

Brief Summary Document

Product

Piranha™ Ureteroscopic Biopsy Forceps

IFU 51618901-01B

Rx Statement

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

This device is restricted to use by or under the supervision of physicians trained in endoscopic urological biopsy procedures.

Content

INTENDED USE/INDICATIONS FOR USE

Biopsy Forceps are designed specifically to collect tissue endoscopically for histologic examinations. These instruments are intended for adult endoscopic urological biopsy such as the acquisition of neoplastic tissue in the kidney and ureter and should not be used for any purpose other than their intended function.

ADVERSE EVENTS

The potential complications that may result from the use of Piranha Ureteroscopic Biopsy Forceps include:

- Tissue Trauma
- Tissue Perforation
- Bleeding/Hemorrhage
- Injury to Kidney
- Injury to Ureter
- Infection
- Inflammation
- Pain/Discomfort
- Ureteral Stenosis

There are no known CONTRAINDICATIONS, PRECAUTIONS or WARNINGS associated with the use of this medical device.