GREENWALD
Manufacturers of Urological and Electrosurgical Instruments and Accessories

Greenwald Surgical Company, Inc.
2688 DeKalb Street • Lake Station, IN 46405-1519 • 219/962-1604 • FAX: 219/962-4009 • Toll-Free:**1-888-962-1829**

Grip-Tip Urethral Suture Guide

Greenwald Catalog No. U515

Study all instructions prior to handling. Familiarization with product function prior to use is strongly recommended. **WARNING: DO NOT DISASSEMBLE PRIOR TO CLEANING AND STERILIZATION.**

Intended use: to assist in exposing and suturing the severed end of the apical urethra prior to reanastomosis with the bladder neck during radical prostatectomy procedures.

This instrument engages the urethra by advancing three equally spaced expansion arms. Advancement of the expansion arms is achieved by turning the proximal end of the handle clockwise. When turned fully to the stop position the outer perimeters of the expansion arms are tangent to an imaginary circle of approximately 45 FR on the 28FR model and 40 FR on the 24FR model.

The expansions arms are retracted by turning the proximal end of the handle counter-clockwise. The expansion arms are fully retracted when the proximal end of the handle is turned counter-clockwise to the stop position.

In the unlikely event that the proximal end of the handle resists counter-clockwise rotation or the expansion arms resist retraction in situ, the instrument can be dismantled by removing the screw located in the distal knurled end of the handle and then pulling the handle assembly away from the main shaft of the instrument. A special "L" shaped tool is provided for this purpose. The instrument must then be returned to the factory for repair. **(ASSEMBLY IN THE FIELD IS NOT RECOMMMEND – ANY ATTEMPT TO ASSEMBLE IN THE FIELD MAY RESULT IN ADDITIONAL DAMAGE TO THE INSTRUMENT)**. The last verification of proper instrument function is performed after sterilization and before the start of the surgical procedure. The instrument should not be used if any difficulty or binding is experienced in advancing or retracting the expansion arms. A spare instrument should be readily available at all times.

Cleaning and sterilizing prior to initial use: **(DO NOT DISASSEMBLE)**.

1. Clean instrument, plastic Luer plug and "L" shaped tool with a surgical cleanser using a soft brush. Clean instrument tip with expansion arms fully extended. Clean handle with expansion arms fully retracted.
2. Force cleansing solution through instrument interior by using a standard Luer syringe (without needle) inserted in the Luer connector on the side of the handle.
3. Rinse items thoroughly. Rinse instrument tip with expansion arms fully extended. Rinse instrument handle with expansion arms fully retracted. Rinse instrument interior using a syringe and water as described above.
4. Shake excess water from instrument and then dry items thoroughly.
5. Steam autoclaving is recommended as the preferred sterilization method. Cold soaking in sterilizing solutions is an acceptable method which must, however, be followed by double rinsing in sterile water (with agitation) and rinsing the instrument interior as described in step 3.

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Before instrument is used, insert plastic plug into the Luer connector.

After the instrument has come in contact with blood and/or tissue, the instrument interior should be flooded with liberal amounts of sterile normal saline using a syringe (as described in step 3). Then soak the instrument in sterile normal saline until reprocessing has been started.

Cleaning and sterilizing after use: **(DO NOT DISASSEMBLE)** Follow the steps below as soon as possible after the surgical procedure has been completed.

A. Flood instrument interior with liberal amounts of warm water using a syringe as described in Step No. 2, Page 1.
B. Flood instrument interior with blood dissolving solution using a syringe as described in Step No. 2, Page 1.
C. Soak instrument in a blood dissolving solution.
D. Repeat steps 1 through 5 as described on Page 1.

Before instrument is used, insert plastic plug into the Luer connector.

Caution: Federal (U.S.A.) Law restricts this device to sale/use by or on the order of a physician.

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RECOMMENDED STERILIZATION PARAMETERS for Gravity-Displacement Steam Sterilization in a Health Care Facility

Unless otherwise indicated, our products are NOT STERILE and must be thoroughly cleaned and sterilized prior to each use.

Do not exceed a temperature of 138°C (280°F)

Parameters for gravity-displacement steam sterilization cycles			
Item	**Exposure time at 121° C (250°F)**	**Exposure time at 132° C (270°F)**	**Drying time**
Wrapped instruments	30 min	15 min	15 to 30 min
Unwrapped nonporous items		3 min	0 to 1 min
Unwrapped nonporous items in mixed load		10 min	0 to 1 min

It is important that the longest drying cycle possible is employed to prevent build up of moisture inside the instrument. If the cycle of your autoclave allows a 30 min. dry time, we recommend using it.

- **Always make sure the product is in good condition and perfect working order before reusing it.**

Sterilization equipment manufacturer's recommendations must be followed. Health care facility protocol should be adhered to.

Since Greenwald Surgical Co., Inc. is not familiar with individual hospital handling procedures, cleaning methods, bio-burden levels, and other conditions, Greenwald Surgical Co., Inc. assumes no responsibility for sterilization of product even if the general above guidelines are followed.

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RECOMMENDED STERILIZATION PARAMETERS for

Dynamic-Air-Removal (Prevacuum) Steam Sterilization in a Health Care Facility

Unless otherwise indicated, our products are NOT STERILE and must be thoroughly cleaned and sterilized prior to each use.

Do not exceed a temperature of 138°C (280°F)

Parameters for dynamic-air-removal (prevacuum) steam sterilization cycles			
Item	**Exposure time at 132° C (270°F)**	**Exposure time at 135° C (275°F)**	**Drying time**
Wrapped instruments	4 min		20 to 30 min
Unwrapped nonporous items	3 min	3 min	N/A
Unwrapped nonporous items in mixed load	4 min	3 min	N/A

It is important that the longest drying cycle possible is employed to prevent build up of moisture inside the instrument. If the cycle of your autoclave allows a 30 min. dry time, we recommend using it.

- **Always make sure the product is in good condition and perfect working order before reusing it.**

Sterilization equipment manufacturer's recommendations must be followed. Health care facility protocol should be adhered to.

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RECOMMENDED STERILIZATION PARAMETERS for Liquid Chemical Sterilization in a Health Care Facility

Unless otherwise indicated, our products are NOT STERILE and must be thoroughly cleaned and sterilized prior to each use.

Parameters for Liquid Chemical Sterilization cycles			
Formulation	**Exposure time at 20°C (68°F)**	**Exposure time at 25°C (77°F)**	**Exposure time at 50°C to 55.5°C (122°F to 132°F)**
2% to 3.5% glutaraldehyde		10 hrs	
7.5% hydrogen peroxide	6 hrs		
0.2% peracetic acid			12 min
It cannot be assumed that all 2% to 3.5% glutaraldehyde formulations are sterilants. The efficacy of glutaraldehyde sterilants depends on the active ingredients, the inactive ingredients, and the pH. Check the product label to confirm the parameters.			

- **Always make sure the product is completely dry before reusing it.**
- **Always make sure the product is in good condition and perfect working order before reusing it.**

Liquid Chemical Sterilization manufacturer's recommendations must be followed. Health care facility protocol should be adhered to.

Since Greenwald Surgical Co., Inc. is not familiar with individual hospital handling procedures, cleaning methods, bio-burden levels, and other conditions, Greenwald Surgical Co., Inc. assumes no responsibility for sterilization of product even if the general above guidelines are followed.

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