



Single-Use

SurgyCut Biopsy Forceps

Instructions for Use



▶ Product Description

U.S. Surgitech's SurgyCut Biopsy Forceps are single-use forceps supplied sterile and intended to be disposed of after use. Biopsy Forceps are used for grasping, preparing, and dissecting tissue and potentially for removing biopsies in cystoscopy.

▶ Intended Use

For use with a cystoscope in minimally invasive procedures to grasp, prepare, and dissect tissue and to obtain biopsy tissue in cystoscopy. The instrument is not intended for use when minimally invasive techniques are contraindicated and is not to be used in open surgical procedures.

▶ Intended User

Trained Surgical Healthcare Professionals.

▶ Inspections

- Inspect the instrument thoroughly before use for damage such as nicks, cuts, pits, and cracks.
- Do not use if the sterile package is opened or damaged.
- When removing the instrument from the surgical site, inspect the jaws again to ensure they are intact.

▶ Patient Population

Surgycut biopsy forceps is suitable for use by adults of all genders.

▶ Single-Use/ Disposable Product, Complications

These devices are designed and sold for single use only. Reprocessing and/or re-sterilization is not permitted. Unauthorized reprocessing and/or re-sterilization can result in:

- Cross-contamination due to ineffective reprocessing/re-sterilization.
- Mechanical fatigue and associated failure due to the effects of reprocessing/re-sterilization.

▶ Shelf Life, storage and Transportation

1. The shelf life of SurgyCut grasping forceps is three years.
2. Devices must be stored in a clean, cool and dry area.
3. Protect from mechanical damage & direct sun light. Handle with extreme care.

▶ Performance Claims

Our disposable biopsy forceps are specifically designed to collect the biopsy samples prioritizing patient comfort and procedural simplicity. Ideal for use in minimally. Invasive surgeries, these single-use instruments offer a secure grip and precise control, enhancing safety and efficiency throughout urological procedures.

▶ Undesirable Side Effects

There are no side effects, associated with the use of device if use by a professional person.

▶ Adverse Effects

Any serious incident or adverse event that occurs in relation to the use of the device should be reported to U.S. Surgitech, Inc. at the contact details provided in this IFU and to the relevant competent authority or regulatory authority, as applicable.

► **Warnings**

- These devices are designed for single use only and are not to be reused, reprocessed, or re-sterilized. Do not use if the sterile package is opened or damaged.
- All procedures should be performed only by physicians with adequate training and knowledge of these procedures.
- Medical literature should be consulted regarding techniques, hazards, contraindications, and complications prior to performance of these procedures.
- Transport and store all products safely at ambient temperatures of 5°C to 30°C and relative humidity of 35% to 65% (non-condensing). Handle with care.
- When removing from the surgical site, inspect the jaws again to ensure they are intact.
- Do not use the product, if the primary packaging is broken

► **Preparation for Use**

1. Using sterile technique, remove the instrument from the packaging. To avoid damage, do not flip the instrument into the sterile field.
2. Inspect the instrument thoroughly for any damage such as nicks, cuts, pits, and cracks.
3. With jaws closed, insert forceps into the accessory channel of the cystoscope.
4. Cystoscopically visualize the area to be biopsied.
5. Advance the forceps to the desired biopsy site, then position the forceps in front of the target tissue.
6. Open the jaws by pushing the plastic spool forward gently and advance into the tissue to be biopsied.
7. Introduce the forceps into the tissue, then advance the thumb ring (causing the jaws to close) and carefully remove the tissue sample.
8. Maintain gentle handle pressure to keep the jaws closed and gently withdraw the forceps from the cystoscope.
9. Continue to apply slight pressure on the handle while withdrawing the forceps from the cystoscope.
10. The tissue sample thus obtained may now be prepared for further examination.
11. Dispose of the device according to hospital protocols after use.

Symbols	Meaning
	Latex Free
	Single Use
	Device cannot be sold to layman
	Keep Away From Sunlight
	Temperature Limits
	Keep Dry
	See Instructions For Use
	Humidity Limits
	Reference Number
	Batch Number
	Do not use if package is damaged
	Date of Manufacturing
	Date of Expiry
	The device is sterilized by Ethylene Oxide