

Fisturasper®



AGI.medical, Inc.
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 USA



0483

Symbols

	Catalog Number
	Lot Number
	Do not reuse. For single use only
	Attention. See Instructions for Use
	Sterilized by ethylene oxide. The product is sterile if the product is not open or damaged.
	Quantity. Contents
	EU-Conformity Symbol
	Use By
	Manufacturer
	Caution: Federal (USA) law restricts this device to sale by or on the order of a Physician
	Contains no natural rubber latex

INDICATIONS FOR USE

Fisturasper is intended for the removal of the epithelial and mucosal lining of fistulas protruding through the skin.

Description

Fisturasper contains several fine plates, arranged and spaced parallel to each other. The edges of the plates are sharp, thereby achieving a rasp effect.

Fisturasper can be used on all fistula (openings out of the body to the skin with mucosal lining, developed on its own, often discharging pus) where as described below, epithelial or mucosal lining needs to be rasped off and transported to the outside, away from the fistula.

The use of *Fisturasper* is especially beneficial in cases where fistulas are located between sphincter muscle fibers, which otherwise would have to be destroyed, which in turn can lead to weakness of the sphincter muscles.

INSTRUCTIONS FOR USE

The soft tissue of a fistula, its epithelial or mucosal lining, is rasped, or scaled off by the sharp edges of the *Fisturasper* plates. The scaled off tissue remains in the spaces of the plates, thereby being removed and transported away from the fistula.

Remove the scaled off tissue with a dry compress and repeat the rasping process until the complete epithelial or mucosal lining has been removed.

Disposal

Fisturasper is for single use only. Dispose *Fisturasper* directly after use in accordance with the applicable regulations for disposable medical products.

DISCLAIMER

In case of non-intended use (misuse) of *Fisturasper*: neither manufacturer nor distributor of *Fisturasper* assume any liability of damage to persons or/and damage of property due to any use which is contrary from the above mentioned intended use (non-intended use, respectively misuse) of *Fisturasper*.

SAFETY NOTES

Definitions

Warning: Could result in death or injury to the patient.

Caution: May result in minor injury to the patient.

Note: May result in property damage or advises on the proper use of the product.

Important Technique: Key instruction aiding the successful use of the product.

Warning: None

Caution: *Fisturasper* is a single use device. Reusing this device may lead to infections, due to transmittance of germs, bacteria, residual proteins, etc.