

ANAL FISTULA REPAIR SYSTEM

Fistula Rasp for removing epithelia of anal fistulas with skin openings, in combination with a plug (acellular matrix)

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Introduction and Objective

Currently, no instrument meets the need for removing anal fistulas.

The main concern with current techniques is the limited tissue ingrowth of max 50% into the "repaired" site.

Thus, the idea of a fistula rasp was born.



Clinical Background

Especially fistulas from the rectum to the skin cause pain, abscess and discharge. This is a common type.

The literature documents that repair of these types of fistulas have a success rate of only about 50 – 60% of all attempts to close the fistula.

Clinical Background

The mucosal lining (epithelium) is the root cause for the high failure rate in permanently closing the fistula.

Bacteria regularly settle on the epithelium. Also, the slimy film secreted by the epithelium hinders the ingrowth of healthy tissue needed to close the fistula. Both factors lead to a high recurrence rate of fistula repair.

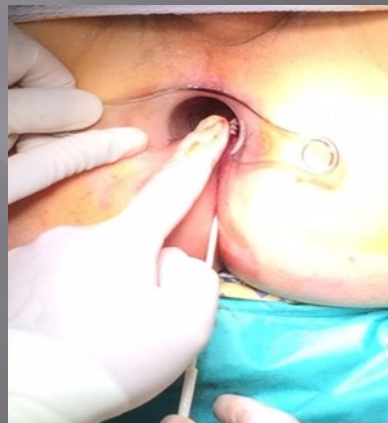
The key to success is the complete removal of epithelial tissue without damaging the sphincter, as some fistulas proceed through the sphincter fibers.

Product Description of Fistula Rasp

- ▣ The Fistula Rasp contains several fine, sharp edged parallel „plates“ with gaps in between.
- ▣ The sharp edges cut into the fistula lining (epithelium), the cut tissue gets stuck in the „plates“, removing the epithelium.
- ▣ If needed, the fistula lining can easily be wiped off with a dry compress and the rasp process can be repeated.



Removal of Epithelium



Rationale

Cleaning the fistula passage by removing the mucosal tissue (epithelium) results in the almost complete absence of bacteria in the fistula passage, therefore greatly increasing the healing properties.

Summary

The properties of the product, namely desquamating and removal of the mucosal tissue (epithelium) via the plates of the Fistula Rasp, are clinically proven and a risk for patients can be excluded.