



GORE[®] BIO-A[®] Fistula Plug

FREQUENTLY ASKED QUESTIONS

GENERAL QUESTIONS ON PROCEDURE TO TREAT FISTULAS:

- **What sort of activity can the patient undertake after the procedure?**

Patients who have undergone a fistula repair procedure may be advised according to the standard of care prescribed by the surgeon. This may include little or no physical activity within two weeks of the procedure. Patients may also be advised to refrain from strenuous physical activity, which may include but is not limited to heavy lifting or running.

- **Do you recommend debriding / curetting the tract?**

We do not have particular recommendation on debriding or curetting the tract prior to placing the plug. The standard of care prescribed by the surgeon should be used in this case.

Gently debriding or curetting the tract creates a non-epithelialized wound bed, which may influence the infiltration of cells that function in wound healing and regeneration of tissue. Care should be taken during debriding since it has the potential to enlarge the fistula tract.

SPECIFIC QUESTIONS REGARDING PLUG USE:

- **Do you close the internal opening of the fistula tract? Close the external opening(s)?**

The disk of the GORE[®] BIO-A[®] Fistula Plug is securely seated at the internal opening by being sutured to or covered with the patient's rectal mucosa. To allow for natural drainage of the fistula tract in the post-operative period, the external (secondary) opening of the fistula tract should not be closed completely.

- **How can I tailor the device to fill the tract?**

While cleaning and preparing the fistula tract, obtain an estimate of the diameter of the tract. Six tubes can fill a fistula tract of approximately 6 mm in diameter. Tubes can be trimmed off as needed to accommodate the diameter of the fistula tract. Care should be taken not to enlarge the fistula tract.

- **What guidelines do you have on trimming the plug (disk or tubes)?**

Using sharp sterile scissors, trim the disk diameter to a size appropriate for the defect allowing for adequate fixation of the disk to the rectal mucosa. Care should be taken to avoid the creation of sharp edges or corners when trimming the disk. In trimming off tube(s) for sizing the plug for the fistula tract: remove the center-most tubes first. Take care to ensure that the disk lies flat and is well apposed to the rectal mucosa at the internal (primary) opening of the fistula tract.

- **What type of suture can I use?**

A 2-0 or 3-0 resorbable suture on an SH needle have been commonly used for suturing the disk to the mucosa.

- **What can I expect post-operatively?**

It is common for patients to experience drainage during the first post-operative month. Post-operative drainage and inflammation peak around four weeks and is considered normal. Patients should be advised that they may experience discomfort during this period. These symptoms will subside as tissue is regenerated and the material is absorbed over six months. Published literature regarding fistula repair with a plug determined that longer follow-up has the ability to account for slow healers¹, and that the decision whether the operation should be considered a failure rests with the individual surgeon, but should not be taken for a minimum of three months².

QUESTIONS REGARDING THE GORE® BIO-A® MATERIAL:

- **What is left once the material is absorbed?**

Cells infiltrate the 3D matrix and replace the web with vascularized soft tissue at an approximate 1:1 ratio as it absorbs over six months. Histology from animal and human explants indicates the tissue is initially a mix of type I and type III collagen with maturation into primarily type I collagen, reflecting a normal wound healing process.

- **How is this different from a “biologic”?**

GORE® BIO-A® Material provides a non-permanent scaffold for tissue generation like biologics, but is made of bioabsorbable polymers (67% PGA:33% TMC). Due to its synthetic nature, the product is consistent and uniform with handling characteristics that facilitate placement and no risk of human or animal source contamination. It is easy to use with no operative preparation, such as soaking or stretching.

- **What is the clinical history of this bioabsorbable tissue scaffold?**

Gore bioabsorbable technology is backed by 15 years of research and clinical use in numerous parts of the body including the mouth, abdominal wall, colon, stomach, heart, lung, liver, pancreas, and spleen.

¹ Wang JY, Garcia-Aguilar J, Sternberg JA, Abel ME, Varma MG. Treatment of Transsphincteric Anal Fistulas: Are Fistula Plugs an Acceptable Alternative? *Disc Colon Rectum* 2009; 52(4):692-697.

² The Surgisis® AFP™ anal fistula plug: report of a consensus conference. *Colorectal Dis.* 2008; 10(1):17-20.

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