

## Cleaning Instructions Quick Reference Guide

GS Medical USA

Part Number:      □ US114-9001 TOWER (and 2-Pronged Inner Sleeve)  
                             □ US114-9004 DILATOR 2



The following cleaning procedure sequence is recommended for the care, cleaning, maintenance, and sterilization of GS Medical surgical instruments. This document is intended to assist central sterilization personnel in safe handling practices that promote effective cleaning, sterilization and maintenance of instruments. The sequence below follows recommendations of the Centers for Disease Control (CDC), as well as other instrument sterilization guidelines.

During surgery, the aforementioned Tower, Inner Sleeve and Dilator becomes filled and contaminated with blood, tissue, bone fragments, and marrow. The hospital must assume responsibility for decontaminating, cleaning, packaging, and sterilizing these instruments before returning to the GS Medical Sales Representative. Thank you for your attention to this important matter.

Any questions concerning the process delineated below should be directed to:

### GS Medical

6 Wrigley

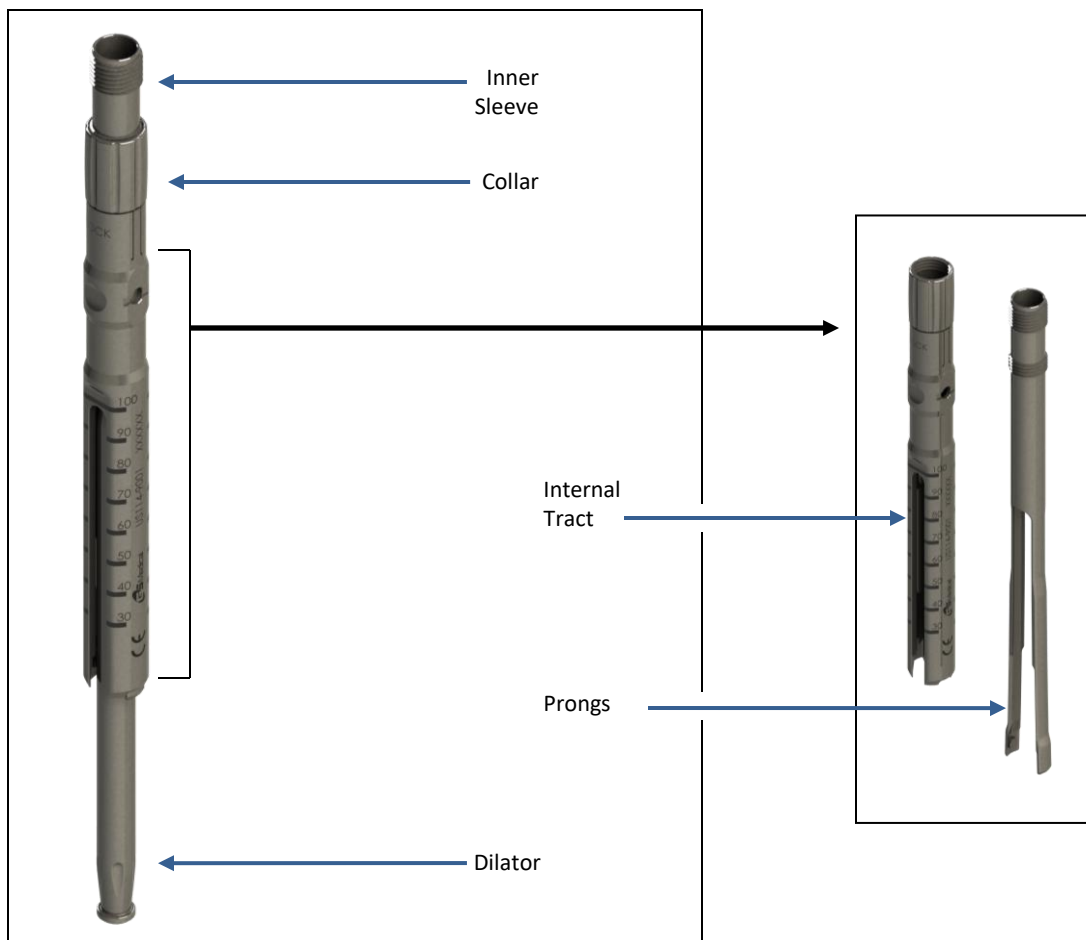
Irvine, CA 92618

1-866-904-8144

### Instrument Diagram

GS Medical USA

- Part Number:      □ US114-9001 TOWER (and 2-Pronged Inner Sleeve)  
                         □ US114-9004 DILATOR 2



**GS Medical USA Recommended Cleaning Sequence:**

1. After use or surgery – Unscrew collar clockwise from TOWER while applying gentle upward pressure on the internal sleeve.



2. Gently remove inner sleeve by pulling the TOWER distally. Clean thoroughly (Refer to attachment A: Instrument Cleaning, Care and Handling Policies).



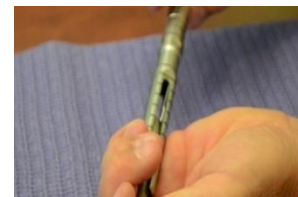
3. Insert the inner sleeve into the top of the TOWER opening and align the two prongs with the internal tracks



4. Insert fully the Dilator 2 in order to guide the two prongs into the TOWER tracks.



5. Once fully seated, the prongs will glide easily towards the distal tip of the TOWER in their designed tracks.



6. Tighten the collar counter clockwise to lock in the inner sleeve with the TOWER.



## Attachment A: GS Medical USA Instrument Cleaning, Care and Handling Policies

### Overview

Surgical instruments are supplied NON-STERILE, and must be sterilized before use. After each use, instruments must be properly cleaned, disinfected, sterilized and stored. The following information outlines the proper steps for reprocessing GS Medical surgical instruments.

### Cleaning Accessories

- Water – Cold deionized or reverse osmosis water should be used, as temperatures above 140°F (60°C) will coagulate proteins, rendering them difficult to remove from contaminated items.
- Detergent – Prepare detergent (i.e., LIQUI-NOX®, Alconox, Inc. 9.5 pH) per manufacturer recommendations ,or typical hospital grade instrument detergent or soap.
- Manual Cleaning Accessories– Brushes, Gloves, Absorbent Disposable Cloth (i.e., KIMWIPE®, Kimtech Science)

### Limitations and Restrictions of Reprocessing

Surgical instruments are designed for their durability and ability to reuse. GS Medical reusable instruments are typically manufactured from steel stainless steel, which permits a long life when handled and maintained properly. Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage to use.

### Cleaning / Disinfecting

- Warnings– When handling sharp instruments use extreme caution to avoid injury; consult with an infection control practitioner to develop and verify safety procedures for all levels of direct instrument contact.

Clean Instruments as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups on instruments in a covered container with water or an appropriate detergent to delay drying. Clean all instruments whether or not they were used or inadvertently contacted blood or saline solution.

- Preparation for Cleaning – The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by design. The cleaning process should include an individual properly gowned with appropriate glove and personal protective equipment. Items with lumens, cannulations, etc. must be carefully cleaned to remove all visible debris from the item.

### **Manual Cleaning and Disinfection**

Clean instruments to remove gross contamination and disinfect instruments to reduce the number of viable microorganisms. Rinse in warm water to remove any gross contamination. Wash with a detergent with a pH of 7.0 to 10.0. Scrub the components with a soft brush. Rinse thoroughly with warm running water. Dry the instrument with a clean, disposable, absorbent cloth. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visibly inspected. If necessary re-clean / disinfect the instrument until it is visibly clean.

### **Automated Cleaning and Disinfecting**

An automatic cleaning process may be used i.e. ultrasonic cleaner or other related type machine that clean and decontaminate items provided their own unique instructions are followed. Be aware that loading patterns, instrument cassettes, and other external factors may change the effectiveness of the cleaning equipment.

### **Inspection, Maintenance and Testing**

Surgical instrument and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their exact performance. To minimize damage, the following should be done. Inspect the instrument and cases for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside and returned to GS Medical or its distributor. Instruments and instrument cases must only be used for their intended purpose.

### **Packaging**

The GS Medical instrument case is intended to protect instrumentation during shipment. Any damage noted should be reported to GS Medical immediately. Damaged packaging may indicate the presence of unsafe product. If the product is damaged, the product should not be used and should be returned.

### **Sterilization**

GS Medical surgical instruments manufactured of stainless steel or titanium may be steam sterilized with no detrimental effects. Steam Sterilization Cycle instruments are supplied NON-STERILE and must be sterilized before use. The recommended sterilization process is high temperature steam autoclave sterilization. It is also recommended that the trays be double wrapped using two standard sterilization wraps.

Validated Cycle is:

Method: Steam Cycle Pre-vacuum Temperature 270°F (132°)

Exposure time: 4 minutes

Drying Time: 20 minutes

### **Storage**

Surgical instruments that will not be utilized within a short period of time and will not be immediately returned to GS Medical must be stored clean, decontaminated, and completely dry. The packaging that items are sterilized in may offer an effective barrier to prevent contamination. Instruments should be stored in a clean area until ready for use.

### **Sterilization**

All instruments must be sterilized according to the instructions outlined in the packaged insert-Instructions For Use (IFU) unless otherwise provided sterile.