

# GORE® BIO-A® Fistula Plug in Complex Fistula Repair

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## Clinical Challenge

A 45-year old female patient presented with a complex fistula and Crohn's disease. The fistula was extrasphincteric with its origin 3-4 cm above the dentate line in the left dorsal aspect. The tract was slightly curved, approximately 8-9 cm long and 4-5 mm in diameter. Intestinal Crohn's disease was stable for more than a year without any medication. The patient had undergone two previous mucosal flap repairs, neither of which resulted in definitive fistula resolution.

## Procedure Overview

A draining seton had been placed for 12 weeks before the plug was implanted in order to permit drainage and reduce inflammation. The fistula repair was accomplished in two stages: 1) secondary tract removal and 2) GORE® BIO-A® Fistula Plug implantation into the primary tract.

The fistula tract was gently debrided and irrigated with a water based solution to remove granulation tissue that may have developed within the fistula. The external opening was excised to remove all superficial epithelium. A suture was thrown through all six tubes of the GORE® BIO-A® Fistula Plug, which was then used to deploy the device. Although this fistula was rather large, the six tubes were sufficient to occlude the tract. At the internal opening, a circumferential mucosal pocket was created to cover the device during the first few days after implantation. The disc was fixed to the mucosa with three bioabsorbable sutures (PDS 2-0). Excess length of tube material was removed at the external orifice.

## Clinical Results

The GORE® BIO-A® Fistula Plug was implanted in September 2009. During the healing process, only moderate drainage was observed from the external opening. These symptoms subsided within the first three months following implantation.

Approximately three months after the procedure, the fistula was completely healed. There was no sign of drainage, and closure of both the internal and external openings of the fistula occurred. Eighteen months following the treatment, the patient continues to do well and is satisfied with the result. Continence was not negatively influenced; the patient was completely continent throughout follow up.

## Surgeon Comments

GORE® BIO-A® Fistula Plug is made of a synthetic, 100% bioabsorbable material. Its macroporous, three-dimensional web structure acts as a scaffold to encourage tissue in-growth. It is an acceptably robust material. Furthermore, the device was quick and easy to be implanted during use. The performance of the GORE® BIO-A® Fistula Plug in this complex and recurrent fistula case is promising. Further study is needed to provide longer-term clinical evidence.



Figure 1. Patient condition before treatment



Figure 2. Plug insertion



Figure 3. Covering the disc with a mucosal pocket



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