Atraumatic anchoring fin technology:

An evaluation of GORE® VIABIL® Biliary Endoprosthesis following acute and chronic implantation, and removal in domestic swine

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Purpose

The purpose of the study was to evaluate the patency and to characterize the tissue response of the swine bile duct following removal of the GORE® VIABIL® Biliary Endoprosthesis. Removal of the device represents the worst case trauma applied to the bile duct by the atraumatic anchoring fins.

Study design

Eight (N = 8) domestic swine were entered into this study. A GORE® VIABIL® Biliary Endoprosthesis with anchoring fins was endoscopically implanted in the bile duct of each animal. Animals were equally divided into two groups. At 3 (±1) days (Group 1) and 39 (±3) days post-implant (Group 2), the GORE® VIABIL® Biliary Device was removed, photographed, and examined by the histopathologist *(Figure 1)*. Following removal, the animals were recovered and remained in-life. The total in-life period was 33 (±3) days for (Group 1) and 69 (±3) days for (Group 2). At the end of each in-life phase, the animals were euthanized. The bile duct of each animal was tested for patency and the tissues were submitted to histology for gross and microscopic examination. Photographs were taken. Implant, device removal, and end-of-life observations were recorded.

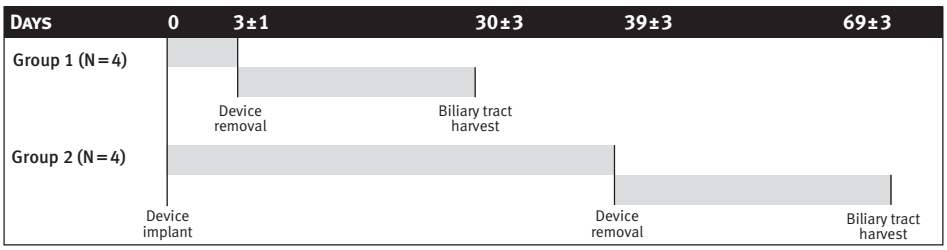

Figure 1: Study timeline.

Results

All animals were successfully implanted with a GORE® VIABIL® Biliary Endoprosthesis and completed the in-life phase without clinical concern.

All attempted device removals were successful using either a snare or sharp tooth graspers. Devices were either withdrawn through the working channel of the endoscope or were removed with the endoscope. Two devices were not present at the time of removal due to undetected migration. Although it was unknown when the devices migrated from the common bile duct, the tissues were examined at biliary tract harvest and also included in histology.

Group 1 (N = 4)

Device removal day 3: The devices were easily removed with minimal manipulations. The devices were patent and generally clear of material in the lumen. The abluminal surfaces of the devices were translucent, and largely devoid of tissue except for small fragments of mucoid material beneath anchoring fins or frame elements *(Figure 2)*. Endoscopically, the bile duct demonstrated minimal to no bleeding following device removal. There was dilation of the papilla, and no apparent perforations of the common bile duct. All ducts were patent.

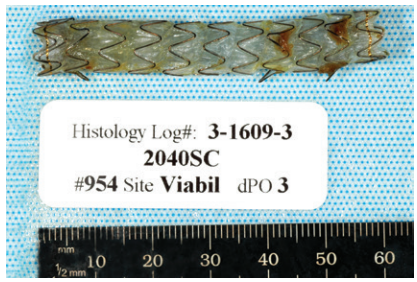

Figure 2: Representative group 1 explant.

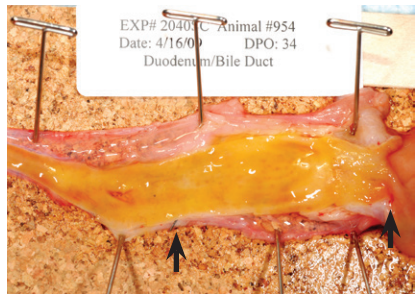

Figure 3: Representative group 1 — Excised bile duct stented segment is the distal ~5 cm of common bile duct (between arrows). The mucosa is intact and the duct maintained patency.

Figure 4: Representative group 2 explant — The abluminal surface is pigmented yellow-brown with the distal pole (duodenal end) brown-black. The lumen is patent. Picture is labeled incorrectly, device is 39 days post-operative (implant).

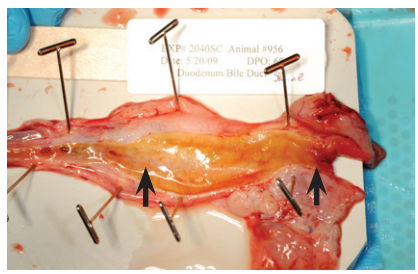

Figure 5: Representative group 2 excised bile duct — Stented segment is the distal ~5 cm of common bile duct (between arrows). The mucosa is intact and the duct maintained patency.

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Biliary tract harvest day 30: There were no significant findings of the excised bile duct *(Figure 3)*. There was no evidence of bile duct trauma, stricture, or stenosis in any animal. The biliary mucosa appeared intact with no evidence of hemorrhage or inflammation. The biliary papilla appeared intact.

Group 2 (N = 2)

Device removal day 39: The devices were removed with minimal manipulations. The devices were patent. The abluminal surfaces of the devices were pigmented and largely devoid of tissue except for small fragments of mucoid material beneath the anchoring fins *(Figure 4)*. Endoscopically, the bile duct following device removal demonstrated minimal to no bleeding. There was dilation of the papilla and no apparent perforations of the common bile duct. All ducts were patent.

Biliary tract harvest day 69: There were no significant findings of the excised bile duct *(Figure 5)*. There was no evidence of bile duct trauma, stricture, or stenosis in any animal. The biliary mucosa appeared intact with no evidence of hemorrhage or inflammation. The biliary papilla appeared intact.

Histology

Groups 1 and 2: The bile duct wall structure was intact in all animals. There were no significant findings in the stented or unstented portion of the bile ducts. There was a normal range of light to moderate infiltrates of lymphocytes within the submucosa. Mucosal epithelium was variably present on all sections, including those from the unstented portions of the duct, and was not associated with a tissue reaction *(Figure 6 and 7)*.

Conclusions

The bile ducts of all eight animals were patent at the time of euthanasia without evidence of bile duct trauma, stricture, or stenosis. Two devices migrated at some unknown time prior to the scheduled removal in Group 2. The remaining six GORE® VIABIL® Biliary Devices were removed easily with minimal manipulations.

In all cases, there was no endoscopic, gross, or histological evidence of tissue damage due to the atraumatic anchoring fins.

Within the scope of this animal study, the GORE® VIABIL® Biliary Endoprosthesis with atraumatic anchoring fins was safely implanted and removed from the biliary tract of domestic swine with minimal impact to the bile duct.

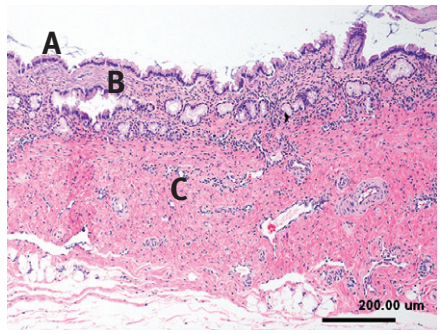

Figure 6A: Representative group 1 anatomy stented common bile duct pig #954 (HE Stain):
A – Mucosal epithelium
B – Lamina propia
C – Muscularis and collagen

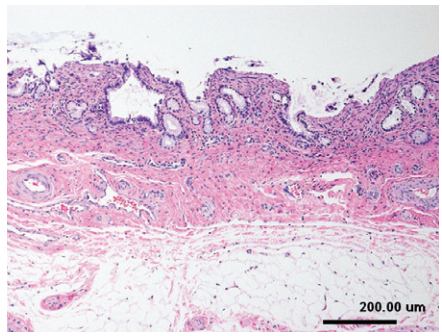

Figure 6B: Representative group 1 anatomy unstented cystic bile duct pig #954.

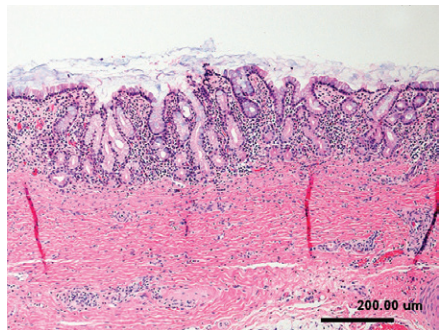

Figure 7A: Representative group 2 anatomy stented common bile duct pig #951.

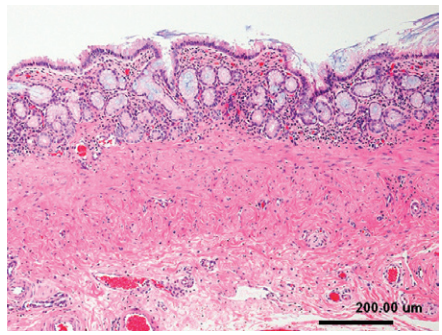

Figure 7B: Representative group 2 anatomy unstented hepatic bile duct pig #951.

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INDICATIONS FOR USE:
USA: THE GORE® VIABIL® Biliary Endoprosthesis is indicated for the treatment of malignant biliary strictures.
EUROPE AND CANADA: The Removable GORE® VIABIL® Biliary Endoprosthesis is indicated for the treatment of benign and malignant biliary strictures and can be removed from such strictures for up to one year post-implant.

Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications. ℞ Only

Products listed may not be available in all markets.