

Cleaning: Rultract® System

Repeated processing has minimal effect on this instrument. End of life is normally determined by wear and damage due to use.

1. Remove excess soil on instrument as soon as is reasonably practical following use.
2. Disassemble Ratchet/Rake per instructions. No disassembly of other products required for cleaning.
3. It is expected that commercially available products for the use of cleaning are used.
4. If using an automated cleaning system (such as a sonicator) use a commercially available detergent approved for automatic use that is ph-neutral or alkaline. Set appropriate wash and rinse cycles according to the manufacturer of the automatic cleaning system's instructions.
5. If cleaning manually, thoroughly clean surface contamination. Soak in a neutral or alkaline pH disinfecting solution or enzymatic cleaner. Do not soak for longer than what is recommended by solution manufacturer.
6. Instrument should be thoroughly rinsed with distilled water after cleaning to remove any residual debris or cleaning agent.
7. Instruments may be lubricated using a small amount of surgical grade lubrication. Let instrument drip dry a few moments before wrapping for sterilization.
8. Visually inspect instrument for any damage prior to use.

CAUTION: Disassemble unit prior to cleaning. The spool cap nut must be unscrewed to separate the spool, spool cap, crank handle assembly and gearbox assembly (see page 33 & 34). ***It is not necessary to remove fasteners or roll pins for proper cleaning and sterilization.*** Further disassembly is not necessary and may void guarantee.

Biocompatibility of Rultract's Medical Devices

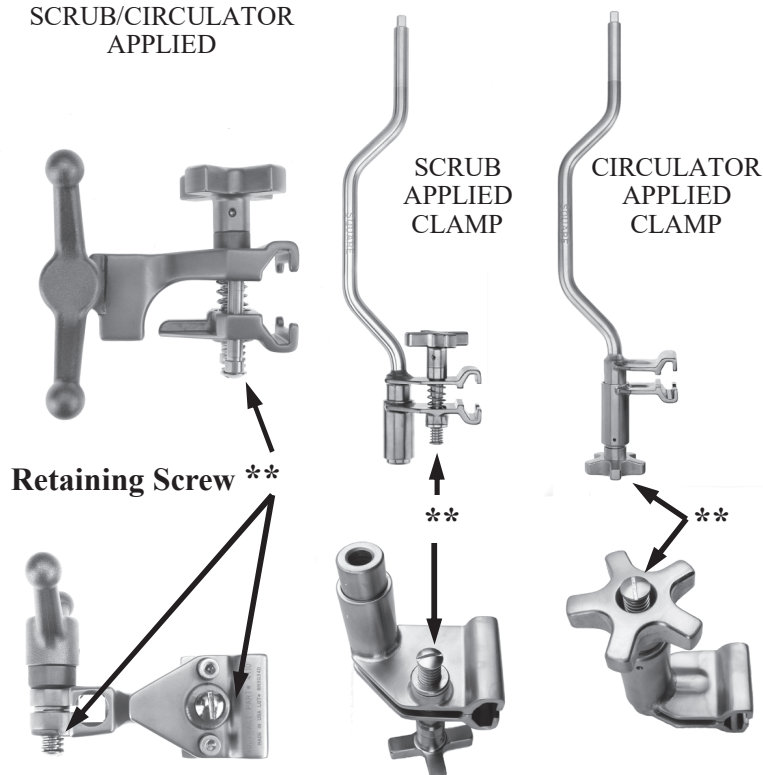
Rultract uses 420, 304 and 17-4 Stainless Steel in its medical products that would have direct contact with patients

SYSTEM COMPONENTS - PREPARE FOR CLEANING CYCLE

Cleaning / Sterilization: Clamp

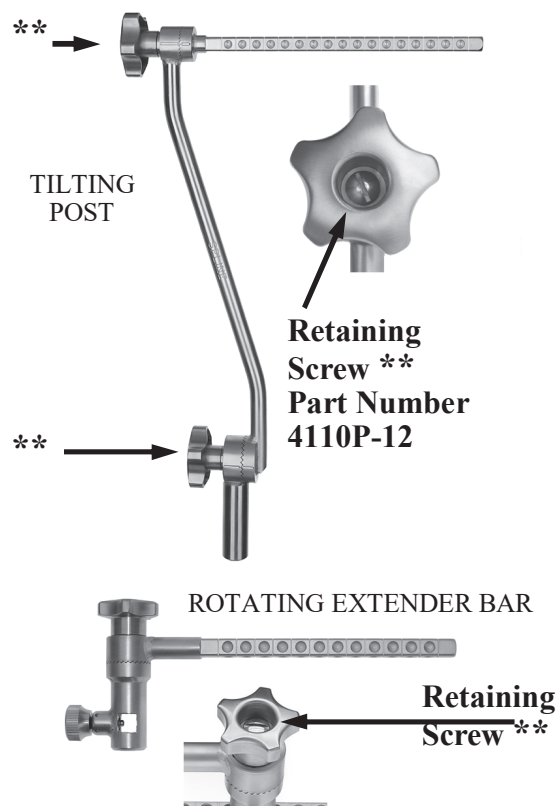
- **Do not disassemble for cleaning or sterilization.**
- Do not remove retaining screw(s).**
- Do not open or close handle (s) completely.
- Jaws should be partially opened.
- Jaws and handles should have free movement.

COMBINATION CLAMP SCRUB/CIRCULATOR APPLIED



Cleaning / Sterilization: Tilting Top Posts and Rotating Extender Bar

- **Do not disassemble for cleaning or sterilization.**
- Do not remove retaining screw (s).**
- Do not open or close knobs completely.
- Loosen knobs for partial separation.
- Sections and knobs should have free movement.

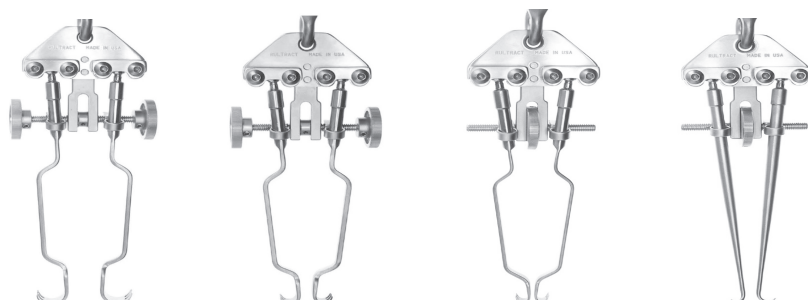


WARNING: Removal of retaining screw (s)** (4110P-12) will cause device to come apart. This will result in failure during use.

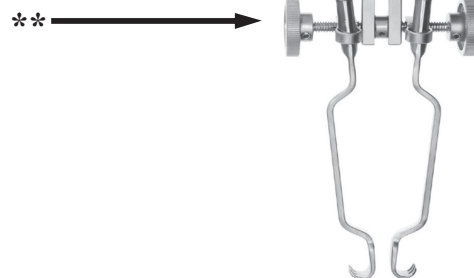
CLEANING: Resternotomy Rake Plates

- **No disassembly required**

4100-52RDL 4100-52RDM 4100-52RDS 4100-52RDH



- **Do not disassemble for cleaning or sterilization..**
- Do not remove Rake Clamp screws.**
- Do not open or close knobs completely.
- Sections and knobs should have free movement.

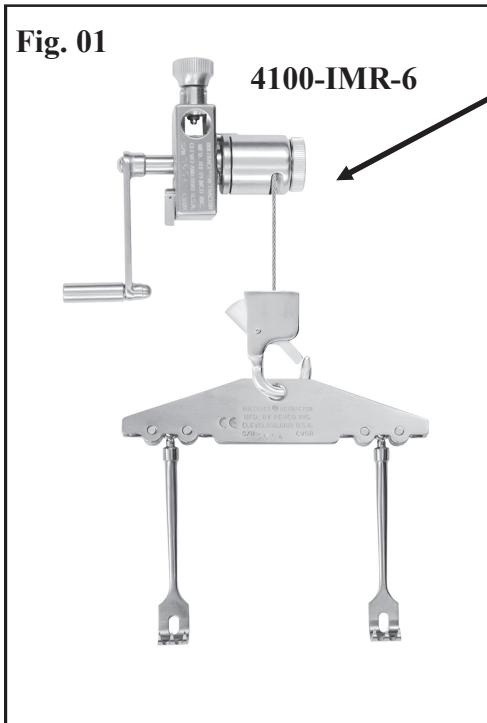


**IN PREPARATION FOR THE CLEANING CYCLE, YOU MUST
DISASSEMBLE RATCHET/RAKE ASSEMBLY, 4100-IMR-6, Fig. 01
INTO 5 PIECES AS SHOWN IN Fig. 02.**

NO FURTHER DISASSEMBLY REQUIRED

Proceed to pages 35-37 for disassembly / reassembly instructions

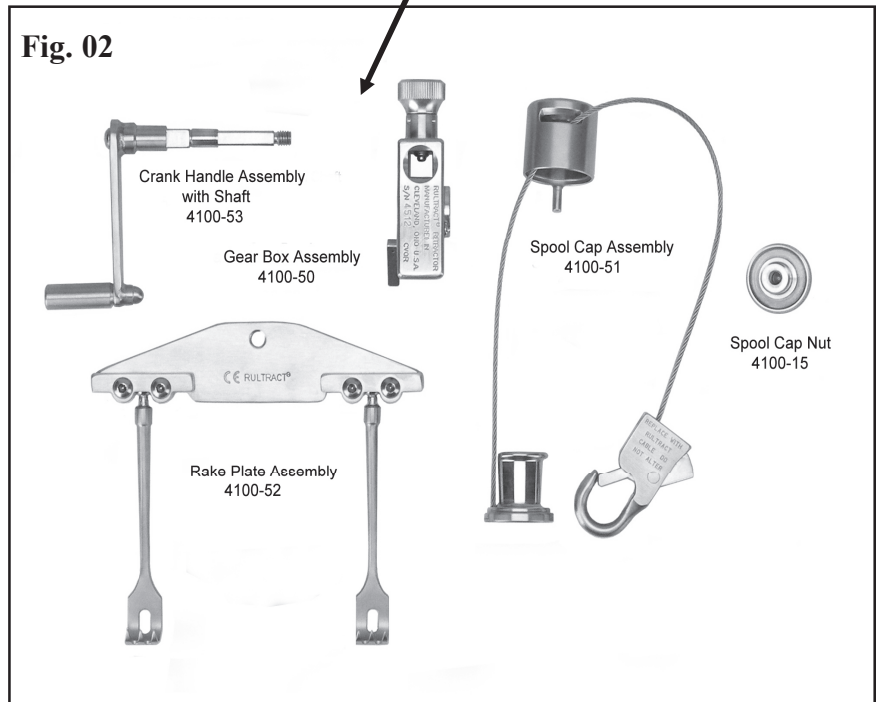
Fig. 01



This is disassembled

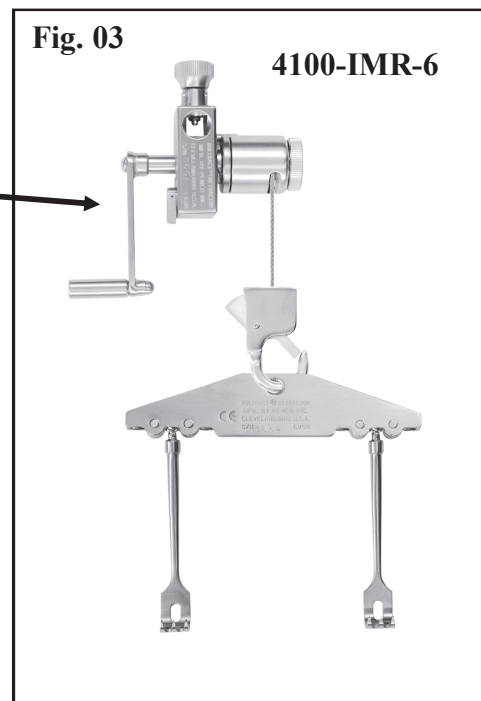
into these **5 pieces** for the Cleaning Cycle...

Fig. 02



...and then,
**ONCE THE CLEANING CYCLE IS
COMPLETE,**
reassembled back into **this**
for Sterilization and Use.

Fig. 03

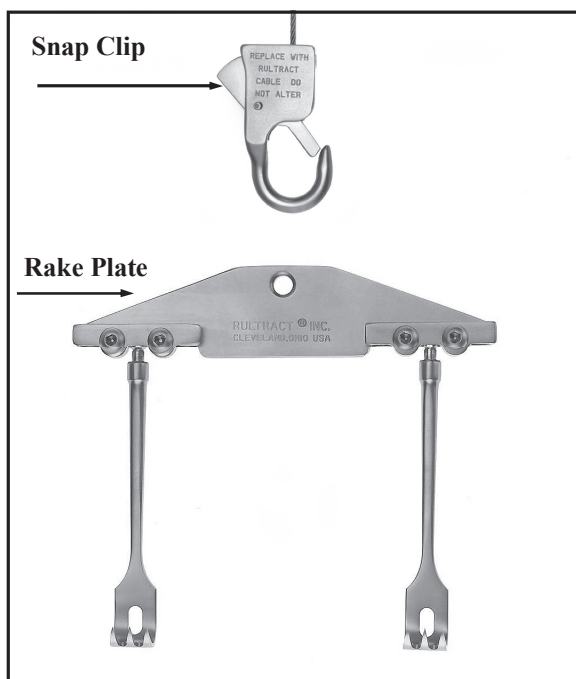


Determine Your Rake Plate System Configuration

STEP 1 RAKE PLATE:

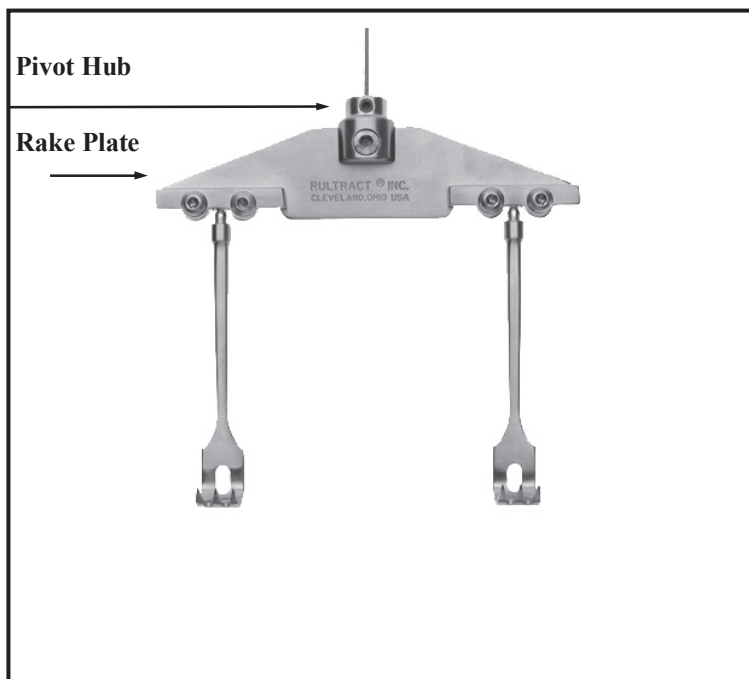
If your system has a Snap Clip and a Rake Plate

Disconnect Rake Plate from Snap Clip



If your system has a Pivot Hub Attached to the Cable and Rake Plate

Do not disassemble Rake Plate from Pivot Hub—Proceed to Step 2



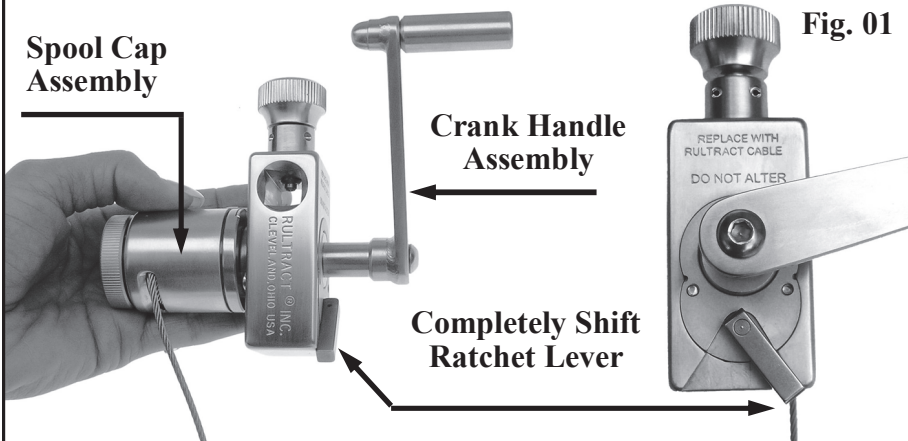
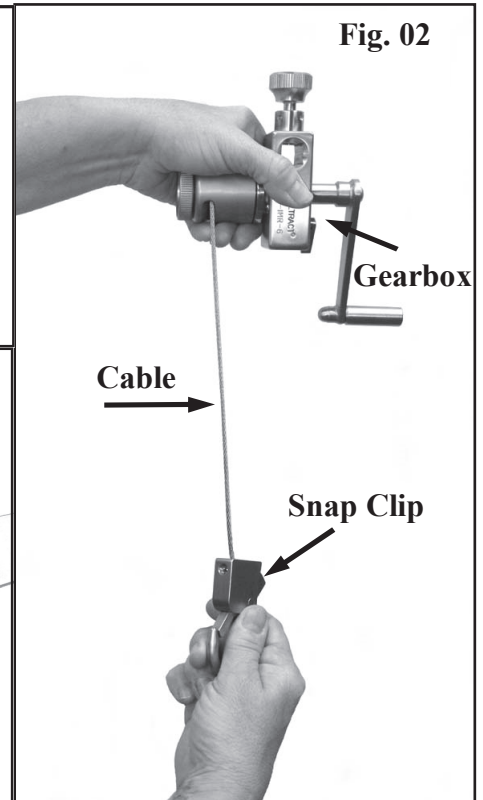
If your system has a Snap Clip Only

Proceed to Step 2



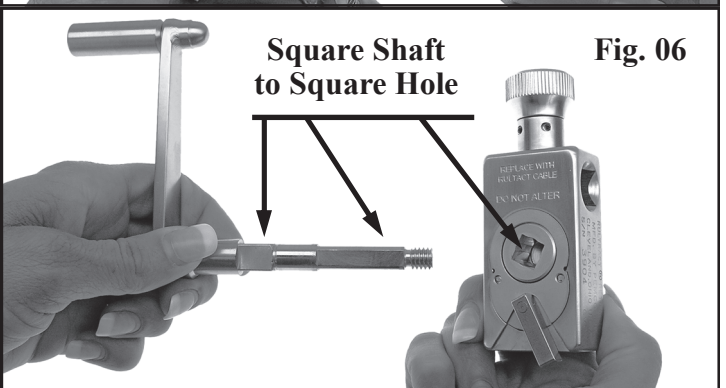
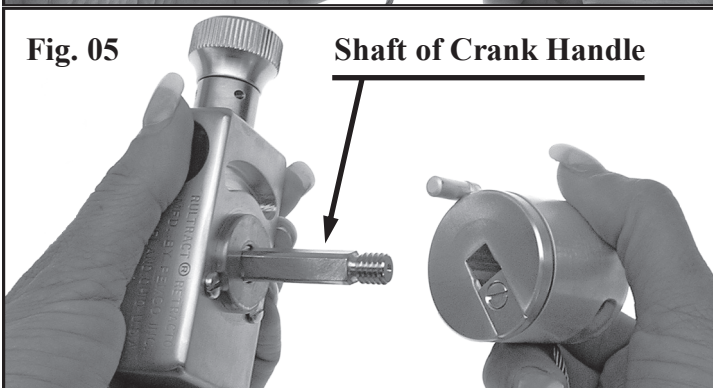
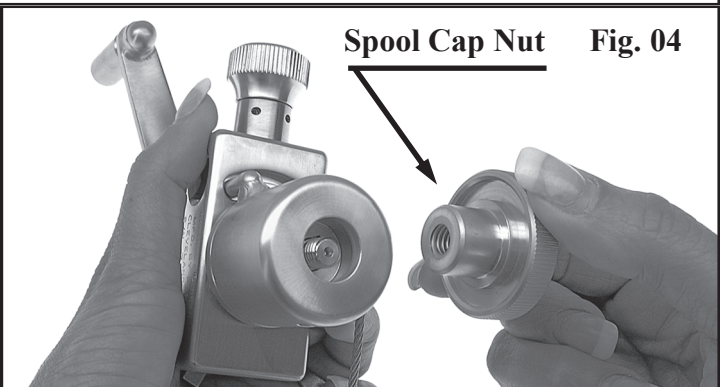
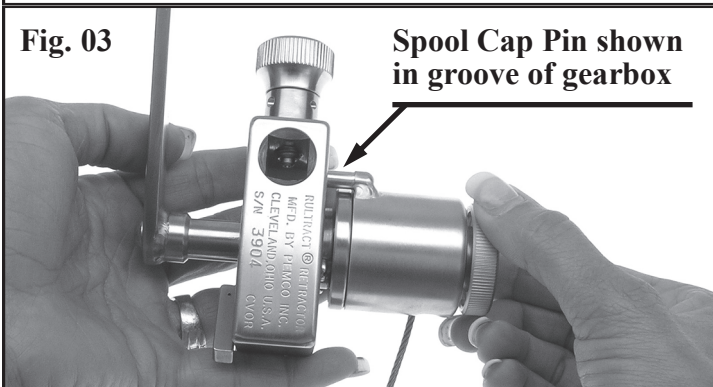
DISASSEMBLE RATCHET FOR CLEANING

STEP 2 PULL CABLE FROM SPOOL : While holding the Ratchet by the Spool Cap Assembly, shift Ratchet Lever to reverse direction (Fig. 01). Pull down on Snap Clip or Rake Plate Assembly to **completely unwind the cable, approximately 16"** (Fig. 02). If cable is jammed or will not unwind freely, proceed to the next step and remove the Spool Cap Assembly. **Note: Worn or Damaged cable must be replaced at this time with a new Rultract® Cable.**



STEP 3 REMOVE SPOOL CAP ASSEMBLY AND CRANK HANDLE ASSEMBLY:

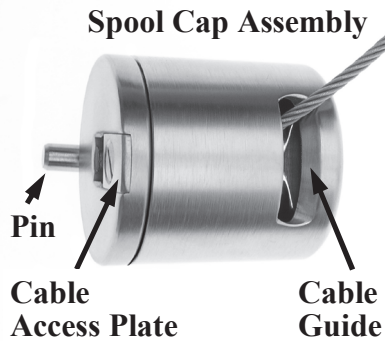
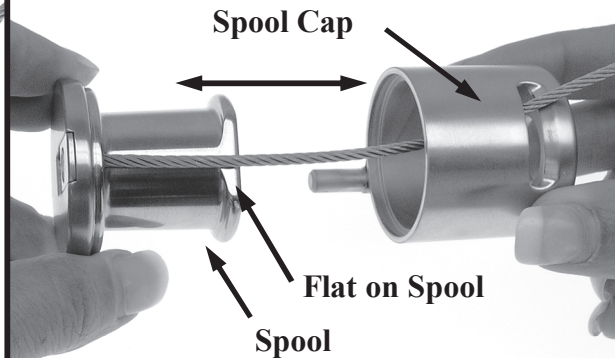
Holding the Crank Handle Assembly as shown, unscrew and remove the Spool Cap Nut using a counter clockwise rotation (Fig. 03 & 04). Slide Spool Cap Assembly from shaft of Crank Handle Assembly (Fig. 05). Slide Crank Handle Assembly out of Gearbox. At this time, note square of shaft and square hole in Gearbox (Fig. 06).



CAUTION: Always insert spool cap pin into the groove of the gearbox. Failure to do so may result in disassembly or damage to the unit.

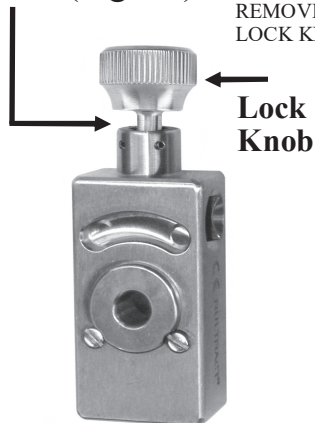
DISASSEMBLE RATCHET FOR CLEANING (continued)
STEP 4 REMOVE SPOOL CAP FROM SPOOL:

To remove Spool Cap from Spool, line up Cable Guide with Pin and Cable Access Plate of Spool (Fig. 07). This will align flat on Spool with Cable Guide and allow the two pieces to separate (Fig. 08). Slide Spool Cap along cable to rest on Snap Clip or Pivot Hub (Fig. 09).

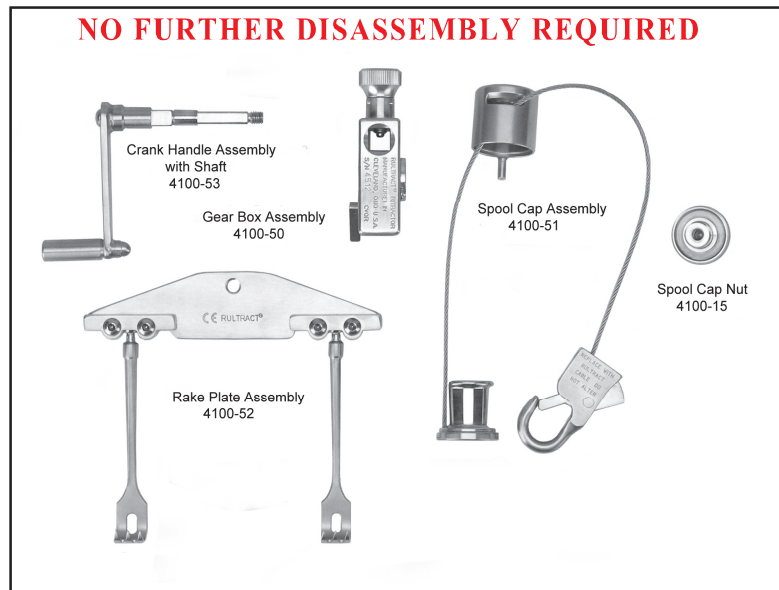
Fig. 09
Fig. 07

Fig. 08

Fig. 10
STEP 5 BACK OUT (OPEN) THE NON-REMOVABLE LOCK KNOB:

The knob should not be open or closed all the way. It should be somewhere in the middle and have some “play” in it. (Fig. 10).

DO NOT REMOVE LOCK KNOB



The Rultract Ratchet Rake Assembly is now completely disassembled into the following 5 pieces and ready to begin the cleaning cycle

NO FURTHER DISASSEMBLY REQUIRED

CAUTION:

Check and tighten all fasteners after the cleaning cycle and prior to sterilization.

Failure to do so may cause components to loosen or disassemble during use

STERILIZATION

The following are GUIDELINES for product sterilization.

The Rultract® retractor assembly is a reusable instrument. It is supplied non-sterile and must be cleaned and sterilized prior to initial use and all subsequent use.

This validated process should be considered as a guideline only. Time, temperature and other conditions required for sterilization may vary according to type of sterilizer, cycle design, wrapping material, and/or other hospital practices.

Sterilization containers must be validated by their manufacturer for use in sterilization process. Validated cycles should be indicated in the container's Instructions for Use.

You must validate your own sterilization practice when it differs from the Instructions for Use provided by the device, container or sterilizer manufacturer.

Recommendations for sterilization may be obtained from AAMI (Association for Advancement of Medical Instrumentation) at <http://www.aami.org/>

Rultract's Sterilization guidelines were validated by Biotest Laboratories Inc. of Minneapolis, Minnesota. The guidelines are as follows: (See next page)

RULTRACT® INSTRUCTIONS FOR USE—STERILIZATION PARAMETERS

Guidelines for Sterilization : Cable should be wound on spool prior to sterilization leaving approximately 1 1/2 to 2 inches exposed. The instruments may be sterilized by the following steam sterilization methods: prevacuum, flash, and steam (gravity) wrapped. The following cycles were verified utilizing a combination of metal instruments and/or metal instruments in a common sterilization tray with a mass up to 40 pounds (18 kg). The wrapped instruments were wrapped with non-woven single use Steriwrap™. (manufactured by Proper).

<u>Option 1: Wrapped instruments</u>	Pre-vacuum Sterilization Parameters (Minimum time and temperature):
	Temperature 132°C (270°F)
	Exposure Time 4 minutes

<u>Option 2: Wrapped instruments</u>	Steam (Gravity) Sterilization Parameters (Minimum time and temperature):
	Temperature 121° C (250°F)
	Exposure Time 30 minutes

<u>Option 3: Unwrapped instruments</u>	"Flash" Sterilization Parameters (Minimum time and temperature):
	Temperature 132° C (270°F)
	Exposure Time 3 minutes

RATCHET/RAKE FASTENERS: CHECK FOR TIGHTNESS AFTER THE CLEANING CYCLE

PRIOR TO STERILIZATION

- ** 4 pcs 4100-33 Rake Clamp Screw to mount Rake Clamps to Rake Plate. (4100-52)
- ** 2 pcs 4100P-05 Cover Plate Screw to retain the Cover Plate on the Gearbox. (4100-50)
- ** 1 pc 4100-15 Spool Cap Nut to retain Spool Cap Assembly. (4100-51)
- ** 1 pc 4100P-11 Cable Access Plate Screw to retain Cable Access Plate. (4100-51)
- ** 1 pc 4100-03A Cable Set Screw to retain Cable in hub. (4100-51)

The following two items should not be removed. If these fasteners are removed a bolt retaining compound must be reapplied.

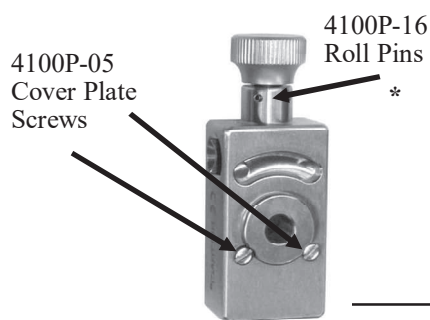
- ** 1 pc 4100-18 Crank Handle Screw to mount Crank Handle to Crank Arm. (4100-53)
- ** 1 pc 4100P-08 Crank Arm Screw to mount Crank Arm to Ratchet Shaft. (4100-53)

CAUTION: ** *Check and tighten all fasteners on the Ratchet/Rake Assembly.*

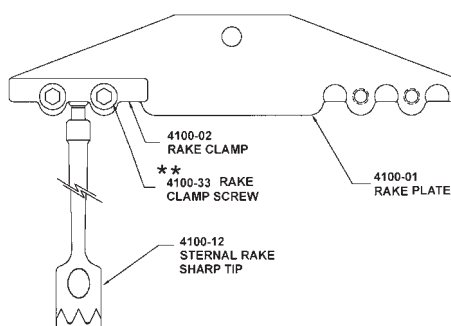
Failure to do so may cause components to loosen or disassemble during use.

CAUTION: ** *Do not remove Roll Pins *(4100P-16). (4100-50)*

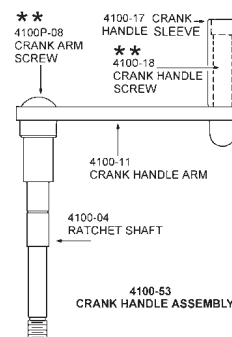
4100-50 Gear Box Assembly



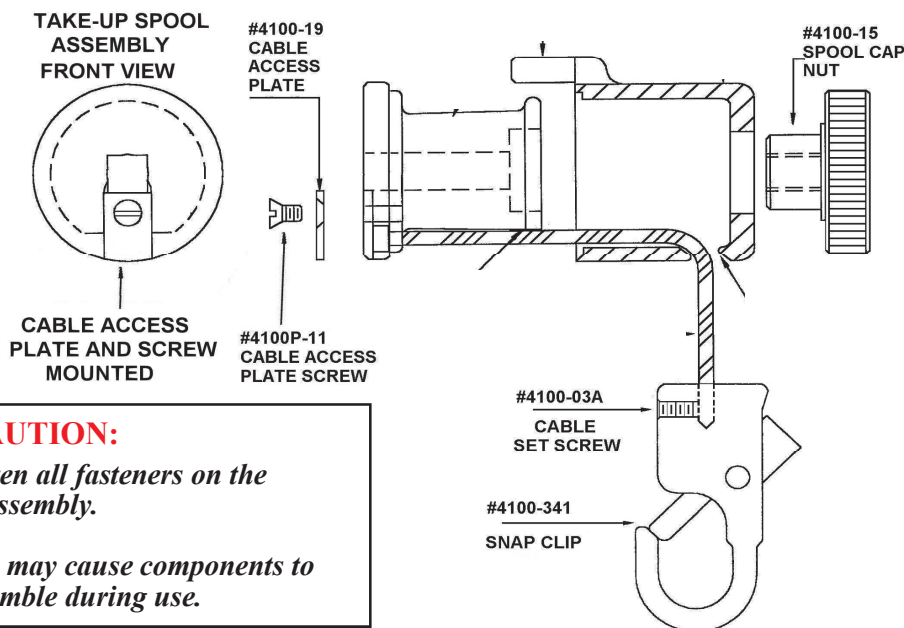
4100-52 Rake Plate Assembly



4100-53 Crank Handle Assembly



4100-51 Spool Cap Assembly Rake



CAUTION:

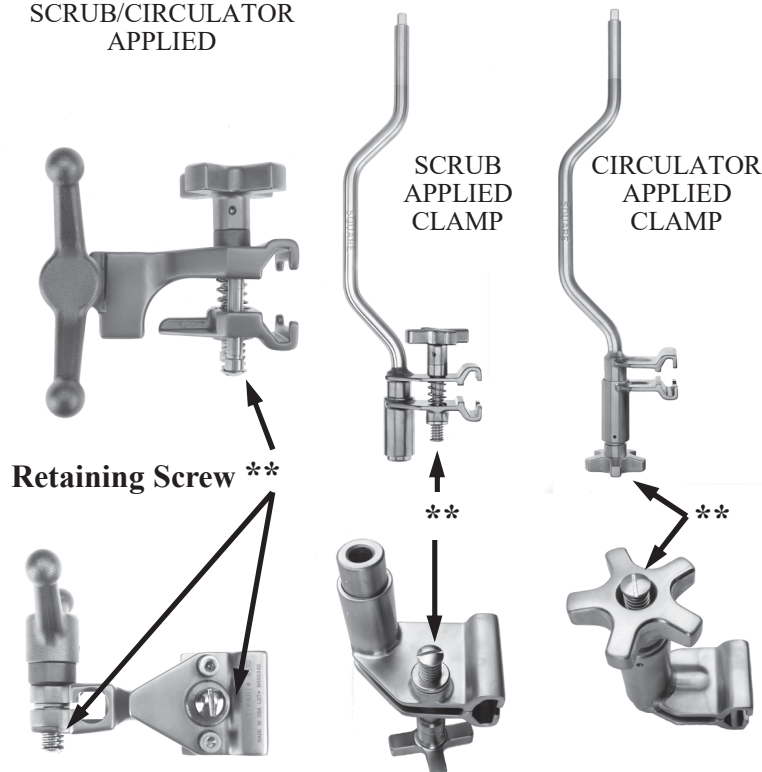
Check and tighten all fasteners on the Ratchet/Rake Assembly.

Failure to do so may cause components to loosen or disassemble during use.

Sterilization: Clamp

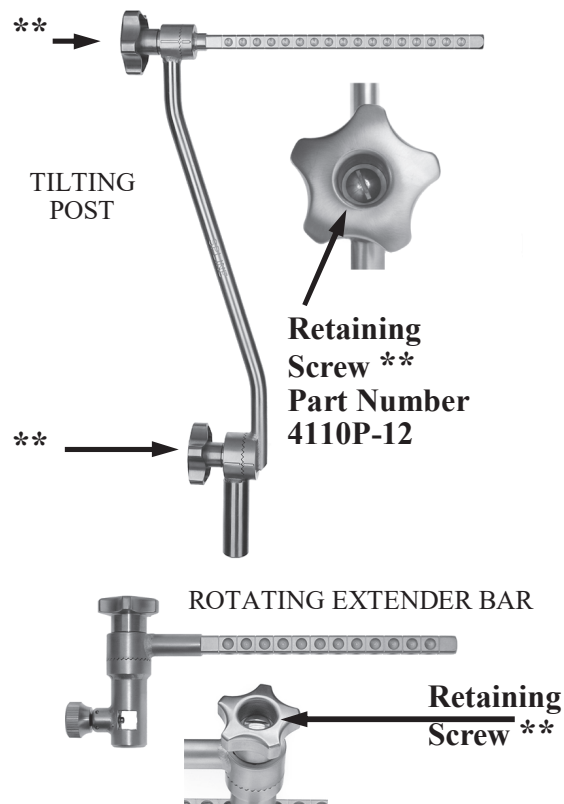
- Do not disassemble for cleaning or sterilization.
- Do not remove retaining screw (s).**
- Do not open or close handle (s) completely.
- Jaws should be partially opened.
- Jaws and handles should have free movement.

**COMBINATION CLAMP
SCRUB/CIRCULATOR
APPLIED**



**Sterilization: Tilting Top Posts
and Rotating Extender Bar**

- Do not disassemble for cleaning or sterilization.
- Do not remove retaining screw (s).**
- Do not open or close knobs completely.
- Loosen knobs for partial separation.
- Sections and knobs should have free movement.

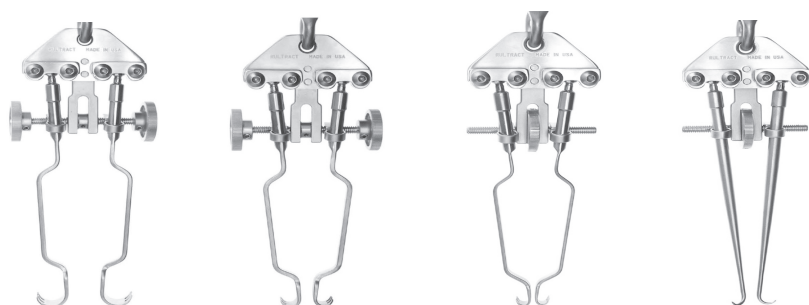


WARNING: Removal of retaining screw (s)** (4110P-12) will cause device to come apart. This will result in failure during use.

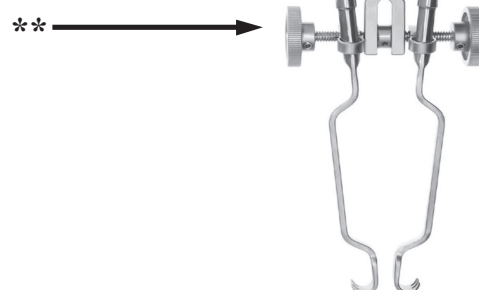
STERILIZATION : Resternotomy Rake Plates

- **No** disassembly required

4100-52RDL 4100-52RDM 4100-52RDS 4100-52RDH



- Do not disassemble for cleaning or sterilization..
- Do not remove Rake Clamp screws.**
- Do not open or close knobs completely.
- Sections and knobs should have free movement.



**IN PREPARATION FOR STERILIZATION, YOU MUST
REASSEMBLE THE 5 PIECES SHOWN IN Fig. 01
BACK INTO THE RATCHET/RAKE ASSEMBLY, 4100-IMR-6, AS
SHOWN IN Fig. 02**

***These 5 pieces need to be reassembled into this
for Sterilization and use.***

Fig. 01

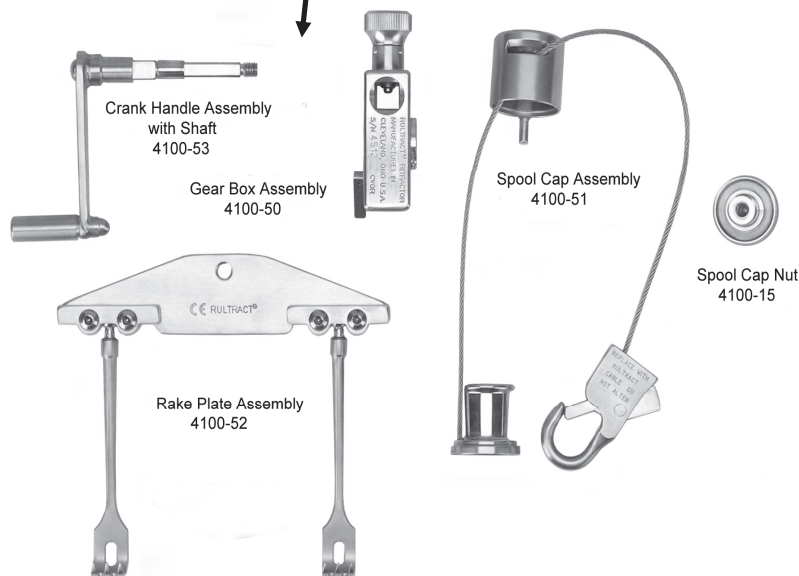
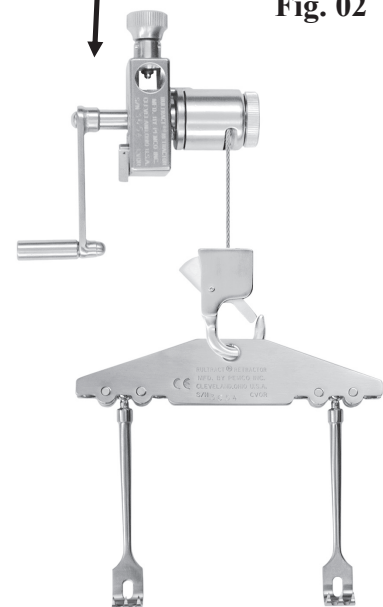


Fig. 02

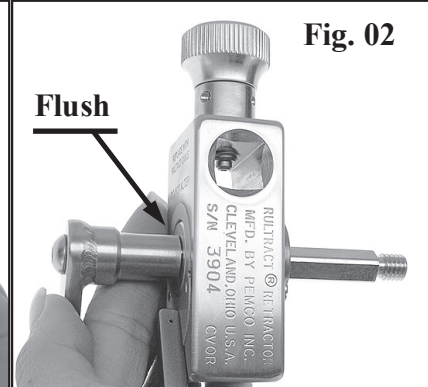
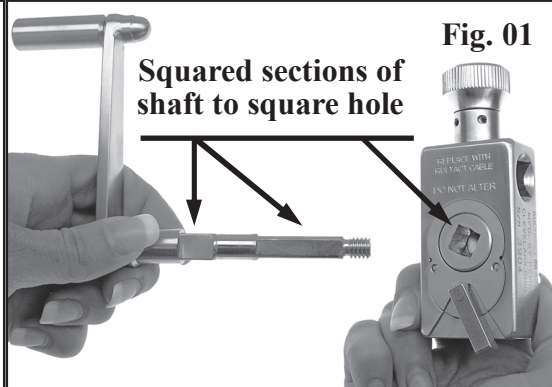


4100-IMR-6

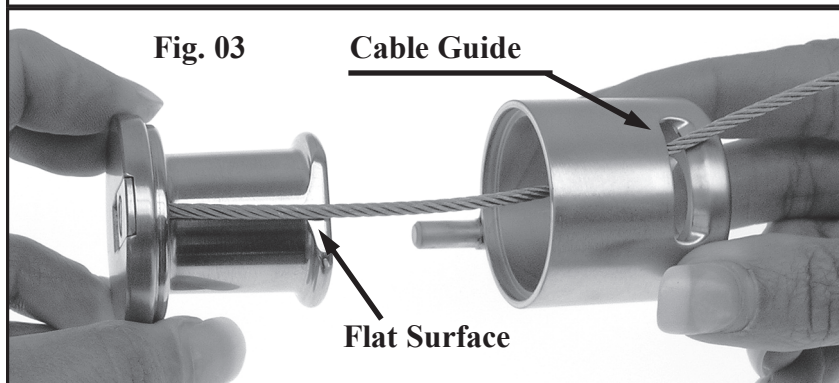
REASSEMBLE RATCHET FOR STERILIZATION AND USE

STEP 1
INSTALL CRANK HANDLE:

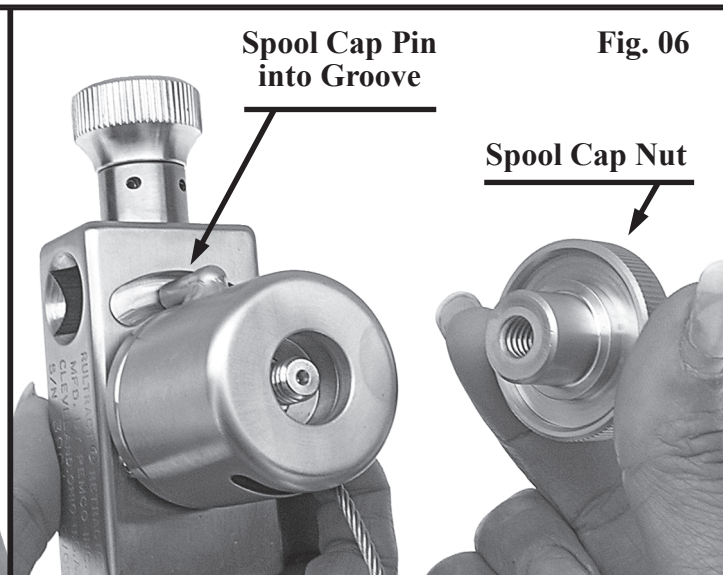
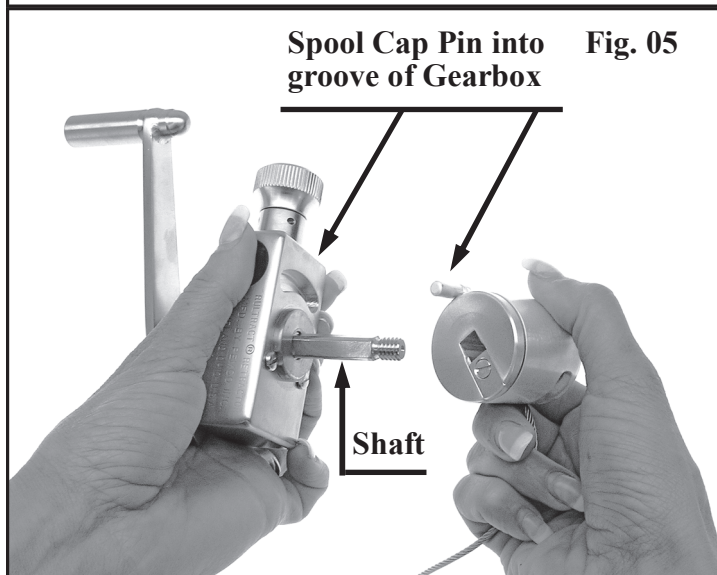
Slide the shaft of Crank Handle into square hole of Gearbox located above the Ratchet Lever (Fig. 01). Note: Both squared sections of the shaft must be completely inserted and flush in gearbox (Fig. 02).



STEP 2 REASSEMBLE SPOOL AND SPOOL CAP: Align the Cable Guide with the flat surface of the Spool (Fig. 03). Slide Spool and Spool Cap together (Fig. 04).



STEP 3 SPOOL CAP ASSEMBLY: While holding the Gearbox and Crank Handle together, line up Spool Cap Pin with the groove in the Gearbox. Slide the Spool Cap Assembly onto the shaft (Fig. 05). Spool Cap Pin must be inserted into groove of Gearbox. While holding Crank Handle Assembly and Gearbox firmly, screw the Spool Cap Nut onto the shaft by turning clockwise. **Hand tighten securely (Fig. 06).**



STEP 4 TEST WINDING FUNCTION:

Allow rake plate to hang freely.** Weight of Rake Plate allows for proper alignment of Cable on Spool. Total length of exposed cable is approximately 16 inches (Fig. 25). Note: Leave one to two inches of Cable exposed to prevent flexing of Cable on Cable Guide at insertion site (Fig. 26). This position protects the Cable from kinking and allows gas or steam to penetrate during sterilization.

DEMONSTRATION
PROPER ALIGNMENT OF
CABLE ON SPOOL WHEN
WOUND CORRECTLY.
Shown without Spool Cap

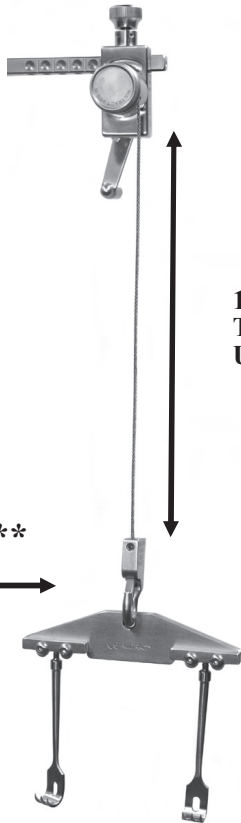
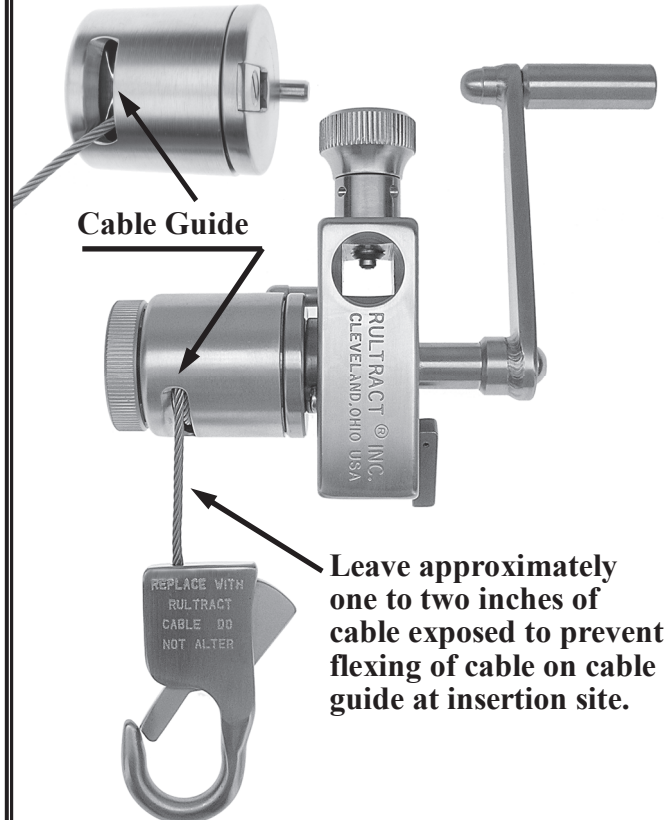


Fig. 25

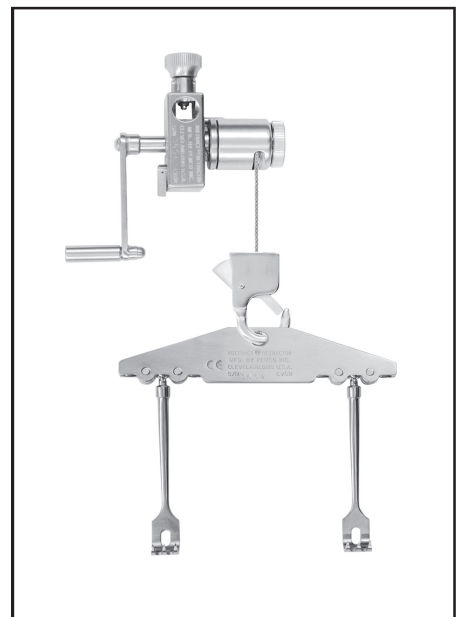
16"
Totally
Unwound

Allow Rake Plate to
Hang Freely while
winding

Fig. 26



**Your Rultract Ratchet
Rake Assembly is now
completely reassembled
and ready for Sterilization
and use** →



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