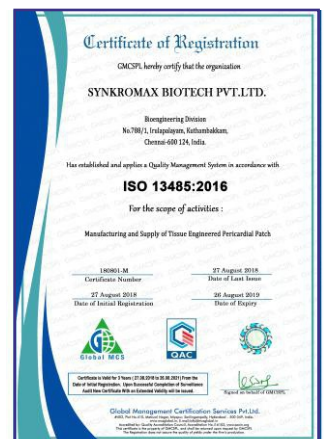


MACROSCOPIC AND MICROSCOPIC PROPERTIES

- **SynkroScaff** is rustic in look on the outer side, so that luminal side is identified easily
- Aesthetic look will damage the fine properties of this product, it will change the ionic charge.
- Being thin and strong, suturability is easier
- Bioactivity and AUTOLOGOUS cell adhesion are sure to happen as ECM structure is not disturbed and cell adhesion molecules are very much present.
- Thinness does not correlate with strength, it has a burst strength of 64K Pascal which is double the strength of Glutaraldehyde treated bovine patches.
- Since it acquires blood supply and with dynamic forces of the body for ms layers of appropriate cells and ECM it grows with the child.

APPLICATIONS

- Atrial septal defect repair
- Neonatal ventricular septal defect repair
- Augmentation of aortic arch
- Pulmonary artery patch- plasty
- As a pericardial tube reservoir in Uni-focalization
- Aortic root augmentation
- Trans-annular patch in Tetralogy of Fallot OR TO MAKE A VALVED CONDUIT OUT OF IT
- Ventriculoplasty in left ventricular aneurysm
- Making a blood vessel to resume anatomical continuity
- VENTRICULAR SEPTAL RUPTURE REPAIR as well as Mitral valve plasty
- Suture-line buttressing and many other surgical procedures from hernia, scalp repairs to wrology surgical procedures.



ISO 13485:2016



CE Certified

FAQ

What is the device?

Our device, **SynkroScaff**, is a biological patch of Tissue engineered Bovine Pericardium that has been preserved in a buffered solution with a shelf life of two year.

What are the available sizes?

SynkroScaff is currently available in three sizes i.e not less than 4 cm × 4 cm; 6 cm × 6 cm and 8 cm × 8 cm.(thickness varies from 0.3mm to 0.5mm)

Are the patches supplied sterile?

Yes, **SynkroScaff** is supplied sterile in consecutive two gamma sterilised packs apart from the gamma sterilised container.

How is SynkroScaff Packed?

SynkroScaff is supplied in a sterile, non-pyrogenic, sealed container and is designed to facilitate convenient, aseptic transfer of the pericardium to the sterile field safely.

Can the patch be cut with scissors?

Yes, **SynkroScaff** may be tailored during surgery to meet the specific configuration.

Can I re-use the unused pieces of a cut patch?

No, Any unused portion of the tissue must be disposed of as a biological waste as per hospital norms.

Can the patches be re-sterilized?

No, the patches cannot be re-sterilized.

What are the benefits of using SynkroScaff?

Compared to synthetic or other available bovine pericardial patches, suturability and easy handling are provided for the surgeons. It has got extracellular matrix intact but without any bovine cells and it integrates with the system.

Cytotoxicity, antigenicity are absent through the proprietary technology

Our processing methodology incorporates an anti-calcification treatment of a proprietary nature.

No Thrombogenicity.

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TESTIMONIALS



Prior Art

- Biomimetic acellular detoxified glutaraldehyde cross-linked bovine pericardium for tissue engineering Mathapati Santosh, Soma Guhathakurta., Materials Science and Engineering: C 33(3), 1561–1572.
- Nanofibers coated on acellular tissue-engineered bovine pericardium supports differentiation of mesenchymal stem cells into endothelial cells for tissue engineering, Mathapati Santosh, Soma Guhathakurta, Nanomedicine 9(5), 623–634.
- Thrombogenicity studies of three different variants of processed bovine pericardium, Soma Guhathakurta, ITBM-RBM(2007), doi:10.1016/j.rbmet.2007.07.003.
- Technique to process xenogenic tissues for cardiovascular implantation – preliminary report, Soma Guhathakurta, Current Science, Volume 91 No.8, 25 October 2006.
- Inflammatory responses of tissue-engineered xenografts in a clinical scenario, Mathapati Santosh and Soma Guhathakurta. Interactive cardiovascular and thoracic surgery 12, no 3(2011): 360–365.



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