



Disposable SurgyNeedle™

Single Site Injection Needle

Instructions for Use

► Product Description

SurgyNeedle™ is a sterile, single-use injection needle intended for use during endoscopic urological procedures. The device is designed to be compatible with most standard cystoscopes and enables controlled injection of physician-selected fluids into targeted tissue. The needle features an ultra-sharp beveled tip for smooth tissue penetration with reduced insertion force, while its semi-rigid construction provides improved stability and control during manipulation.

► Clinical Benefits

When used as intended, SurgyNeedle™ provides the following clinical benefits:

- Precise delivery of injectable agents to targeted tissue.
- Improved procedural control through its semi-rigid shaft design.
- Reduced insertion force due to the ultra-sharp beveled needle tip.
- Supports efficient workflow by providing a sterile, ready-to-use disposable device.

► Intended User

- This device is intended to be used only by qualified healthcare professionals, including physicians and other trained medical personnel experienced in endoscopic urological procedures.
- Users should be familiar with cystoscopic techniques and the appropriate administration of injectable agents before using this device.

► Inspections

- Before use, inspect the package and device carefully.
- Verify that the sterile package is unopened and undamaged.
- Confirm that the expiration date has not passed.
- Inspect the device for any signs of damage, deformation, or contamination.
- Do not use the device if the packaging is damaged or if any component appears defective.
- Ensure compatibility with the intended endoscope before use.

► Patient Population

- SurgyNeedle™ is intended for use in patients requiring physician-directed endoscopic injection procedures during cystoscopy or other compatible urological interventions.
- The treating physician is responsible for determining patient suitability based on clinical judgment.

► Contraindication

SurgyNeedle™ should not be used if the sterile barrier has been compromised, the device has exceeded its expiration date, or the device is damaged or shows signs of malfunction. The device is contraindicated for use in procedures or anatomical locations other than those for which it is intended. Additionally, it should not be used in patients for whom the selected injectable agent is contraindicated, as determined by the treating physician.

► Disposal

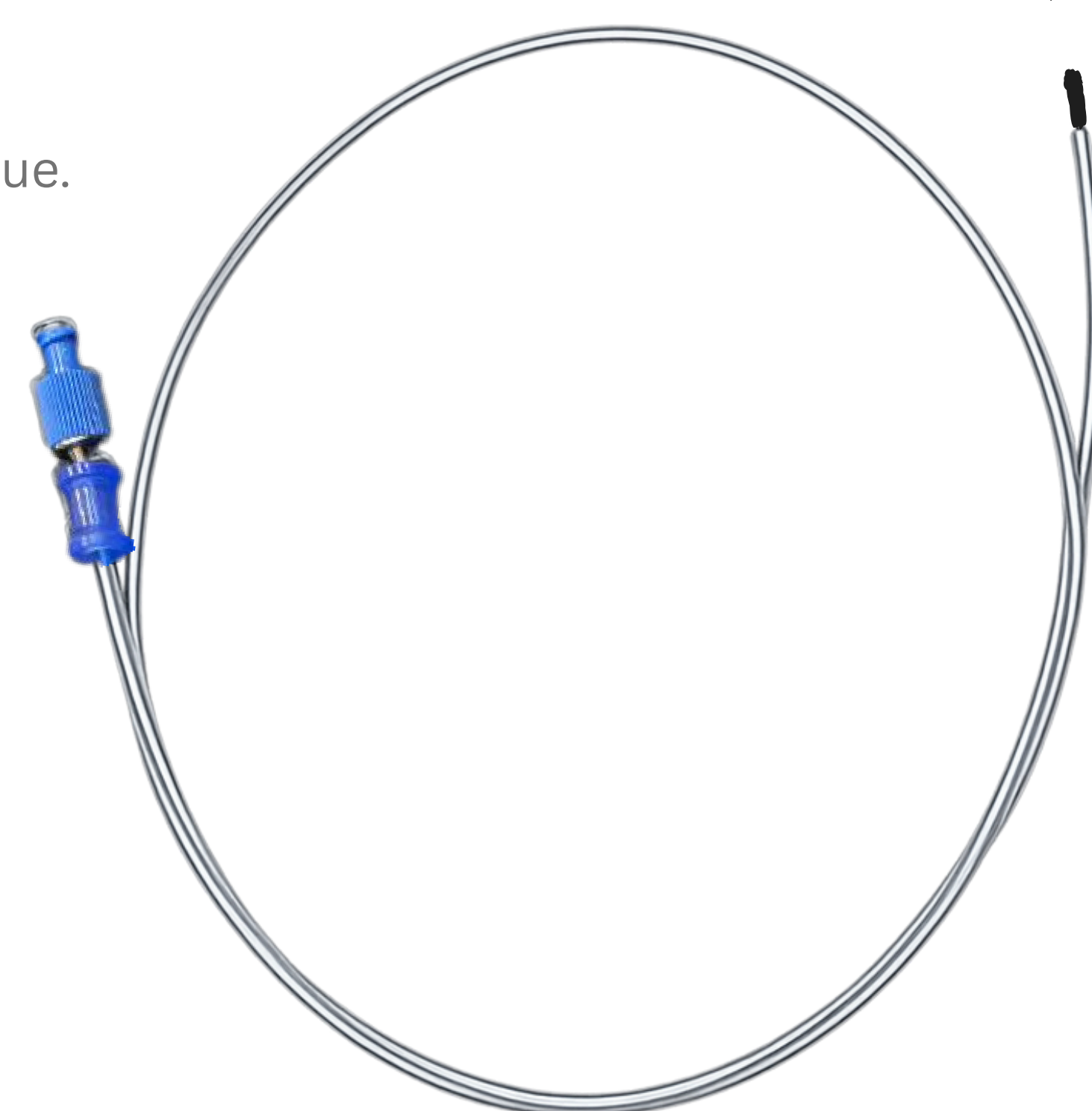
- After use, dispose of the device immediately as a contaminated sharp in accordance with hospital protocols and applicable local, state, and national regulations governing biohazardous and sharps waste.

► Single-Use/ Disposable Product

- SurgyNeedle™ is supplied sterile and is intended for single-patient use only. The device must not be reused, reprocessed, or resterilized, as doing so may compromise its sterility and performance, potentially resulting in cross-contamination, infection, device malfunction, and patient injury.



ALWAYS SHARP, ALWAYS STERILE





► Shelf Life, storage and Transportation

Store SurgyNeedle™ in its original unopened packaging in a clean, dry environment, away from direct sunlight and excessive humidity. The device should be maintained at 5 to 30 degree centigrade storage room temperature and has a shelf life of three years.

► Performance Claims

- SurgyNeedle™ is designed to provide smooth tissue penetration through its ultra-sharp beveled needle while offering controlled stability during endoscopic manipulation. The device is compatible with most standard cystoscopes and delivers reliable single-use performance in a sterile, ready-to-use format, helping to support procedural efficiency and consistent clinical performance.

► Undesirable Side Effects

- The use of SurgyNeedle™ may be associated with undesirable side effects related to the procedure or the administered injectable agent, including temporary discomfort at the injection site, minor bleeding, localized swelling, irritation of surrounding tissue, or a localized inflammatory response. The nature and severity of these effects may vary depending on the patient's clinical condition, procedural technique, and the injectable material used. Patients should be monitored following the procedure in accordance with established clinical practice and institutional protocols.

► Precautions

- Use only by trained healthcare professionals.
- Verify compatibility with the intended cystoscope prior to use.
- Handle the needle carefully to prevent accidental injury.
- Use aseptic technique throughout the procedure.
- Do not bend or modify the needle.
- Avoid excessive force during advancement.
- Confirm correct needle placement before injection.
- Follow the instructions provided by the manufacturer of the injectable agent.

► Warnings

- Sterile unless package is opened or damaged.
- Do not use if the sterile barrier is compromised.
- Single-use only. Do not reuse, reprocess, or resterilize.
- Do not use after the expiration date.
- Needle is sharp—exercise caution to prevent accidental needlestick injury.
- Failure to follow these instructions may result in patient injury, infection, or device malfunction.

► Preparation for Use

- Verify that the package is intact and within the expiration date.
- Open the sterile package using aseptic technique.
- Remove the device carefully without damaging the needle.
- Inspect the device for defects or damage.
- Introduce the device through a compatible cystoscope according to standard clinical practice.
- Advance the needle to the desired treatment site.
- Perform the injection according to physician preference and the instructions supplied with the injectable agent.
- Upon completion of the procedure, carefully withdraw the device.
- Dispose of the device immediately in an approved sharps container.

Symbols	Meaning
	Latex Free
	Single Use
	Keep Dry
	Sterile by EO
	See Instructions For Use
	Humidity Limits
	Reference Number
	Batch Number
	Keep Away From Sunlight
	Temperature Limits