FAQs – GORE® SYNECOR Biomaterial Website

Can a patient with an implanted device made from PTFE and polyglycolic acid/trimethylene carbonate (PGA/TMC) copolymer safely undergo radiation and/or chemotherapy?

Yes. The amount of radiation needed to degrade PTFE is substantially above the patient survival dose. There have been no specific studies conducted to assess the impact of radiotherapy or chemotherapy on our PGA/TMC material. There is clinical evidence, however, of acceptable outcomes of patients receiving postoperative chemotherapy following implantation of GORE® BIO-A® Tissue Reinforcement. Additionally, GORE® BIO-A® Tissue Reinforcement is gamma irradiated during sterilization at doses that are typically much higher (i.e., up to 500x) than therapeutic radiation doses.

Has there ever been an allergic reaction to a Gore product made from PTFE and PGA/TMC material?

No. Since PTFE is one of the most inert and biocompatible polymers available, there has never been a confirmed allergic reaction to a Gore PTFE product. There have been no allergic cases reported to Gore on our PGA/TMC material and it is not expected to elicit an allergic response.

How will a device made from PTFE and PGA/TMC show up on CT, MRI, or X-rays?

Because of the density differences between PTFE and the rest of the body, high resolution imaging techniques, such as CT and MRI, will reveal PTFE, both immediately following implant and after ingrowth at longer time frames. X-rays offer a fairly low resolution level and will not show a PTFE product.

Because of the inherent chemical and density differences between the PGA/TMC polymer and the rest of the body, adequately high resolution imaging techniques, such as CT and MRI, should reveal the presence of the implant. The material will not be damaged nor interfere with the MRI other than by being visible. However, the original signal will slowly fade as the implant degrades and is assimilated into the tissue.