Bovine Pericardial Tissue Patch

Instructions for use – English (CE)

STERILE

Device Description

The Bovine Pericardial Tissue Patch consists of one piece of bovine pericardial tissue that is cross-linked using Tisgenx's manufacturing process and selected to have minimal thickness variation. This device is provided sterile. A variety of sizes and tapered models are available but may also be tailored by the surgeon if required. The Bovine Pericardial Tissue Patch comes in the following sizes:

Model	Size (cm)
XM-04	0.6 x 8
XM-05	0.8 x 8
XM-05T*	0.8 x 8
XM-06	1 x 6
XM-07	1 x 10
XM-07T*	1 x 10
XM-08	1 x 14
XM-08T*	1 x 14
XM-09	1.5 x 8
XM-10	1.5 x 10
XM-10T*	1.5 x 10
XM-11	1.5 x 16

Model	Size (cm)
XM-12	2 x 9
XM-13	2.5 x 15
XM-14	4 x 4
XM-15	4 x 6
XM-16	4 x 16
XM-17	5 x 6
XM-18	5 x 10
XM-19	6 x 8
XM-20	6 x 10
XM-21	7 x 10
XM-22	8 x 14
XM-23	10 x 16

*These tissue sizes are tapered.

Indications For Use

The Bovine Pericardial Tissue Patch is intended for use as a surgical patch for cardiac and vascular reconstruction and repair, soft tissue deficiency reconstruction and repair, and reinforcing the suture line during general surgical procedures.

Contraindications

Do not use if allergic to tissue of bovine animal origin.

Warnings

The Bovine Pericardial Tissue Patch should only be used for procedures stated in the Indications For Use section. The safety and efficacy of Bovine Pericardial Tissue Patch has not been demonstrated for other procedures outside of the scope of the Indications For Use.

Prior to implantation, the rinsing procedure described in the Rinse Procedure section must be performed to reduce the amount of glutaraldehyde storage solution present on the Bovine Pericardial Tissue Patch. Additions of other solutions, drugs, chemicals, or antibiotics to the glutaraldehyde or rinse solution may cause irreparable damage to the tissue.

Precautions

Careful handling and preparation of the Bovine Pericardial Tissue Patch is required to avoid damage to the device. Devices that have been dropped, damaged, or mishandled in any way may not be used for human implantation.

- The Bovine Pericardial Tissue Patch is for **single use** only. Reuse, reprocessing, and/or resterilization of the device and/or failure may result in patient injury, illness or serious event. Unused pieces of Bovine Pericardial Tissue Patch must be discarded and **not reused**.
- Perform a visual inspection of the container prior to opening. If the seal is broken or if the container is damaged, contents may not be sterile and may cause infection in the patient. If the integrity of the device's container is compromised, **do not use**. If packaging is intact, open the container and inspect the contents. An adequate amount of glutaraldehyde storage solution should be present to cover the tissue and prevent drying. If the integrity of the container is compromised or if an adequate amount of glutaraldehyde is not present, **do not use** the device for human implantation.
- The storage conditions indicated in the Storage section must be followed. Do not freeze the device. Exposure to temperatures below 0°C (32°F) or above 40°C (104°F) may seriously damage the Bovine Pericardial Tissue Patch and render it **unfit for use**.
- The device must be rinsed according to the Rinse Procedure section prior to implantation. The Bovine Pericardial Tissue Patch storage solution contains glutaraldehyde which may cause irritation of the skin, eyes, nose, and throat and may also cause skin sensitization. Ensure adequate ventilation and avoid breathing in storage solution vapor during handling. Minimize skin contact. In case of contact, immediately flush area with water. If contact with the eyes occurs, seek immediate medical attention.
- **Do not use** traumatic instruments to handle the Bovine Pericardial Tissue Patch as damage may occur.
- **Do not use** the Bovine Pericardial Tissue Patch if it is damaged. Device integrity may be compromised.
- **Do not attempt** to repair the Bovine Pericardial Tissue Patch. Use a new Bovine Pericardial Tissue Patch if damage has occurred.
- **Do not resterilize**. Unused pieces of Bovine Pericardial Tissue Patch should be discarded.
- **Do not let** the Bovine Pericardial Tissue Patch dry out. Keep the tissue moist by keeping it irrigated with sterile saline on both sides.
- **Do not use** if the device is expired.

Potential Complications

Potential complications include the following:

- Restenosis
- Pseudoaneurysm formation
- Infection
- Thrombosis
- Calcification
- Fibrosis
- Vessel occlusion

- Patch rupture
- Dilatation
- Myocardial infarction
- Bleeding
- Cerebrospinal fluid leakage
- Stroke
- Vascular stenosis

Complications may also result from individual patient reaction to the implanted device or to physical or chemical changes in the components. Such complications may require reoperation and replacement of the bovine pericardial tissue patch.

Medical literature has also reported complications relating to bovine pericardium preserved using glutaraldehyde which include inflammatory reaction, sterile abscess, infection, fibrous thickening and severe hemorrhaging.

The principal complications that have been reported for bovine pericardial tissue patch are fibrosis and infection. These complications are observed only in a small minority of patients after implantation of the bovine pericardial tissue patch.

Adverse Effects

The Bovine Pericardial Tissue Patch is designed for cardiac and vascular reconstruction and repair, soft tissue deficiency reconstruction and repair, and reinforcing the suture line during general surgical procedures. The symptoms experienced from improper functioning of an implanted Bovine Pericardial Tissue Patch are similar to symptoms that arise from deficiencies in the natural organ. The implanting surgeon is responsible for informing the patient of the symptoms that indicate improper functioning of the Bovine Pericardial Tissue Patch which include the following:

1. Complete heart block and right bundle branch block in procedures involving cardiac repair near the A-V conduction bundles.
2. Late immune system attacks on glutaraldehyde-fixed bovine pericardium with subsequent tissue deterioration.
3. Calcification and histological signs of deterioration have been reported in animal studies with bovine pericardium. Phagocytosis accompanied by chronic inflammatory infiltrate between bovine pericardium and surrounding host tissue with focal degradation of implant collagen consistent with host vs. graft reaction.
4. Epicardial inflammatory reactions and patch adhesions to the heart is an adverse effect from bovine pericardium used for pericardial closure. Pericardial adhesions may increase the difficulty of repeat sternotomy.

How Supplied

One Bovine Pericardial Tissue Patch is provided sterile by Liquid Chemical Sterilization and non-pyrogenic and packaged in glutaraldehyde storage solution in a sealed container.

Storage

The Bovine Pericardial Tissue Patch should be stored at room temperature, 25°C (77°F). **Do not** expose the device to temperatures below 0°C (32°F) or above 40°C (104°F) as serious damage to the Bovine Pericardial Tissue Patch may result.

Directions for Use

Exercise care and caution while handling the Bovine Pericardial Tissue Patch. Wash surgical gloves thoroughly to remove all powder residues before handling or use powder free gloves.

Choose the required Bovine Pericardial Tissue Patch model as appropriate for the type of procedure being performed. Verify that the correct Bovine Pericardial Tissue Patch model is selected. Carefully inspect the container and seal for damage. If no damage is observed, open the container. If required, the Bovine Pericardial Tissue Patch may be cut to the appropriate size. Bovine Pericardial Tissue Patch is for **single use** only and should not be **resterilized** or repaired.

Rinse Procedure

Ensure that the tissue and rinse solution avoid contact with sources of lint or particulates such as towels and linens. Handle the contents of the container aseptically to prevent contamination.

Take three sterile containers and fill with the appropriate amount of saline as determined for each patch in the table below.

Remove the Bovine Pericardial Tissue Patch by grasping its corners with sterile, atraumatic forceps and immediately transfer to the first container of sterile saline and submerge the Bovine Pericardial Tissue Patch completely. Using the same forceps, gently agitate the Bovine Pericardial Tissue Patch in the container for two minutes. repeat two more times, each time transferring to a new container of sterile saline. Allow the Bovine Pericardial Tissue Patch to remain in the rinse container until ready for use.

Model	Size(cm)	Surface Area (cm^2)	Rinse Procedure
XM-04	0.6 x 8	9.6	Three rinses in 500 mL saline for 2 minutes each with gentle agitation
XM-05	0.8 x 8	12.8	
XM-05T	0.8 x 8	12.8	
XM-06	1 x 6	12	
XM-07	1 x 10	20	
XM-07T	1 x 10	20	
XM-08	1 x 14	28	
XM-08T	1 x 14	28	
XM-09	1.5 x 8	24	
XM-10	1.5 x 10	30	
XM-10T	1.5 x 10	30	
XM-11	1.5 x 16	48	
XM-12	2 x 9	36	
XM-13	2.5 x 15	75	
XM-14	4 x 4	32	
XM-15	4 x 6	48	
XM-17	5 x 6	60	
XM-19	6 x 8	96	
XM-16	4 x 16	128	Three rinses in 1,000 mL of saline for 2 minutes each with gentle agitation
XM-18	5 x 10	100	
XM-20	6 x 10	120	
XM-21	7 x 10	140	
XM-22	8 x 14	224	
XM-23	10 x 16	320	

Rinse procedure for sizes not listed in the table

For any patch size not listed in the table, use the following rinse instructions, which maintains the same ml/surface area as in the table.

Patch length (cm) x Patch width (cm) x 2 = Patch Area (cm^2)

For patches with a surface area < 100 cm^2, use a rinse volume of 500 mL.

For patches with a surface area of 100-320 cm^2, use a rinse volume of 1,000 mL.

Take three sterile containers and fill with the appropriate amount of saline as determined above.

Implantation

If required, cut and/or trim the Bovine Pericardial Tissue Patch to the desired shape. During implantation, prevent drying by irrigating the Bovine Pericardial Tissue Patch with sterile saline.

Surgical Technique

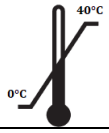
It is at the discretion of the implanting surgeon to carefully evaluate the short- and long-term risks and benefits and to consider alternative methods of treatments for each patient on a case-by-case basis. It is beyond the scope of this Instructions For Use to instruct the surgeon on specific surgical procedures. The implanting surgeon is responsible for employing the appropriate surgical techniques in accordance with the Warnings, Precautions, and Directions For Use.

The benefits and risks of using the Bovine Pericardial Tissue Patch should be disclosed to the patient before surgery. Medical follow-up with the patient is advised so that complications can be promptly diagnosed and properly treated to minimize danger to the patient.

Refer to the symbol legend at the end of this document.

Symbol Legend

Symbol	Definition
SN	Serial number
REF	Reference number
	Manufacturer
	Date of Manufacture
	Expiration date
	Caution
	Consult instructions for use
EC REP	CMC Medical Devices & Drugs S.L., C/ HoracioLengo Nº 18, CP 29006, Málaga, Spain Tel: +34951214054 Email: info@cmcmedicaldevices.com www.cmcmedicaldevices.com

Symbol	Definition
STERILE	Sterile
	Do not resterilize
	Do not re-use
	Temperature limit
	Fragile/Handle with care
	Do not use if package is damaged
	Non-Pyrogenic
CE 1434	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) 469 Pulawska Street 02-844 Warsaw Country : Poland Phone : +48 (22) 46 45 200 Email : polskie.centrum@pcbc.gov.pl Website : www.pcbc.gov.pl Notified Body number : 1434

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Revision Record

ECO #	Date of Distribution	Revision	Description of Change
256	08/05/20	NEW	Initial Release
278	12/15/20	R01	New Sizes XM-01 - XM-03 were included in the size table and in the rinse procedure table. The Notified Body Address was updated and an Effective Date was included in the footer.
322	5/23/21	R02	Removed Sizes XM-01 - XM-03 from the size table and the rinse procedure table
325	1/28/22	R03	Rinse Procedure Table updated to reflect the correct amount of saline to use, starting with XM-16 and below.
326	2/1/22	R04	Removed information regarding XM-01 to XM-03 from the Device Description and How Supplied sections. Phone and email updated on pg. 4
338	4/4/22	R05	Updated phone to +1 (949) 670-0403 on page 4