

### **Antibiotics Interaction Literature Search**

In an effort to evaluate the validity of the statement in the Glycar Pericardial Patch IFU which reads: “Antibiotics and/or anti-cycotics must NOT come in contact with the SJM Pericardial Patch with EnCap technology as these are known to alter the cross-link characteristics of tissue fixed in aldehyde preparations”, a literature search was performed.

The search was conducted using PubMed.gov search engine via the University of Minnesota Library Subscription. The terms utilized in the search were as follows (all fields were searched for matching terms):

(glutaraldehyde fixation) AND (effects of antibiotics))  
(bovine pericardium) AND (antibiotics)  
(glutaraldehyde fixed tissue)AND (antibiotics)  
(glutaraldehyde) AND (effects of antibiotics)  
(pericardium) AND (effects of antibiotics)  
(extra cellular matrix) AND (effects of antibiotics)  
(bioprosthetic heart valve tissue) AND (effects of antibiotics)  
(aldehyde fixation ) AND (antibiotic exposure)

Four articles were found to be pertinent to the IFU statement in question. Two of the articles indicate an increase in durability of glutaraldehyde fixed tissue exposed to antibiotics. An additional article that is related to the scope of this search describes the use of a glutaraldehyde fixed bovine wound dressing treated with gentamycin. Also, an article was discovered that points to a possible decrease in calcification development on tissue that is glutaraldehyde fixed and exposed to antibiotic solutions.

Each article citation and a short summary for each are provided.

1. Raghavan D, Starcher BC, Vyavahare NR. Neomycin binding preserves extracellular matrix in bioprosthetic heart valves during in vitro cyclic fatigue and storage. *Acta Biomater.* 2009 May; 5(4): 983-992.

The article written by Raghavan et al. describes a study in which the team looks at the effect of adding neomycin sulfate to traditional glutaraldehyde fixed bioprosthetic heart valve cusps. The results of the study suggest the addition of the neomycin trisulfate showed increased glycosaminoglycans retention after 10 million and 50 million accelerated fatigue cycles and after 1 year of storage in glutaraldehyde storage. The study authors conclude that use of neomycin binding to the tissue cusps prior to standard glutaraldehyde crosslinking may increase tissue stability and valve durability.

2. Moses O, Shemesh A, Aboodi G, Tal H, Weinreb M, Nemcovsky CE. Systemic tetracycline delays degradation of three different collagen membranes in rat calvaria. *Clin. Oral Impl. Res.* 20, 2009: 189-195.

The article written by Moses et al. describes a study that quantifies the effect of systemic tetracycline on the degradation of collagen membranes. Membrane disks were separated into non cross linked, glutaraldehyde cross-linked, and ribose cross-linked and implanted into the skull of 40 rats. The results of the study showed statistically significant interactions between the membranes and administered tetracycline. The study suggests that tetracycline administered in sub-antibacterial doses (in this study 50% of minimal recommended antibacterial dose as mg/kg) may reduce biodegradation and enhance bio-durability of collagen members.

3. Chandy T, Vasudev S, Rao G. Changes in Pericardial Decalcification Due to antiplatelet Agents: In Vitro Studies. *Artificial Organs.* 1998; 22(8): 666-671.

This article describes a study conducted to determine the effects of an aspirin solution (in combination with vitamins, antibiotic, or an anesthetic) on glutaraldehyde fixed pericardial tissue. The calcification process of the tissue immersed in the three different aspirin solutions was observed. The authors of the study concluded that the finds suggest that the aspirin solutions may be beneficial for prevention of thrombosis and calcification. This article does not specifically address the effect of the aspirin/antibiotic solution on the fixed tissue.

4. Chanda J, Rao SB, Mohanty M, Muraleedharan CV, Arthur VL, Bhuvaneshwar GS, and Valiathan MS. Use of glutaraldehyde-gentamycin-treated bovine pericardium as a wound dressing. *Biomaterials* 1994; Volume 15(1): 68-70..

This article describes the use of a glutaraldehyde bovine pericardial patch used for wound healing purposes. The patch is treated with gentamycin and the article discusses no effects of the antibiotic on the tissue properties or characteristics of the pericardial patch.

SJM did not find any articles indicating that a negative interaction occurs when glutaraldehyde fixed bovine pericardium is exposed to antibiotic agents. The literature found during this search points toward a positive effect in regards to tissue durability.

For more information on the Glycar Pericardium Patch, please contact Glycar (Pty) Ltd.

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