



Memo

DATE: 14 October 2016

SUBJECT: Religious Concerns- Porcine Derived Medical Devices

To Whom It May Concern,

We are grateful that you have expressed interest in the use of our product and look forward to the possibility of supporting you and your needs in the years to come. At Cook Medical, we strive to put the patients at the forefront of everything we do. We understand that you have expressed some level of concern surrounding the use of Cook's Biodesign[®] product as it relates to various religious restrictions. This memo is intended to provide additional information about our Biodesign[®] products, the source material, and processing techniques so that their use can be properly evaluated related to religious implications.

Our Biodesign[®] products are derived from porcine small intestinal submucosa (SIS). The detailed processing that the product undergoes decellularizes the material, leaving behind a three-dimensional, acellular, collagen-rich extracellular matrix (ECM). Many products used in healthcare come from animal or cadaveric sources, including organs and tissue.

All Cook Biodesign[®] products are manufactured using a multi-step, rigorously controlled, disinfection process that has been validated by an independent virology laboratory to inactivate all known viral types. This process has been audited and found to be appropriate by both the United States Food and Drug Administration (FDA) and TUV, a certified notified body within the European Union.

We recognize that since our product is derived from pigs, there is some level of scrutiny on whether it is acceptable to perform surgery using our device on those of Jewish and Muslim faith. While we leave the ultimate decision on whether the product should be used to each physician or patient, there are a few points we'd like to highlight from several sources that may be valuable when deciding if the product is appropriate for use.

In accordance with the Jewish faith, members of the faith are forbidden to eat pork or raise pigs. However, Judaism also greatly values preserving life and reducing suffering.¹ It has been stated that if a porcine product is used to save a Jewish life, all religious laws are automatically suspended because Jewish law permits the violation of certain rules to achieve the higher good of protecting life.² Conflicting views within the faith have created a wide range of opinions on the matter. Some believe that all use of porcine products are prohibited, while others believe that followers of Judaism are not forbidden to derive benefit from porcine products, although they are prohibited from consuming pork.¹ People in different countries, generations, or family configurations vary in how they approach Jewish law and medical issues.³



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The best mode of action is to inform the patient that product is being used and allow them to get specific permission or interpretation from their rabbi, unless the hospital has a specific protocol for these issues.

In similar fashion, Islam also has prohibition when it comes to consumption of porcine products. This faith also greatly values life, as it is considered a duty to save life.⁴ While pork is unacceptable to be consumed, it is acceptable in situations for which no lawful alternative is found.⁵ Others believe that, compared to a porcine-derived product, the use of a non-animal alternative is the preferred option, despite whether it takes longer to heal or is more expensive.⁶ With that said, if there is no appropriate product available, our product has been deemed acceptable by religious leaders in the past. In the history of our product, there have been a wide range of opinions on the use of the material. Therefore, it is recommended that the Muslim patients be involved in the decision-making related to their medical care. Consulting with their local cleric will ensure that the surgical product is acceptable.^{1,6}

Hopefully this information is valuable to you. As mentioned previously, our material has been studied extensively and been used in all regions of the world. However, we value patients and want to respect the cultures and customs of all potential patients. We look forward to working with you. Please let your sales representative know if you have any further questions or concerns.

Sincerely,

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