

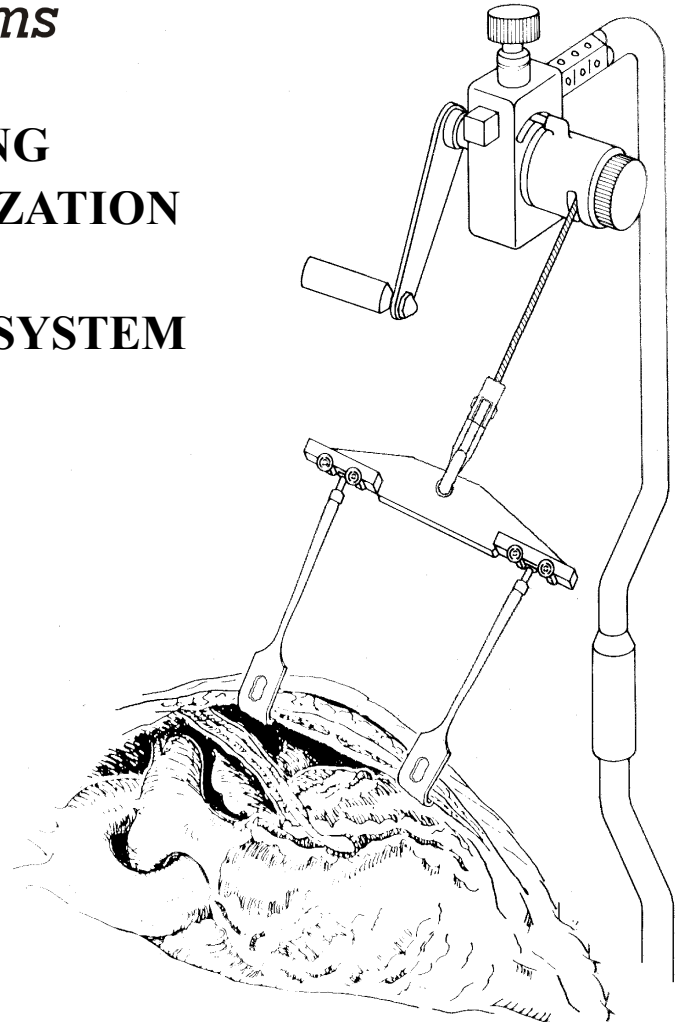
Rultract[®]

SKYHOOK
Surgical Retractor Systems[™]

**STERILE PROCESSING
CLEANING AND STERILIZATION
INSTRUCTIONS
RULTRACT RETRACTOR SYSTEM
SPD INSERVICE**

Rultract FDA Information

FDA Establishment:
RULTRACT INC
5663 Brecksville Road
Independence, OH 44131
Registration #: 1530504
FEI Number#: 3000717741
Owner Operator # 10060024
Listing # D345513



*Rultract has established a medical industry standard for surgical retraction.
The systems provide gentle, uniform lift with maximum exposure.*

*For further information contact Rultract[®] directly at rultract@rultract.com or visit
our website, www.rultract.com. Toll Free 888.550.5695.*

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Rultract Inc. 5663 Brecksville Rd. Cleveland, Ohio 44131 U.S.A.
 Email: rultract@rultract.com Website: www.rultract.com

CLEANING

RULTRACT® CLEANING INSTRUCTIONS

RULTRACT® INSTRUCTIONS FOR USE

CLEANING

Cleaning: Rultract® System

Repeated processing has minimal effect on this instrument. End of life is normally determined by wear and damage due 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 32)

DO NOT remove fasteners or roll pins for proper cleaning and sterilization.

Further disassembly is not necessary and may void warranty and/or damage the product.

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.

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

CHECK PAGE NUMBER REFERENCES

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IN PREPARATION FOR THE CLEANING CYCLE, YOU MUST DISASSEMBLE RATCHET/RAKE ASSEMBLY, 4100-IMR-6, Fig. 01,

AS SHOWN IN Fig. 02

NO FURTHER DISASSEMBLY REQUIRED

Proceed to pages 29-32 for disassembly instructions

Fig. 01

4100-IMR-6

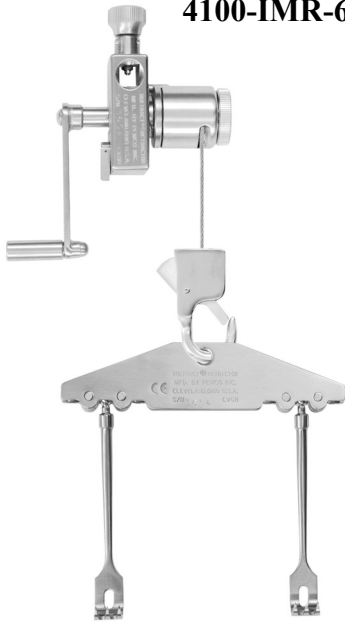
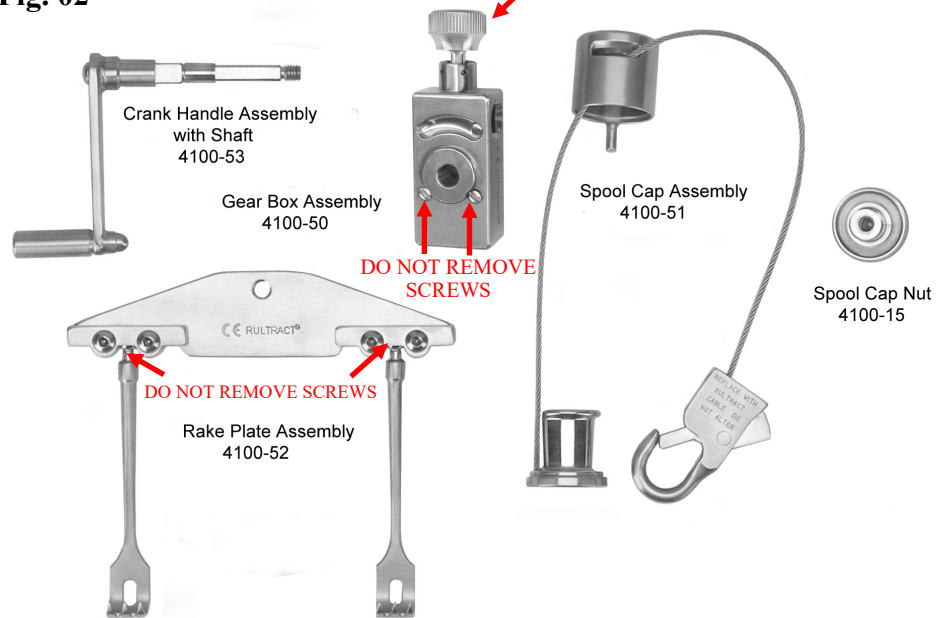


Fig. 02

DO NOT REMOVE LOCK KNOB

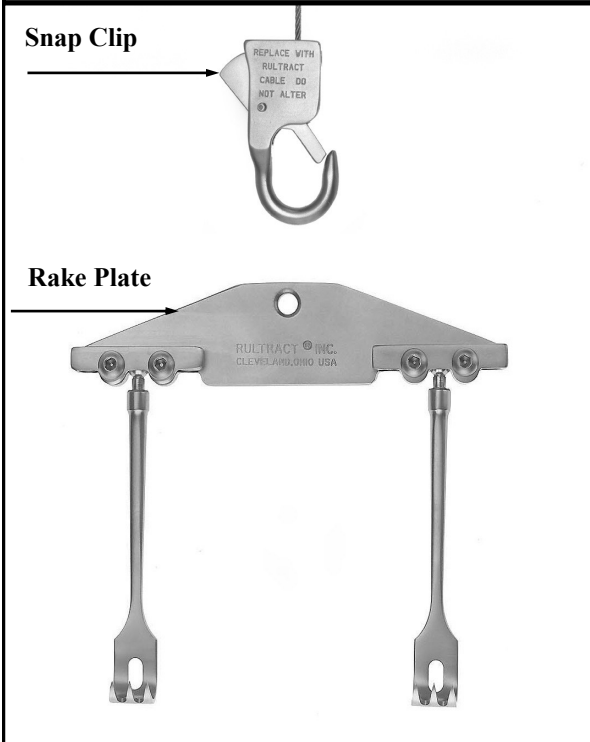


Determine Your Rake Plate System Configuration

STEP 1 RAKE PLATE:

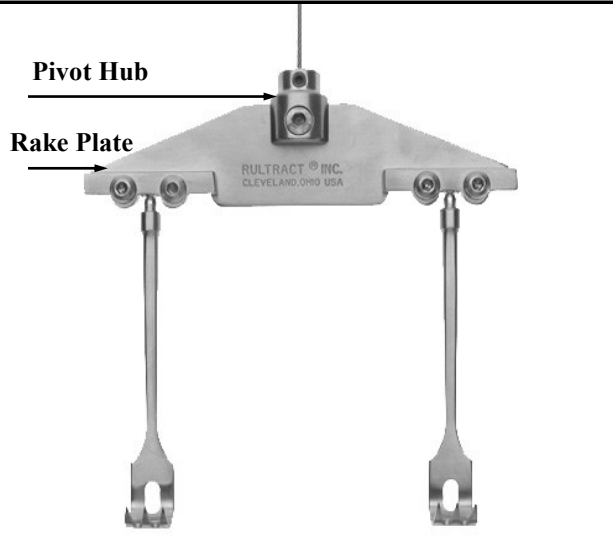
If your system has a Snap Clip and a Rake Plate

Disconnect Rake Plate from Snap Clip



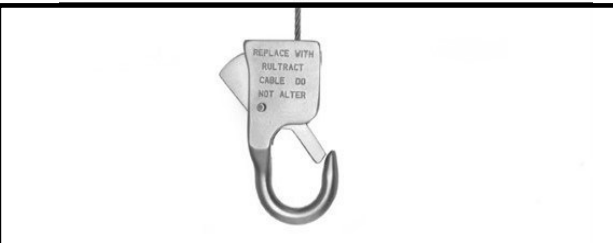
If your system has a Pivot Hub Attached to the Cable and Rake Plate

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

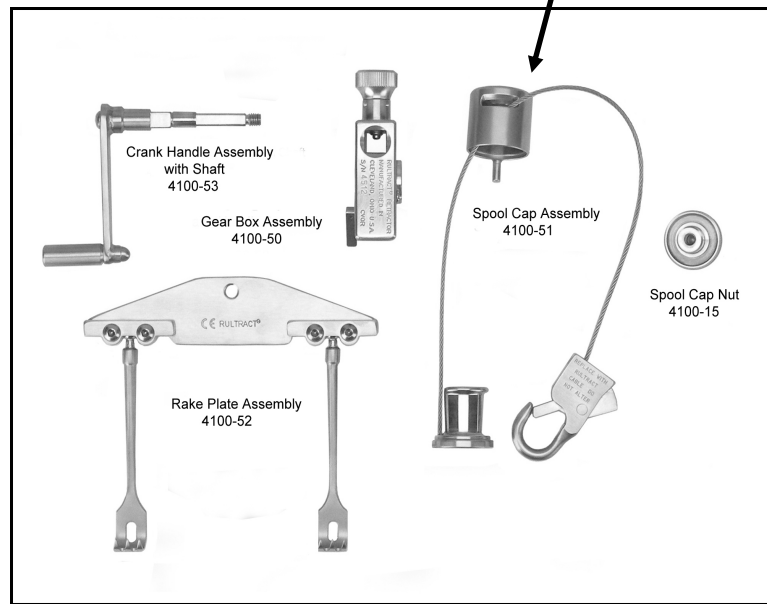


If your system has a Snap Clip Only

Proceed to Step 2



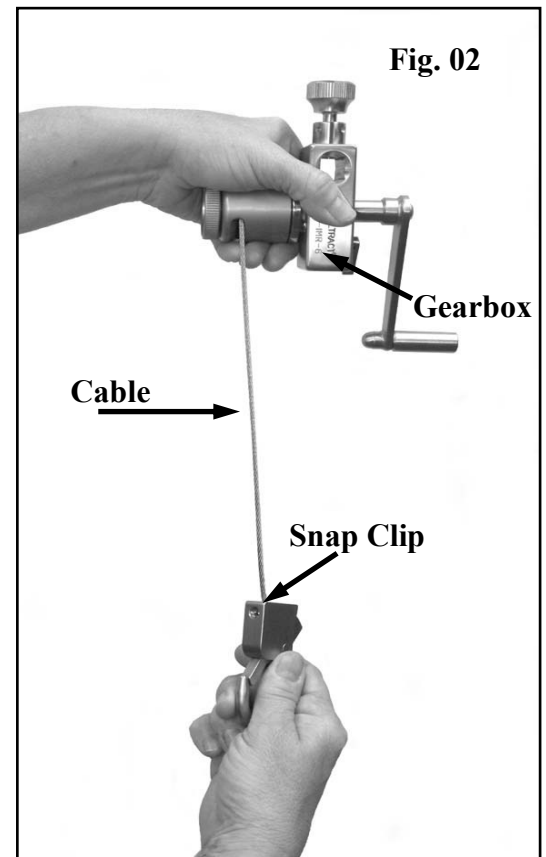
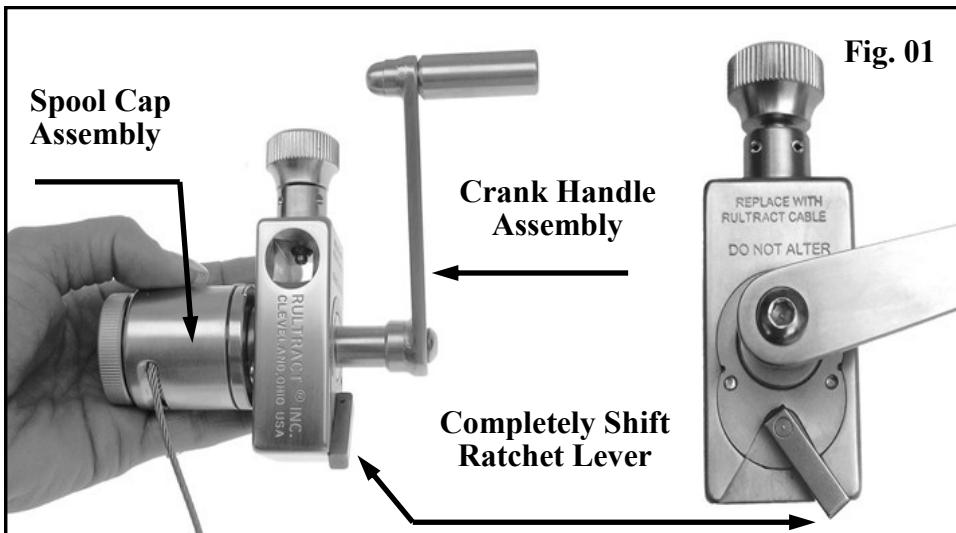
DISASSEMBLE RATCHET ASSEMBLY FOR CLEANING (PAGES 30-32)



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.

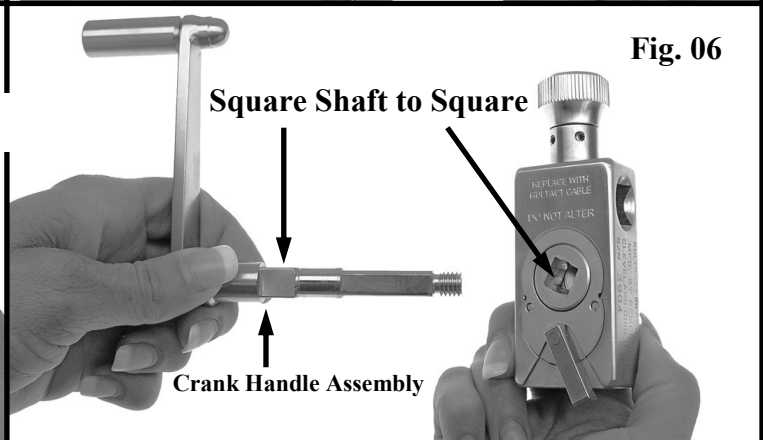
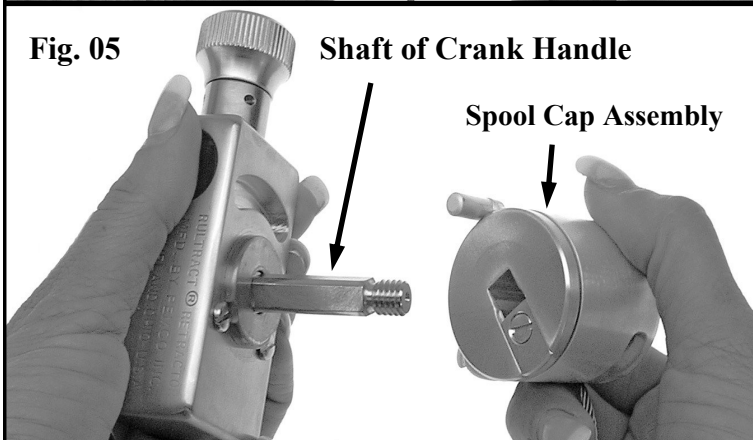
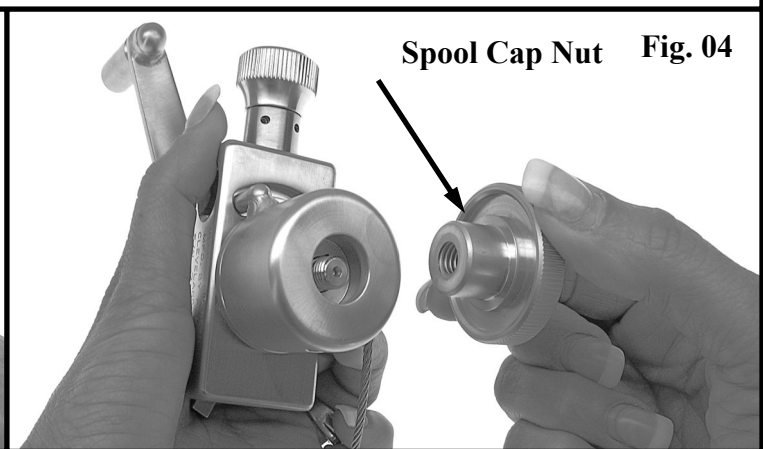
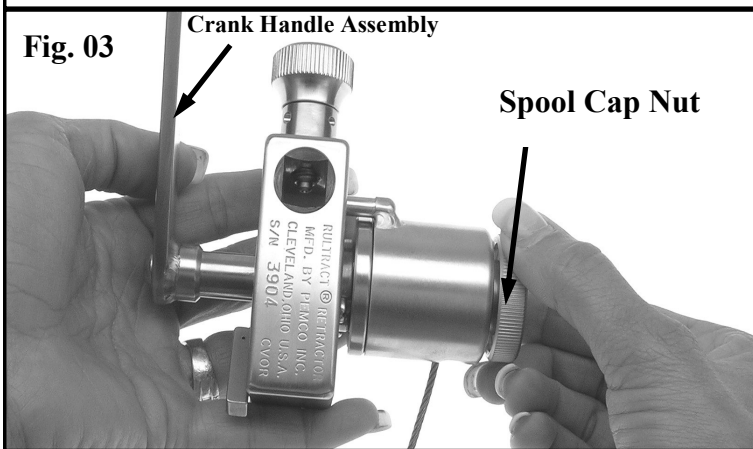
Note: Worn or damaged cable must be replaced at this time with a new Rultract® Cable.



DISASSEMBLE RATCHET ASSEMBLY FOR CLEANING (continued)

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).

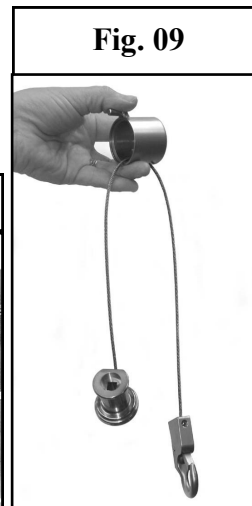
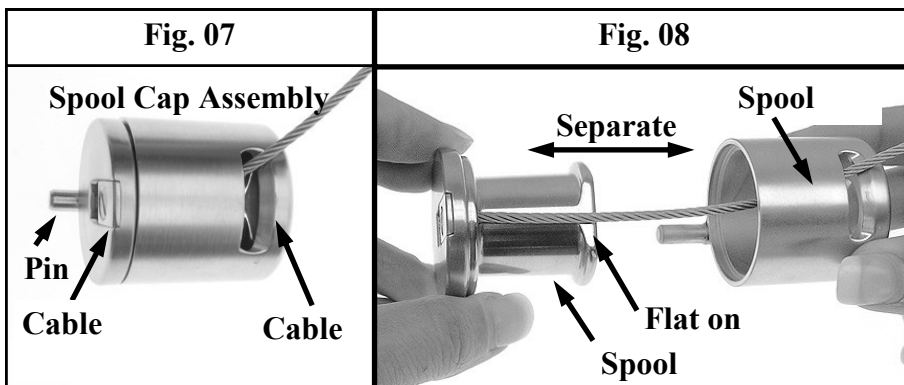


DISASSEMBLE RATCHET ASSEMBLY FOR CLEANING (continued)

STEP 4 SEPARATE SPOOL CAP FROM SPOOL:

To separate Spool Cap from Spool, line up Cable Guide and Pin and Cable Access Plate of Spool. (Fig. 07)

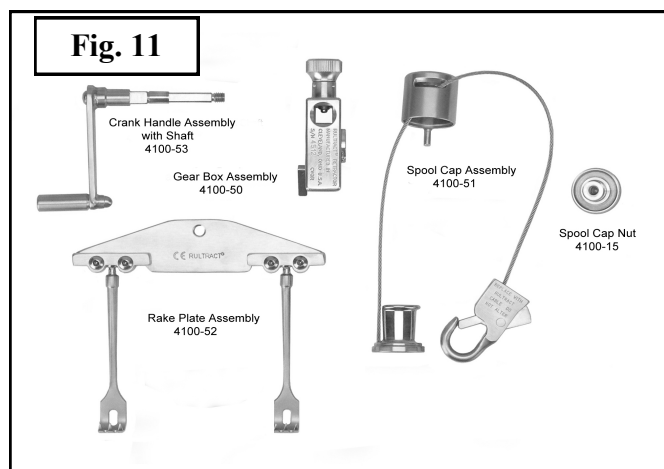
This will align flat on Spool with Cable Guide and allow the two pieces to separate. (Fig. 08)



Slide Spool Cap along cable as shown in (Fig. 09).

Do not disassemble any further than Fig. 11.

The Rultract Ratchet Assembly is now completely disassembled and ready to begin the cleaning cycle

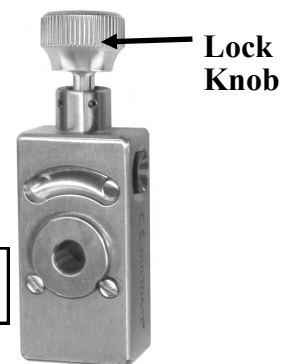


Do not disassemble any further

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 THE LOCK KNOB**



Knobs may “freeze” if sterilized in a fully open or closed position.

CAUTION:

Check and tighten all fasteners as indicated on pages 42-46 after the cleaning cycle and prior to sterilization and each use.

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

SYSTEM COMPONENTS - RESTERNOTOMY RETRACTORS PREPARE FOR CLEANING CYCLE

CLEANING: Resternotomy Rake Plates

- **No disassembly required**

Resternotomy Rake Plates:

4100-52RDL	Resternotomy Assist, Large	18mm Rakes
4100-52RDM	Resternotomy Assist, Medium	12mm Rakes
4100-52RDS	Resternotomy Assist, Small	8mm Rakes
4100-52RDH	Resternotomy Assist, Hooks	

CAUTION:

As Indicated on Page 10

**CHECK AND TIGHTEN ALL FASTENERS ON THE
RAKE PLATE ASSEMBLY
AFTER THE CLEANING CYCLE AND PRIOR TO STERILIZATION**

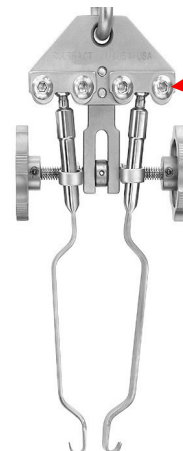
4100-52RDL



4100-52RDM



4100-52RDS



4100-52RDH



DO NOT REMOVE
RAKE CLAMP-
SCREWS

DO NOT REMOVE
RAKE CLAMP-
SCREWS

**Do not fully open or close the knobs for sterilization.
Knobs may “freeze” if sterilized in a fully open or closed position.**

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Surgical Retractor Systems

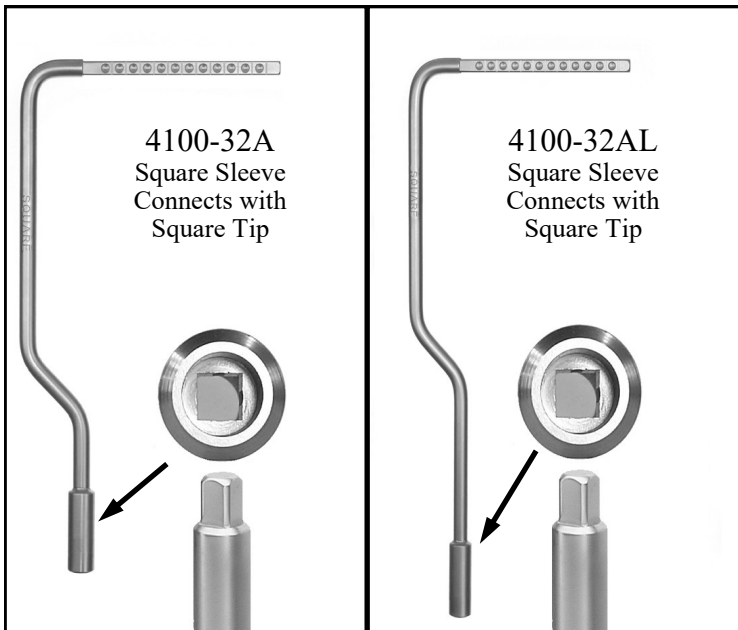
SYSTEM COMPONENTS - TOP POSTS PREPARATION FOR CLEANING CYCLE

CLEANING: Top Posts

- **No disassembly required**

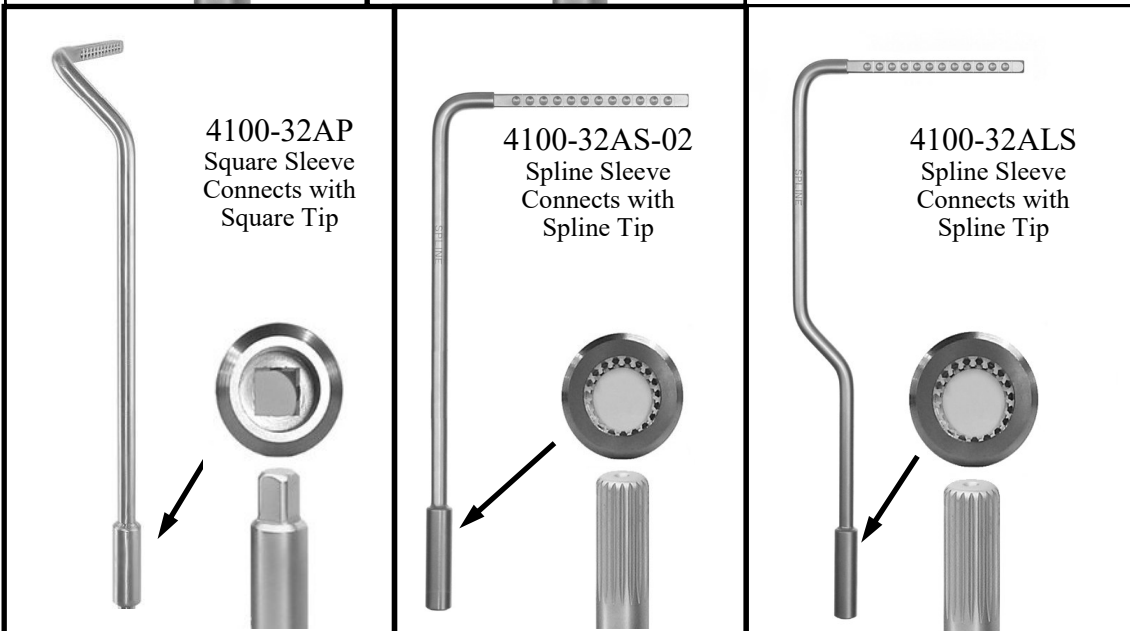
TOP POSTS: Square and Spline inserts

4100-32A	Square Top Post - standard length -	9 1/2" x 18" long (square insert)
4100-32AL	Square Top Post - extended length -	9 1/2" x 22" long (square insert)
4100-32AP	Offset Square Top Post -	9 1/2" x 20" long (square insert)
4100-32AS-02	Spline Top Post - standard length -	9 1/2" x 19" long (spline insert)
4100-32ALS	Spline Top Post - extended length -	9 1/2" x 23" long (spline insert)



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**SYSTEM COMPONENTS - ONE PIECE AND TILTING TOP POSTS
PREPARATION FOR CLEANING CYCLE**

ONE PIECE POST: Round Base

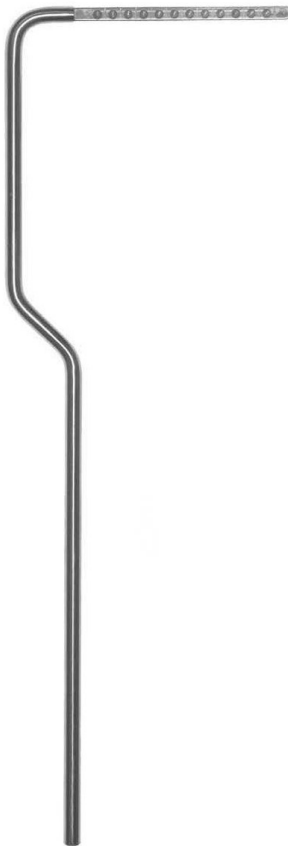
4100-08 One piece post -
9 1/2" x 30" long

CLEANING One Piece Post

- **No disassembly required**

THIS ITEM HAS BEEN DISCONTINUED

4100-08 One Piece Post
No Collar 30" Long



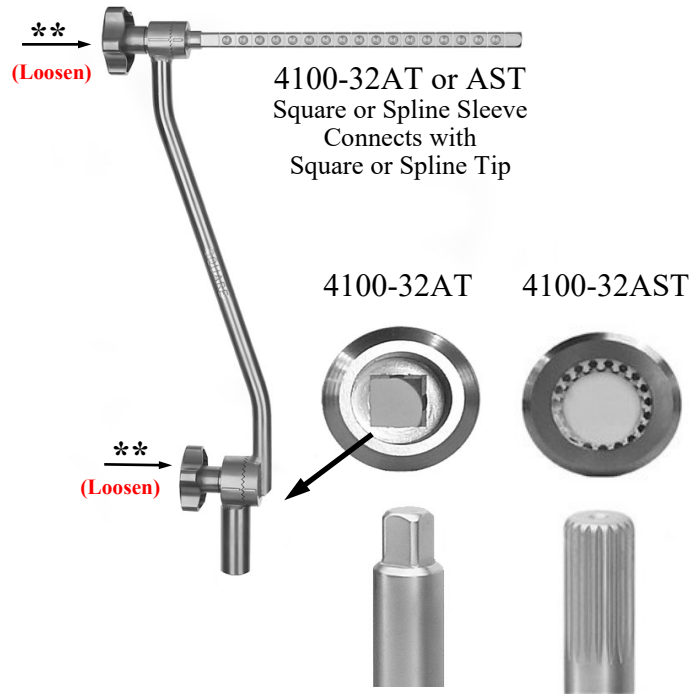
TILTING TOP POSTS: Square and Spline inserts

4100-32AT Square Tilting Top Post - 12 1/2" x 20" long

4100-32AST Spline Tilting Top Post - 12 1/2" x 21" long

CLEANING Tilting Top Posts

- **No disassembly required.**
- **Do not remove retaining screws.****
- **Do not open or close handles completely.**
- **Loosen knobs for partial separation. Knobs may "freeze" if sterilized in a fully open or closed position.**
- **Sections and knobs should have free movement (rotate freely).**




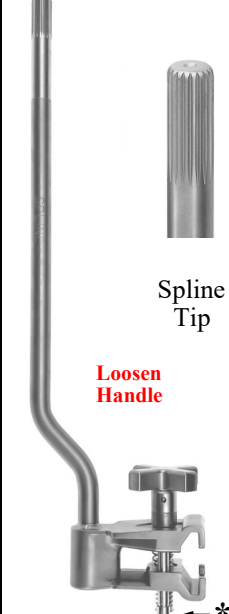
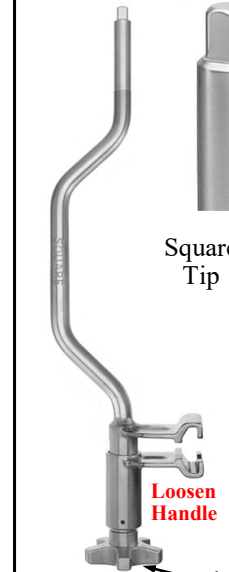
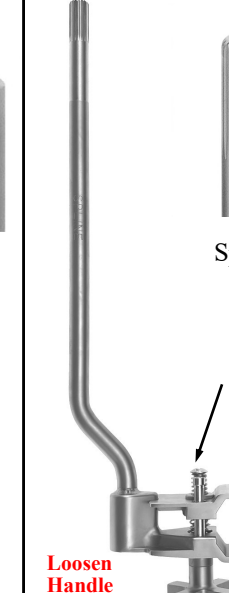
WARNING: Removal of retaining screw(s) (4110P-12) will cause device to come apart. This will result in failure during use.**

DO NOT REMOVE RETAINING SCREWS **


SYSTEM COMPONENTS - POST CLAMPS PREPARATION FOR CLEANING CYCLE

CLAMPS: *Square and Spline Tip*


4150	Square Tip, Double Bend Post/Clamp, Scrub Applied - 19" long
4150S-02	Spline Tip, Single Bend Post/Clamp Scrub Applied - 19" long
4160	Square Tip, Double Bend Post/Clamp, Circulator Applied - 20" long
4160S-02	Spline Tip, Single Bend Post/Clamp, Circulator Applied - 20" long

 <p>Square Tip</p>	 <p>Spline Tip</p>	 <p>Square Tip</p>	 <p>Spline Tip</p>
4150 Scrub Applied	4150S-02 Scrub Applied	4160 Circulator Applied	4160S-02 Circulator Applied

SQUARE TIP
90° Angle



SPLINE TIP
18° Increments



CLEANING: Clamp

- **No disassembly required.**
 - **Do not remove retaining screw.****
 - Do not open or close handles completely.
 - Jaws should be partially opened.
- Jaws and handles should have free movement. (open and close & rotate freely)

Handles may “freeze” if sterilized in a fully open or closed position.

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

DO NOT REMOVE RETAINING SCREWS **

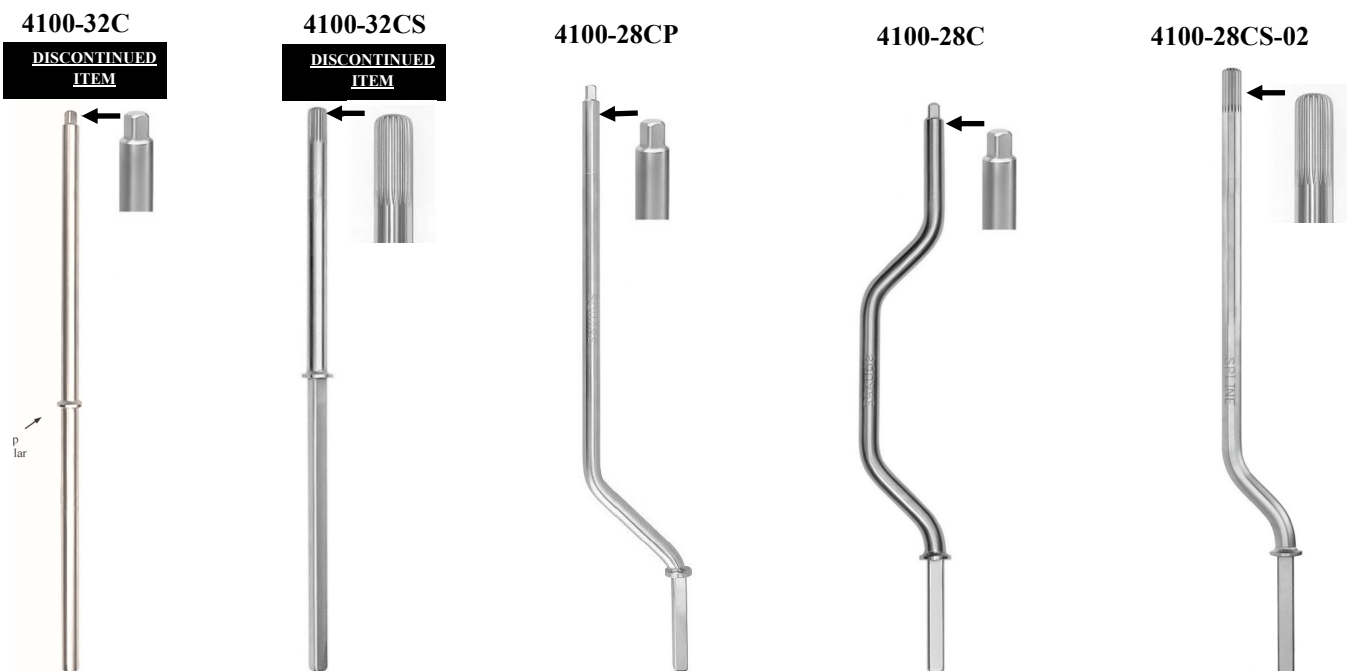
**SYSTEM COMPONENTS - BOTTOM POSTS AND COMBINATIONS CLAMPS
PREPARATION FOR CLEANING CYCLE**

BOTTOM POSTS: Square and Spline Tip

- 4100-32C Square Tip Bottom Post w/ collar - 5/8" Dia. x 20" long
- 4100-32CS Spline Tip Bottom Post w/ collar - 5/8" Dia. x 20" long
- 4100-28C Square Tip Double Bend Bottom Post - 5/8" Dia. x 18" long
- 4100-28CP Offset Square Tip Bottom Post - 5/8" Dia. x 20" long
- 4100-28CS-02 Spline Tip Single Bend Bottom Post - 5/8" Dia. x 18" long

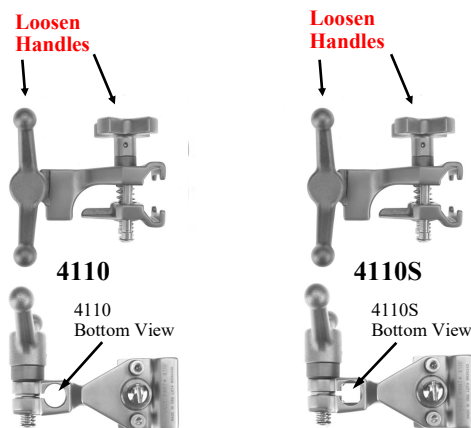
CLEANING Bottom Posts

- **No disassembly required.**



CLEANING: Clamp

- **No disassembly required.**
- **Do not remove retaining screw.****
- **Do not open or close handles completely.**
- **Jaws should be partially opened.**
Jaws and handles should have free movement. (open and close & rotate freely)



Handles may "freeze" if sterilized in a fully open or closed position.

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

DO NOT REMOVE RETAINING SCREWS **

SYSTEM COMPONENTS - EXTENDER BARS

PREPARATION FOR CLEANING CYCLE

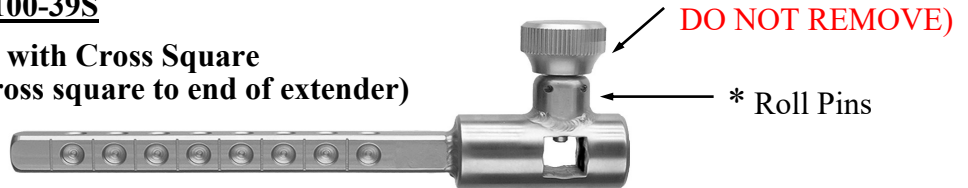
- **No disassembly required.**
- **Do not remove retaining roll pins* or screw. ****
- **Back out (open) the non-removable Lock Knob**

- **Loosen knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)**
- **Knobs may “freeze” if sterilized in a fully open or closed position.**

Loosen Lock Knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)

4100-39S

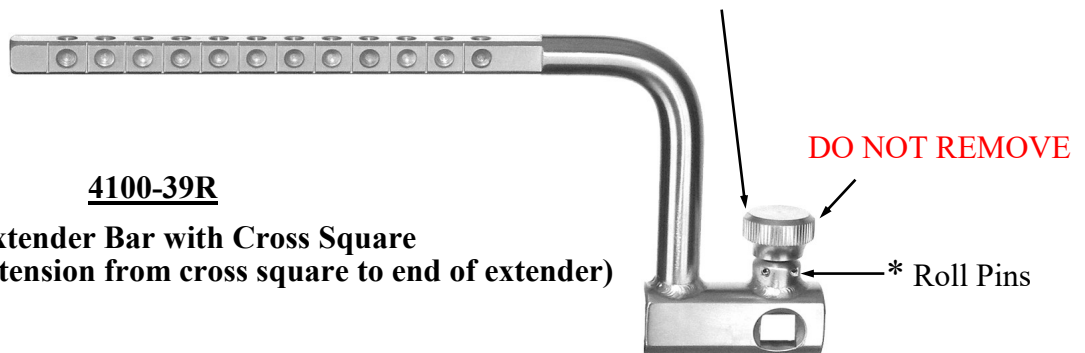
**Extender Bar with Cross Square
(6 1/2" extension from cross square to end of extender)**



Loosen Lock Knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)

4100-39R

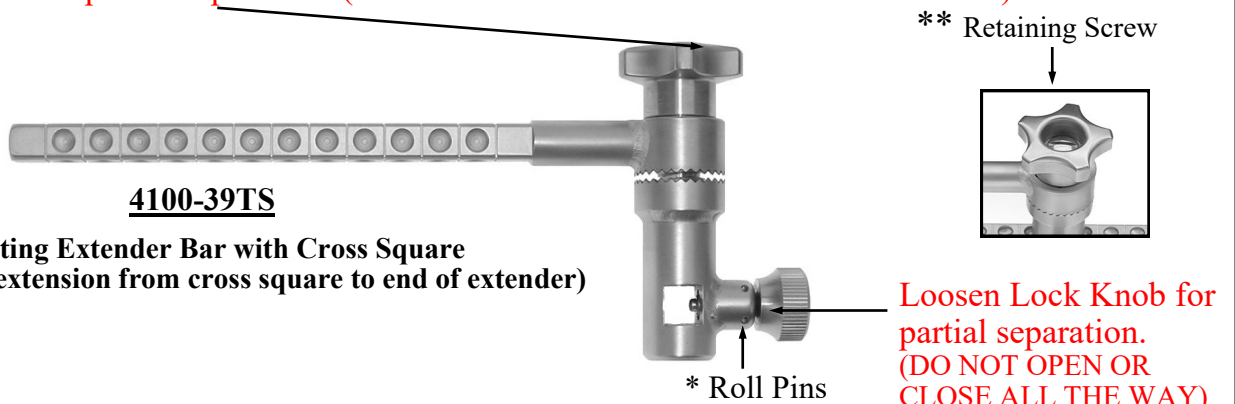
**Riser Extender Bar with Cross Square
(4" rise and 10 1/2" extension from cross square to end of extender)**



Loosen Knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)

4100-39TS

**Rotating Extender Bar with Cross Square
(2" rise w/ 9" extension from cross square to end of extender)**



Knobs may “freeze” if sterilized in a fully open or closed position.

Once the Ratchet Assembly has been disassembled and all of the components have completed the cleaning cycle, Rultract recommends that the Ratchet Assembly be reassembled prior to sterilization.

Please refer to pages 47-49 for reassembly instructions.

RULTRACT® INSTRUCTIONS: AFTER CLEANING CYCLE - PREPARE FOR STERILIZATION

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.

RULTRACT® INSTRUCTIONS FOR USE—STERILIZATION PARAMETERS

Guidelines for Sterilization :

CAUTION: Reassemble prior to sterilization. See pages 47-49.

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 and steam (gravity) wrapped or by using a rigid container system.

The following cycles were verified utilizing a combination of wrapped metal instruments or metal instruments in a common rigid container system with a mass up to 40 pounds (18 kg).

The wrapped instruments were wrapped with non-woven single use Steriwrap™.

Option 1: Wrapped Instruments or Instruments in Rigid Container System:

Pre-vacuum Sterilization Parameters
(Minimum time and temperature):
Temperature 132°C (270°F)
Exposure Time 4 minutes
Drying Time 30 minutes

Option 2: Wrapped Instruments or Instruments in Rigid Container System:

Steam (Gravity) Sterilization Parameters
(Minimum time and temperature):
Temperature 121° C (250°F)
Exposure Time 30 minutes
Drying Time 30 minutes

DO NOT remove fasteners or roll pins for cleaning and sterilization.

**RULTRACT® INSTRUCTIONS: AFTER CLEANING CYCLE -
PREPARE FOR STERILIZATION**

CAUTION:

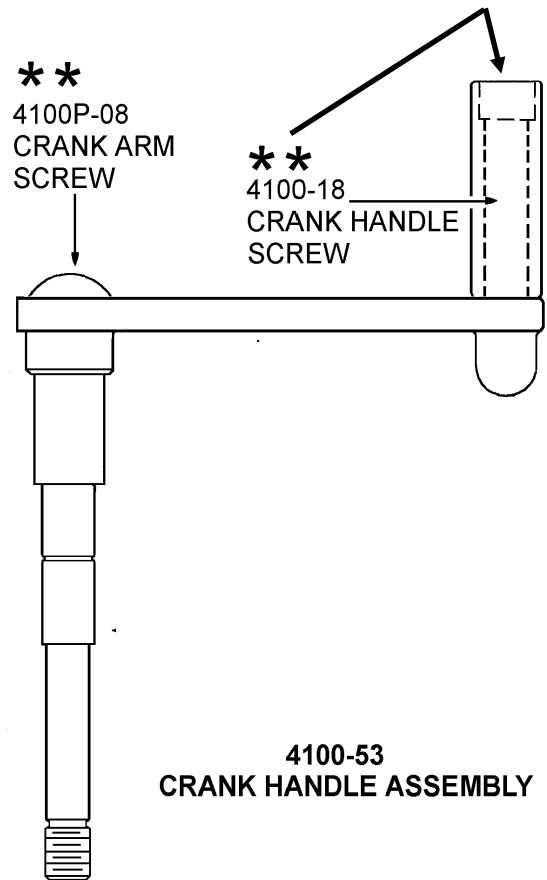
*Check and tighten all fasteners on
the Ratchet/Rake Assembly.*

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

**The following two items
should not be removed.**

***If these fasteners are removed a bolt
retaining compound must be reapplied.***

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

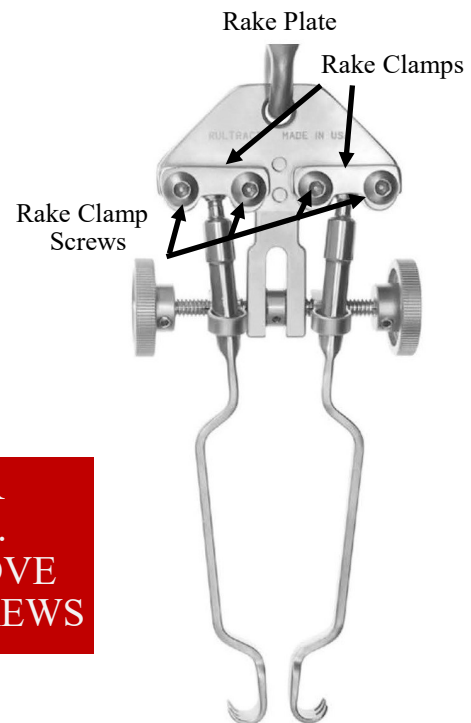
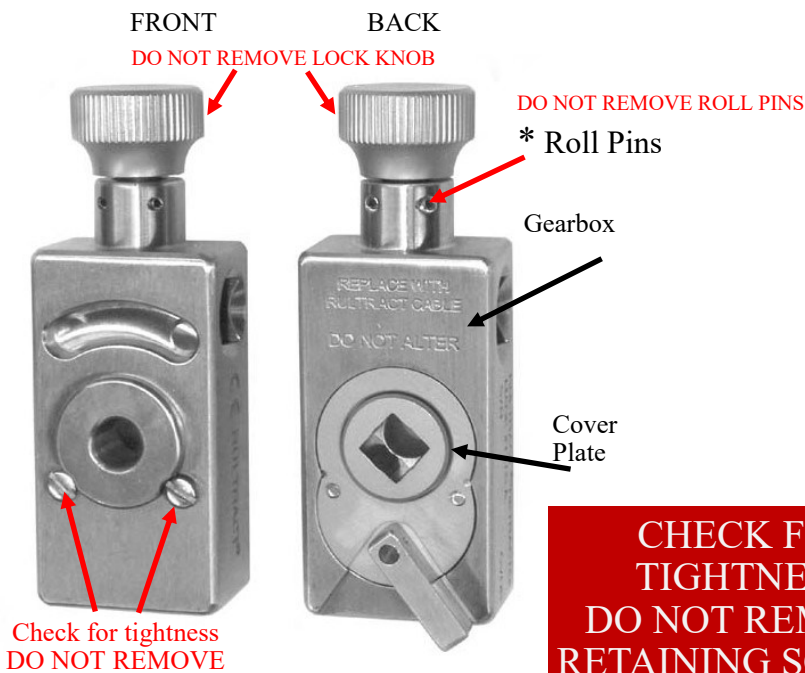


RATCHET/RAKE FASTENERS:
CAUTION:
CHECK AND TIGHTEN ALL FASTENERS
ON THE RATCHET RAKE ASSEMBLY
AFTER THE CLEANING CYCLE AND PRIOR TO STERILIZATION

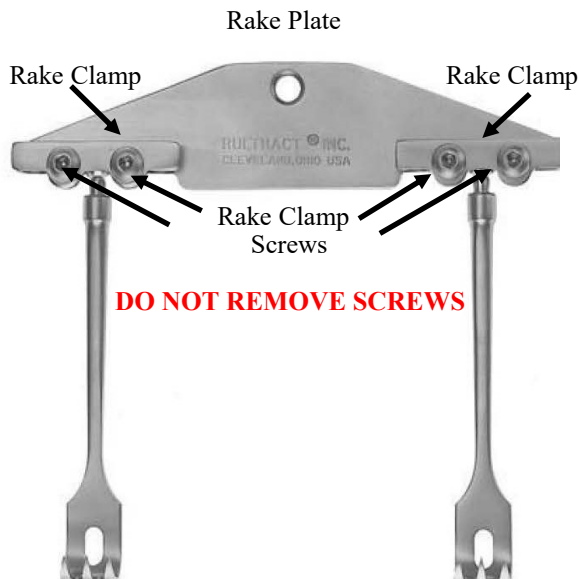
FAILURE TO DO SO MAY CAUSE COMPONENTS TO LOOSEN OR
DISASSEMBLE DURING USE

Cover Plate Screws to retain the Cover Plate on the Gearbox.

Rake Clamp Screws to mount Rake Clamps to Rake Plate



CHECK FOR TIGHTNESS.
DO NOT REMOVE
RETAINING SCREWS



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RULTRACT® INSTRUCTIONS: AFTER CLEANING CYCLE - PREPARE FOR STERILIZATION

FASTENERS: CAUTION:
CHECK AND TIGHTEN ALL FASTENERS
ON THE FOLLOWING COMPONENTS
AFTER THE CLEANING CYCLE AND PRIOR TO STERILIZATION.
FAILURE TO DO SO MAY CAUSE COMPONENTS TO LOOSEN OR
DISASSEMBLE DURING USE

RULTRACT IFU SYSTEM COMPONENTS - PREPARE FOR STERILIZATION

DO NOT REMOVE RETAINING SCREWS

Sterilization: Clamp

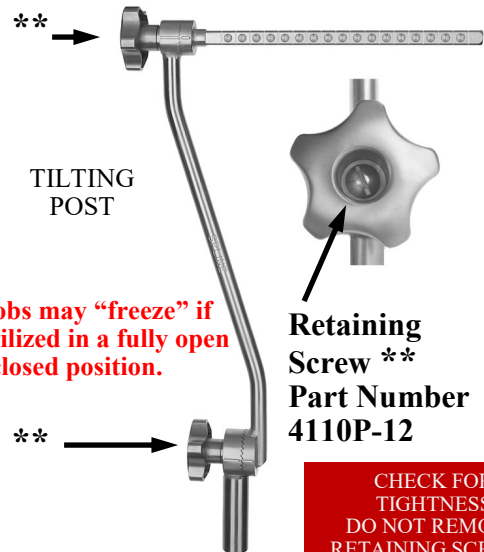
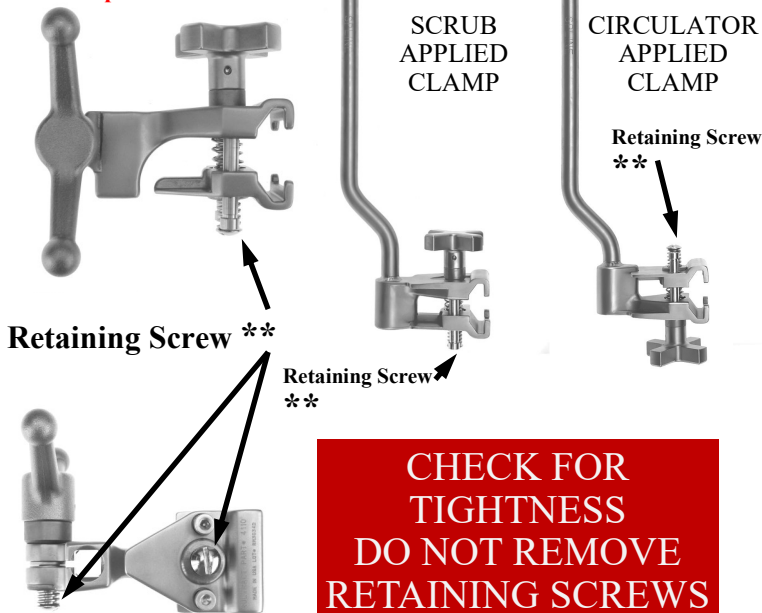
- Do not disassemble for cleaning or sterilization.
- Do not remove retaining screw (s).**
- Do not open or close handle (s) completely.
- Jaws should be partially opened.
- Jaws and handles should have free movement.

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.

COMBINATION CLAMP
 SCRUB/CIRCULATOR
 APPLIED

Knobs may “freeze” if
 sterilized in a fully open or
 closed position.



Rultract FDA Information

FDA Establishment:
 RULTRACT INC
 5663 Brecksville Road
 Independence, OH 44131
 Registration #: 1530504
 FEI Number*: 3000717741
 Owner Operator # 10060024
 Listing # D345513



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

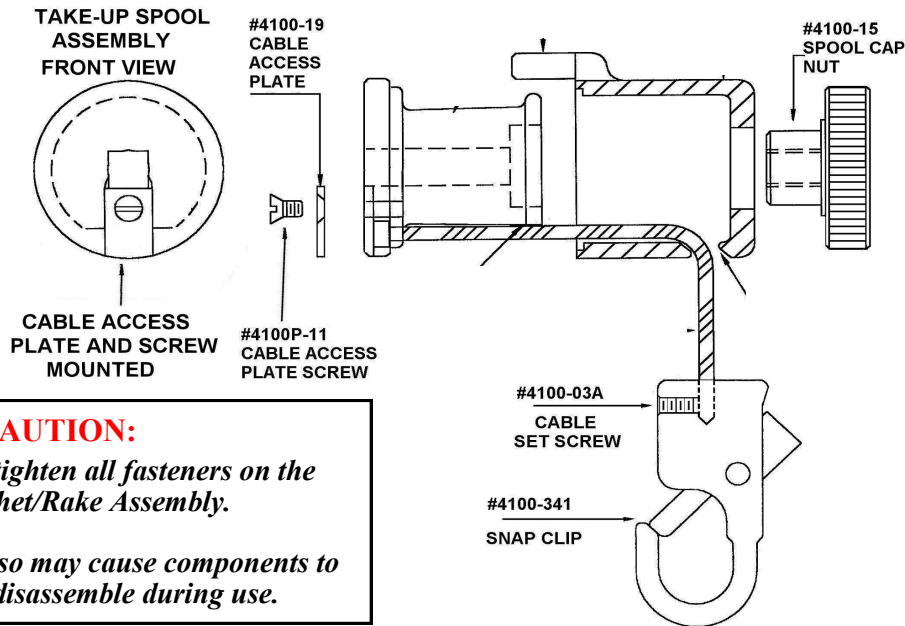
Tightening Knobs may “freeze” if sterilized in a fully open or closed position.

SPOOL CAP ASSEMBLY FASTENERS:
CHECK FOR TIGHTNESS AFTER THE CLEANING CYCLE AND
PRIOR TO STERILIZATION

- ** 1 pc. 4100-15 Spool Cap Nut to retain Spool Cap Assembly.
- ** 1 pc. 4100P-11 Cable Access Plate Screw to retain Cable Access Plate.

SPOOL CAP ASSEMBLY

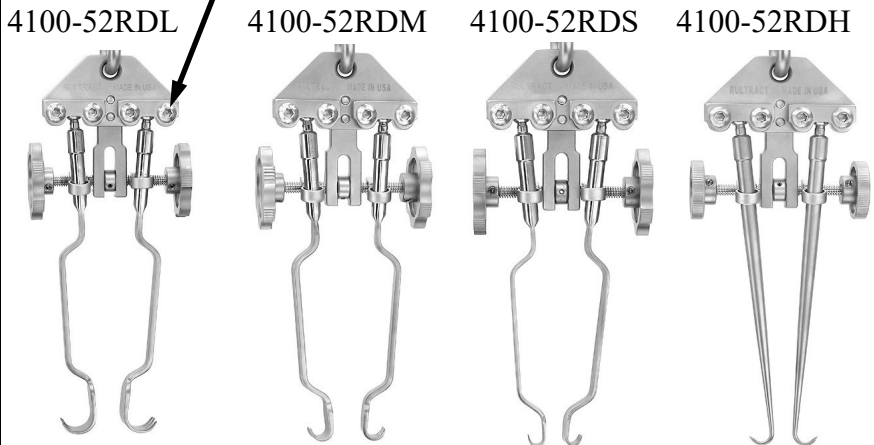
4100-51 Spool Cap Assembly Rake



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: Resternotomy Rake Plates
 • **No disassembly required**

CHECK ALL RAKE CLAMP SCREWS FOR TIGHTNESS. DO NOT REMOVE.



- 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.

Knobs may "freeze" if sterilized in a fully open or closed position.

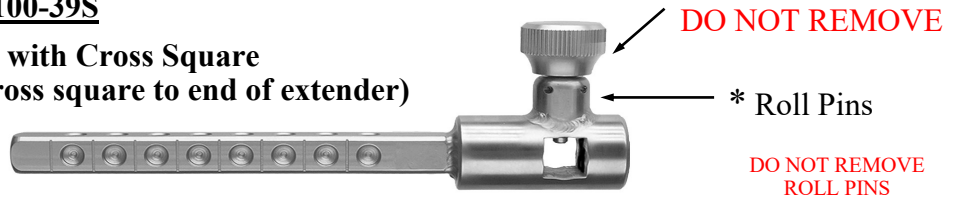
**** DO NOT REMOVE RAKE CLAMP SCREWS ****

**RULTRACT® INSTRUCTIONS: AFTER CLEANING CYCLE - PREPARE FOR STERILIZATION
EXTENDER BARS**

- **No disassembly required.**
- **Do not remove retaining roll pins* or screw.****
- **Back out (open) the non-removable Lock Knob**
- **Loosen knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)**
- **Knobs may “freeze” if sterilized in a fully open or closed position.**

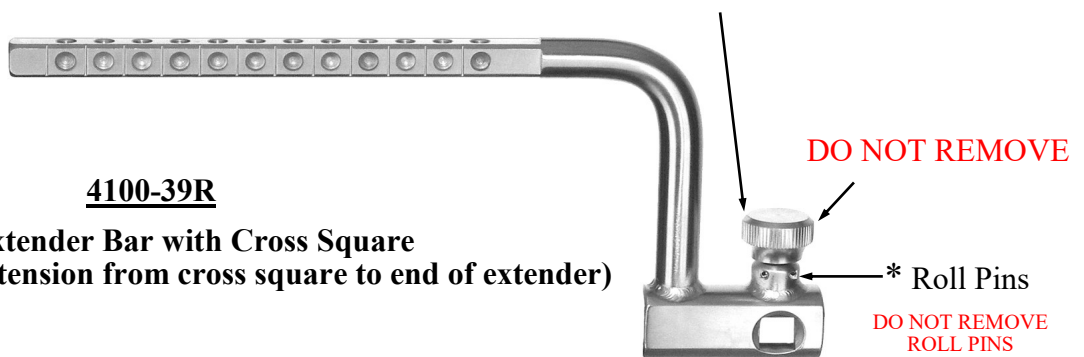
Loosen Lock Knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)

4100-39S
Extender Bar with Cross Square
(6 1/2" extension from cross square to end of extender)



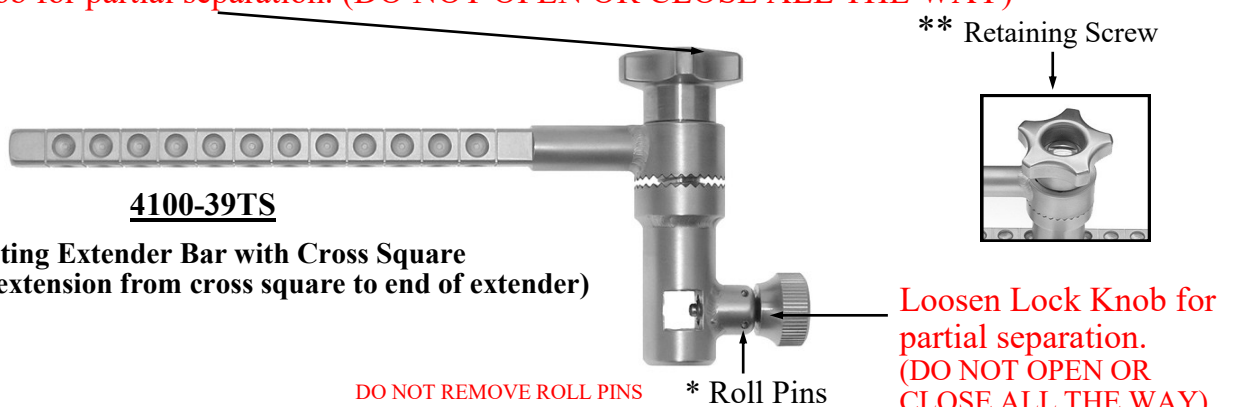
Loosen Lock Knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)

4100-39R
Riser Extender Bar with Cross Square
(4" rise and 10 1/2" extension from cross square to end of extender)



Loosen Knob for partial separation. (DO NOT OPEN OR CLOSE ALL THE WAY)

4100-39TS
Rotating Extender Bar with Cross Square
(2" rise w/ 9" extension from cross square to end of extender)

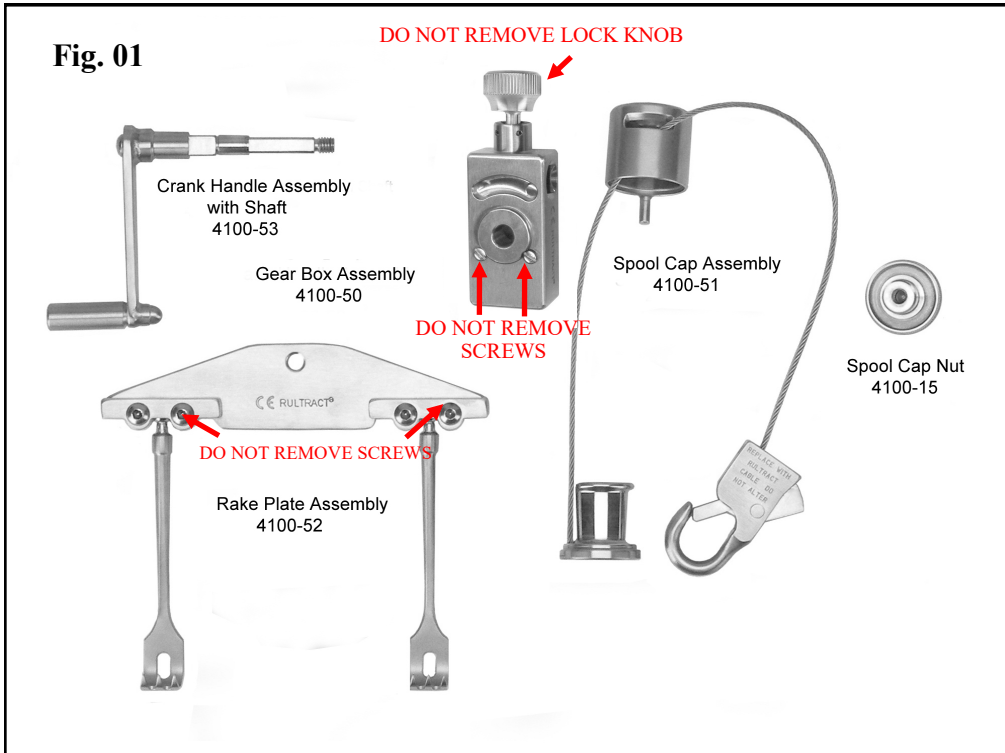


Knobs may “freeze” if sterilized in a fully open or closed position.

**RULTRACT® INSTRUCTIONS:
AFTER CLEANING CYCLE - PREPARE FOR STERILIZATION**

**IN PREPARATION FOR STERILIZATION, YOU MUST
REASSEMBLE RATCHET/RAKE ASSEMBLY, 4100-IMR-6, (Fig. 01),
AS SHOWN IN Fig. 02**

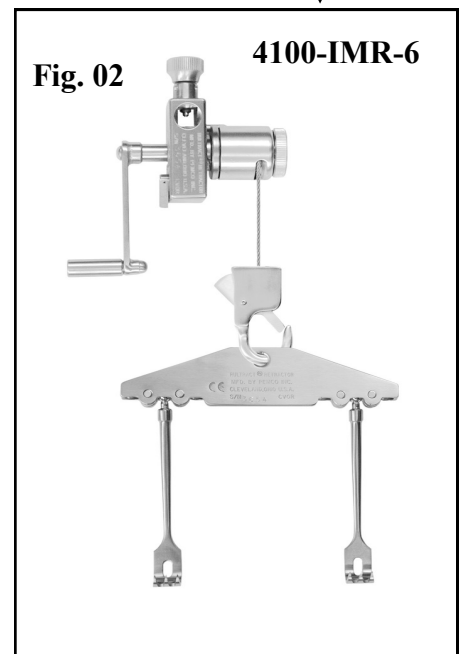
Proceed to pages 47-49 for assembly instructions



REASSEMBLE THIS



TO THIS



Rultract FDA Information

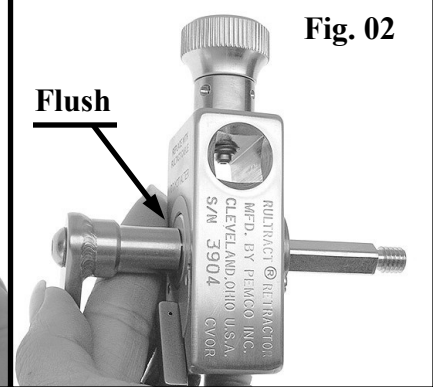
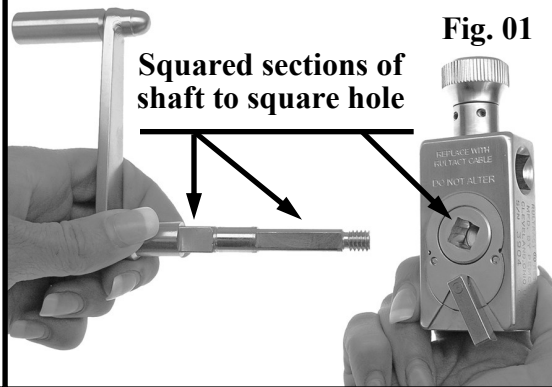
FDA Establishment:
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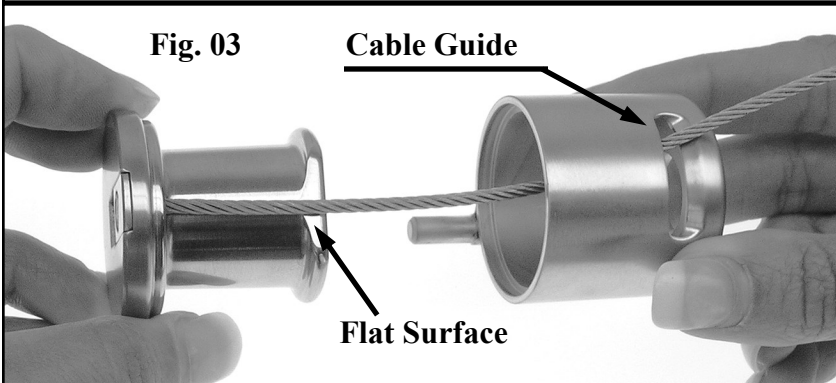
REASSEMBLE RATCHET FOR STERILIZATION AND USE

**STEP 1
INSTALL CRANK HANDLE:**

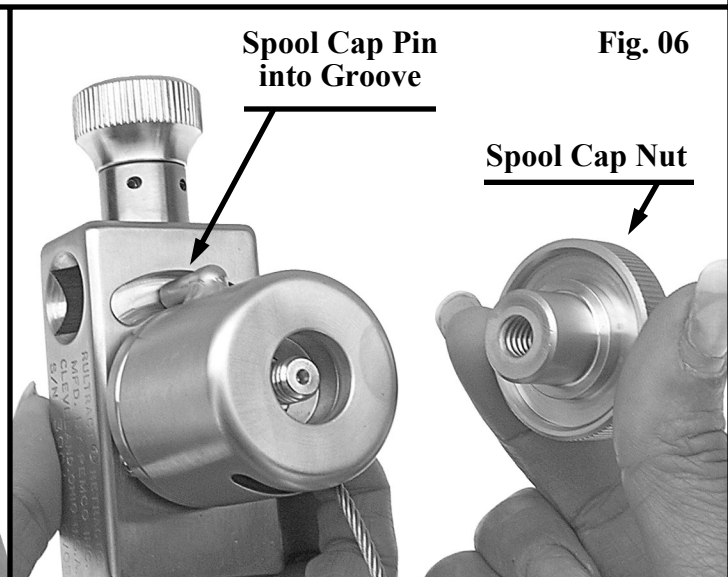
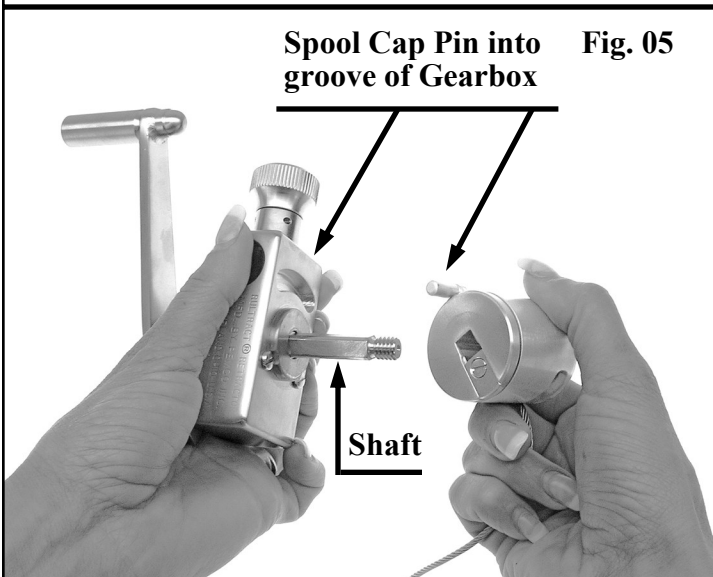
Slide the shaft of Crank Handle into square hole of Gearbox located above the Ratchet Lever (Fig. 01). Note: Both squared sections of the shaft must be completely inserted and flush in gearbox (Fig. 02).



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).



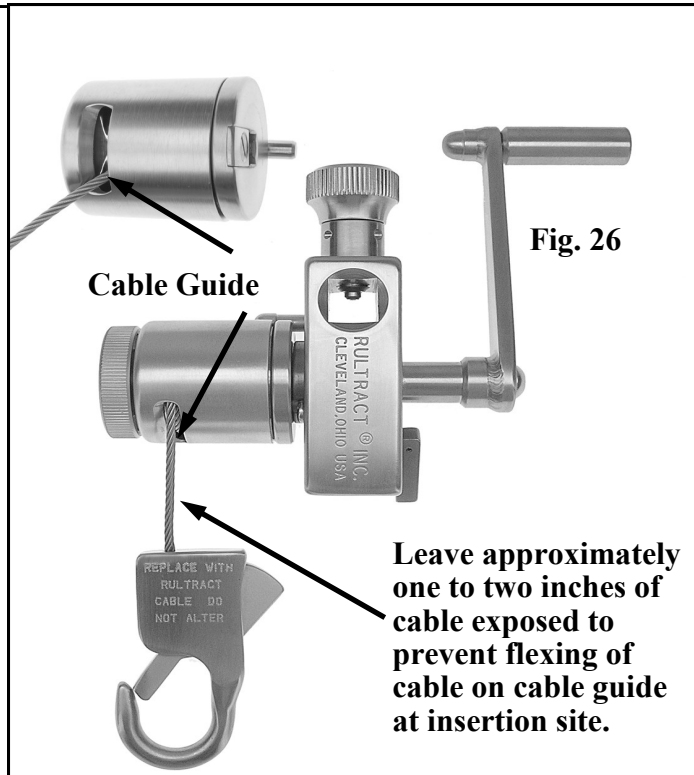
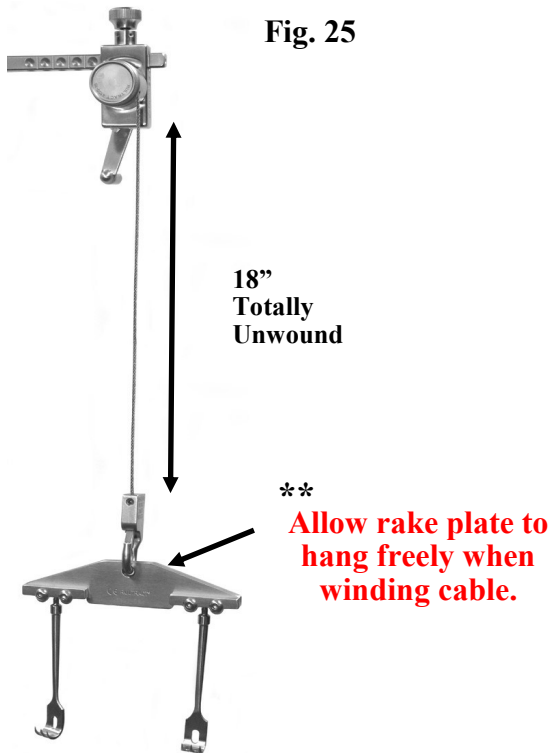
STEP 3 SPOOL CAP ASSEMBLY: While holding the Gearbox and Crank Handle together, line up Spool Cap Pin with the groove in the Gearbox. Slide the Spool Cap Assembly onto the shaft (Fig. 05). Spool Cap Pin must be inserted into groove of Gearbox. While holding Crank Handle Assembly and Gearbox firmly, screw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



**REASSEMBLE RATCHET ASSEMBLY FOR STERILIZATION AND USE
(STEPS 4 AND 5)**

STEP 4 TEST WINDING FUNCTION:

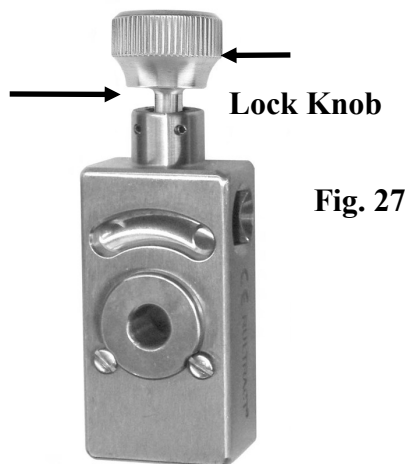
Allow Rake Plate or Snap Clip to hang freely. Weight of Rake Plate or Snap Clip allows for proper alignment of Cable on Spool. Total length of exposed, unwound Cable is approximately 18 inches (Fig. 25). **Note: Leave one to two inches of Cable exposed to prevent flexing of Cable on Cable Guide at insertion site** (Fig. 26). This position protects the Cable from kinking and allows gas or steam to penetrate during sterilization.



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. 27).

Knob may “freeze” if sterilized in a fully open or closed position.



**** DO NOT REMOVE THE LOCK KNOB ****

ATTEMPTING TO REMOVE THE LOCK KNOB WILL DAMAGE THE GEARBOX AND IT WILL REQUIRE FACTORY SERVICE TO REPAIR

The Rultract Ratchet Assembly is now completely reassembled and ready for sterilization and use

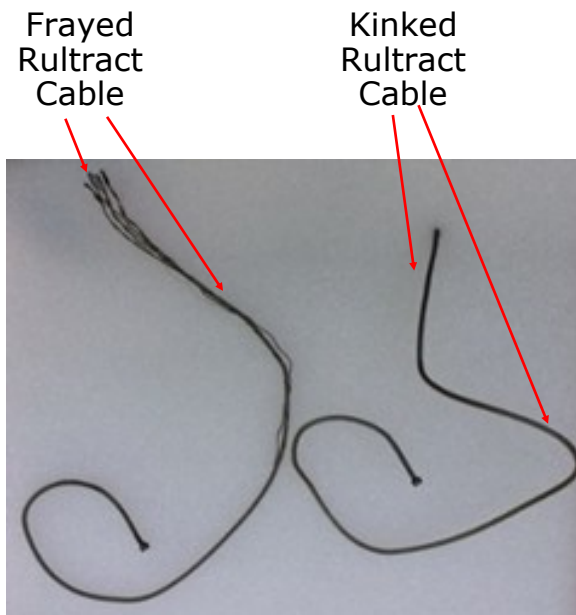
RULTRACT® INSTRUCTIONS FOR USE PREPARE FOR STERILIZATION

REASSEMBLE RATCHET FOR STERILIZATION AND USE

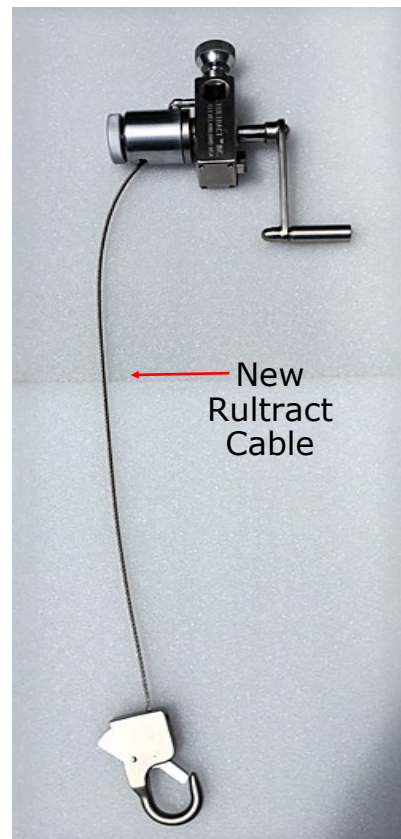
WARNING:

- ** Cables worn or damaged through mishandling must be replaced with a new Rultract® Cable.**
- ** Do not attempt to repair, cut, alter or modify the Cable in any way.**
- ** Cutting and reattaching the Cable will cause it to weaken and fray.**
- ** This will result in failure during use and can lead to serious injury or death.**

Note: Worn or Damaged cable must be replaced with a new Rultract® Cable.



Frayed and Kinked cables will cause the Rultract to bind up and not wind/unwind properly



RULTRACT[®] RETRACTOR CABLE REPLACEMENT INSTRUCTIONS

Rultract, Inc. is the ONLY authorized service center in the U.S.A.

When your Rultract[®] instrument needs repair or service, contact Rultract Inc. at service@rultract.com. **All instruments must be decontaminated before being returned for service.** Repair charges will apply to instruments repaired outside the warranty.

Any modification or alteration by user or unauthorized service vendor is potentially dangerous, could put the hospital, operating room staff and patient at risk, and can lead to serious injury or death.

SERVICE INTERVAL: Complete factory service of your Rultract Skyhook Retractor System (including a cable change)

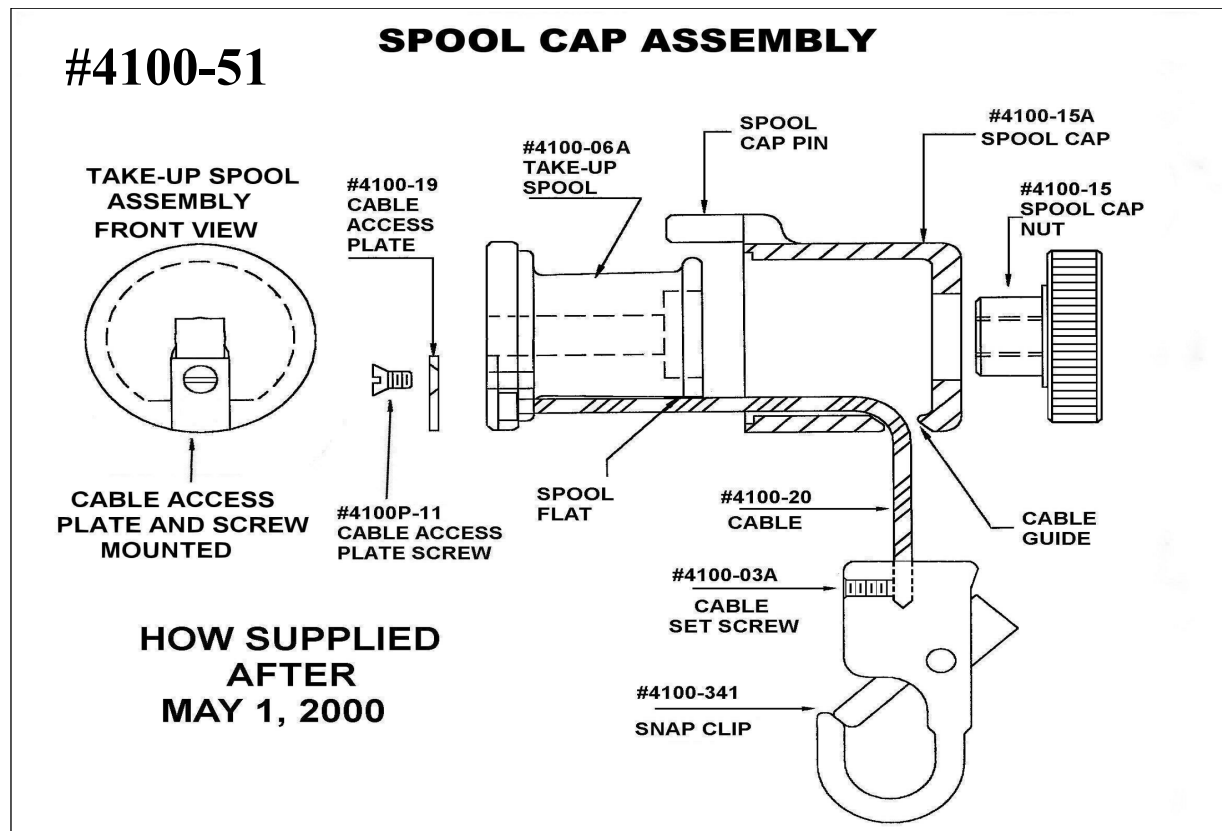
****If using a surgical device tracking system to track cases, i.e. Censitrac: 400 cases.**

****If not using a surgical device tracking system to track cases, i.e. Censitrac:
Every 12-24 months dependent on frequency of use.**

WARNING: Cables worn or damaged through mishandling prior to the factory service interval, must be replaced with a new Rultract[®] cable. Do not attempt to repair, cut, alter or modify the cable in any way. **Cutting and reattaching the cable will cause it to weaken and fray. This can result in failure during use and can lead to serious injury or death.**

HANDLING OF RULTRACT[®] RETRACTOR

The Rultract Retractor System uses An OEM specific cable which holds the Snap Clip and Rake Plate. If the proper OEM pieces are not used and the pieces are not serviced in regular intervals by a factory trained technician, they could separate during surgery possibly causing serious injury or death.



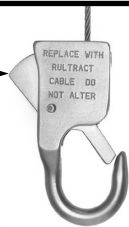
Determine Your Rake Plate System Configuration

STEP 1 RAKE PLATE:

If your system has a Snap Clip and a Rake Plate

Disconnect Rake Plate from Snap Clip

Snap Clip



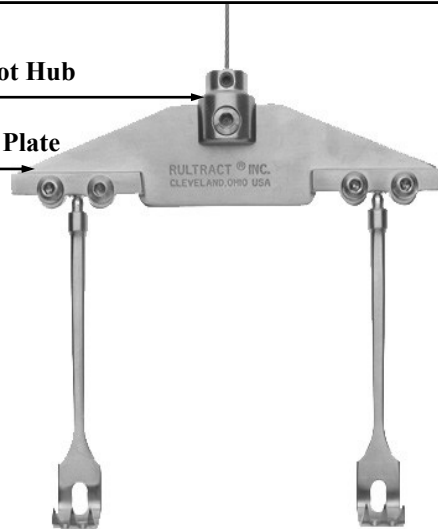
Rake Plate



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

Pivot Hub

Rake Plate

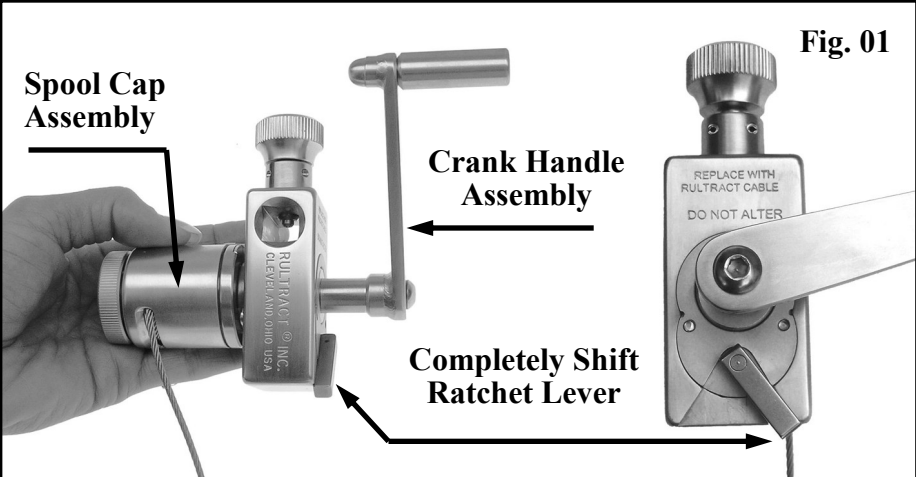
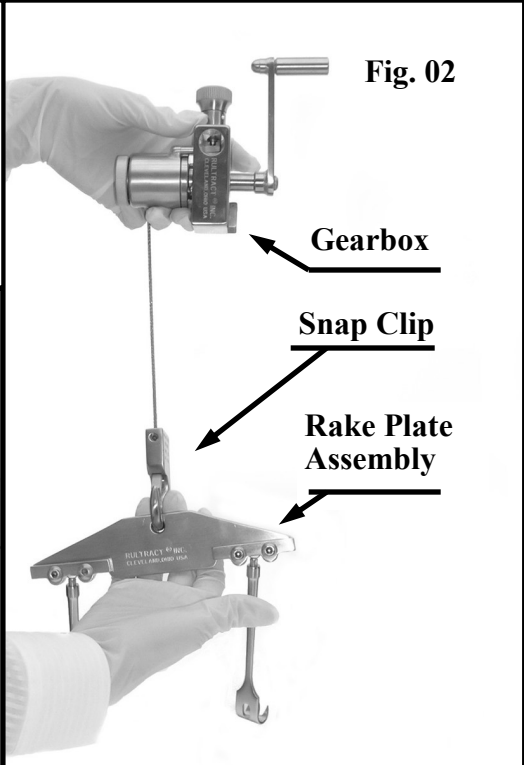


If your system has a Snap Clip Only

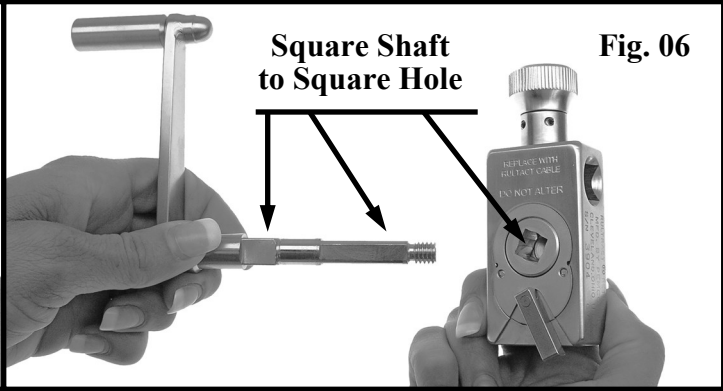
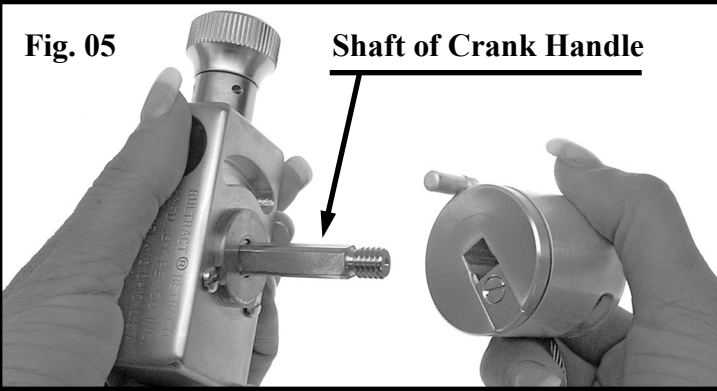
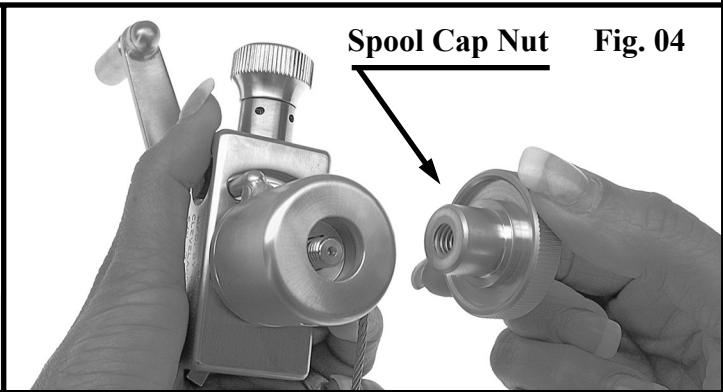
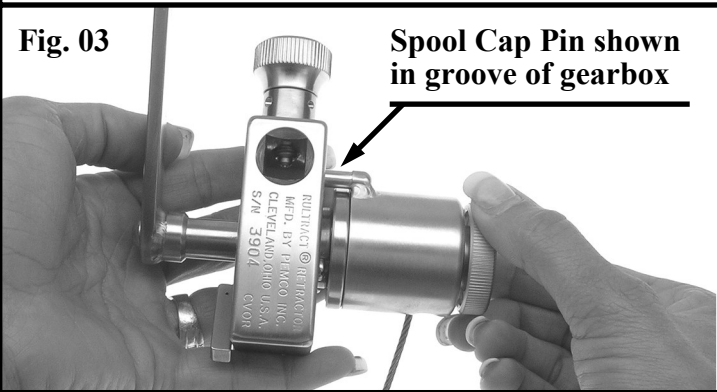
Proceed to Step 2



STEP 1 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 2 REMOVE SPOOL CAP 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).

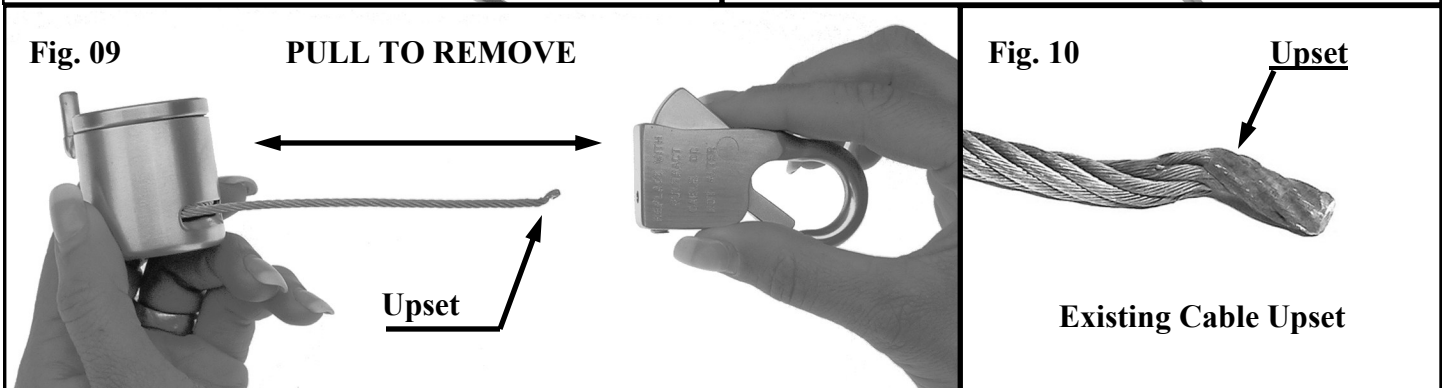
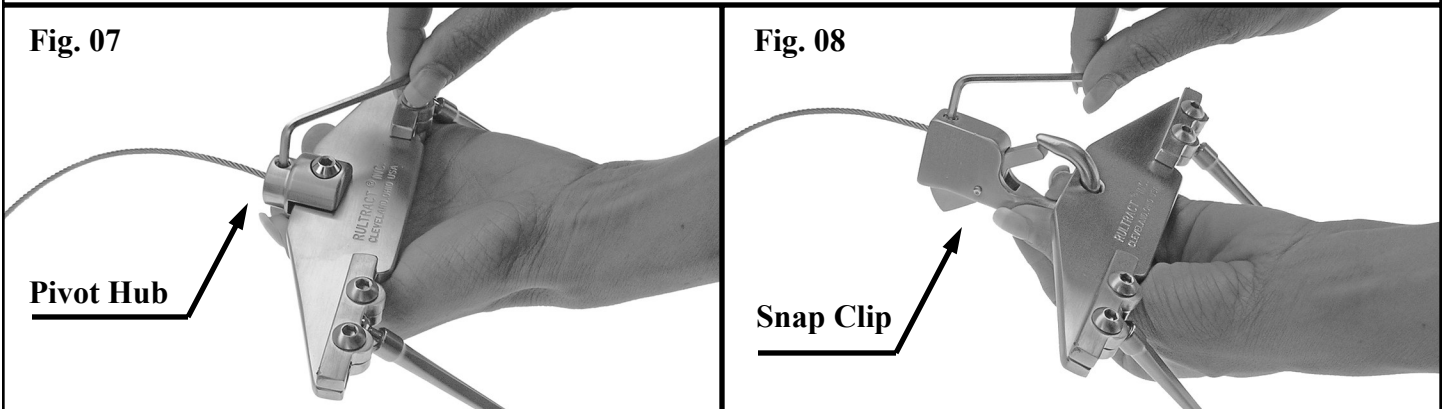


CAUTION: Always insert spool cap pin into the groove of the gearbox. Failure to do so may result in disassembly or damage to the unit.

STEP 3 REMOVE CABLE FROM PIVOT HUB OR SNAP CLIP:

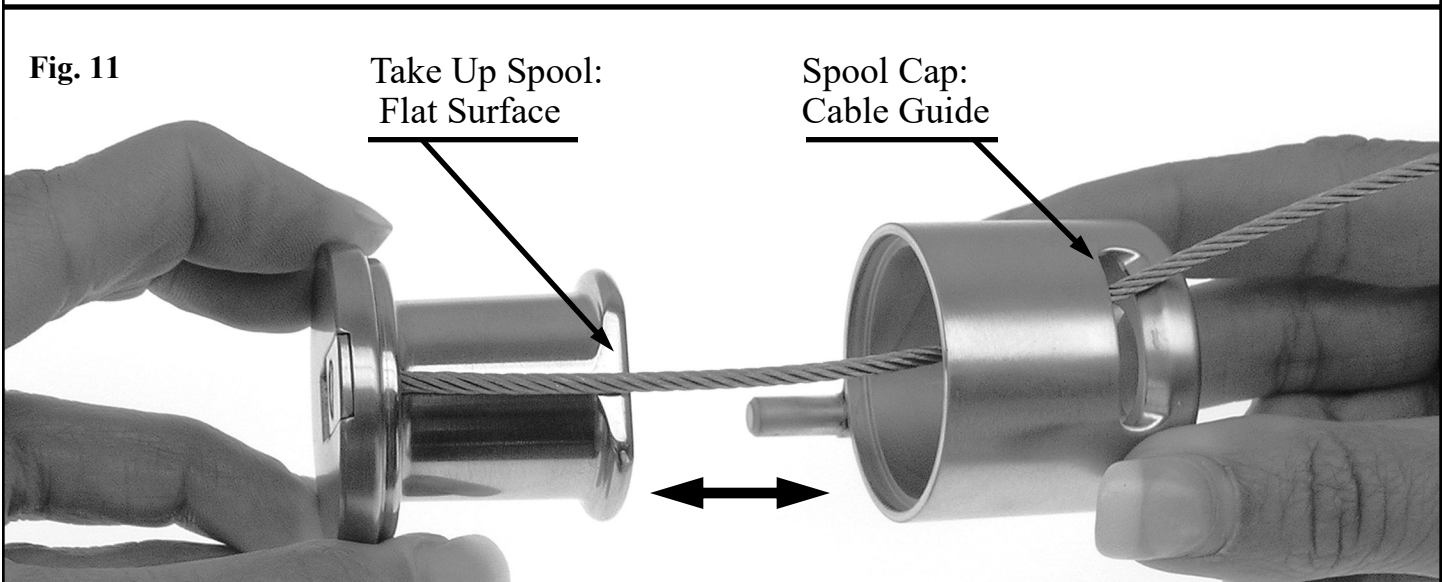
With Cable completely unwound, hold Pivot Hub or Snap Clip in one hand. Insert 1/8" allen wrench (supplied with cable replacement pack) into Cable Set Screw (Fig. 07 or 08). Loosen a minimum of two full turns. It is not necessary to completely remove set screw. To remove Cable, hold the Spool Cap Assembly in one hand and pull on hub (Fig. 09). Note: Set Screw has created an upset in the existing cable (Fig. 10).

WARNING: Always wear eye protection when removing cable.



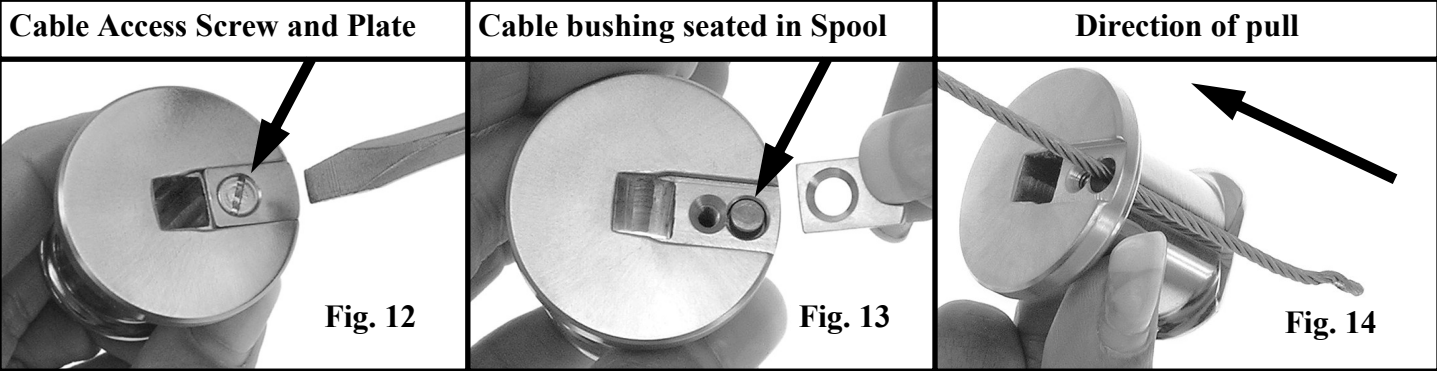
STEP 4 SEPARATE SPOOL CAP AND TAKE UP SPOOL:

Pull Cable completely through the Spool Cap cable guide (Fig. 11). At this time note the flat surface of the Spool.



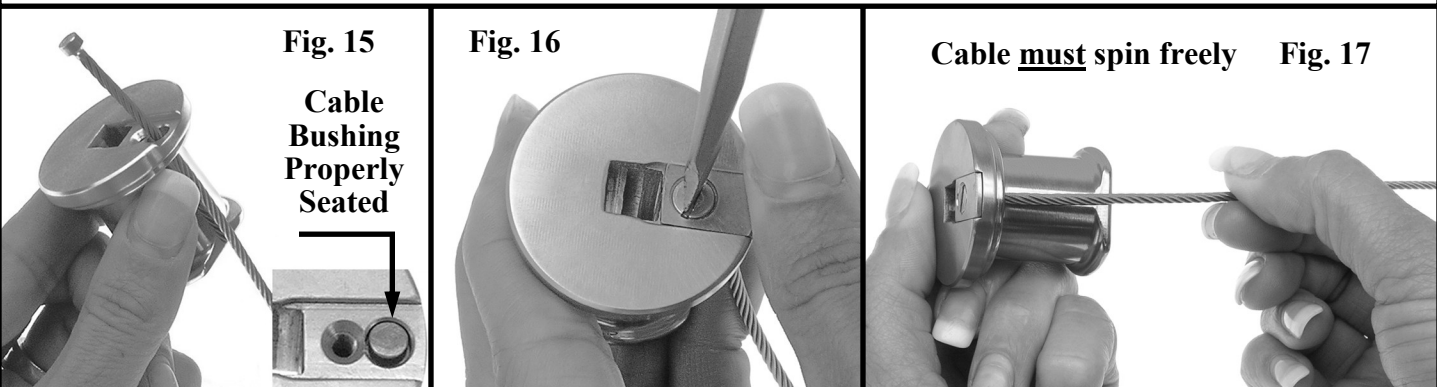
STEP 5 REMOVE CABLE FROM SPOOL:

While holding the Spool, remove the Cable Access Plate Screw and Cable Access Plate (Fig. 12). Note: Orientation of Cable Access Plate and screw, flush with all surfaces. Cable Bushing is seated in Spool (Fig. 13). Pull Cable through the hole (Fig. 14).



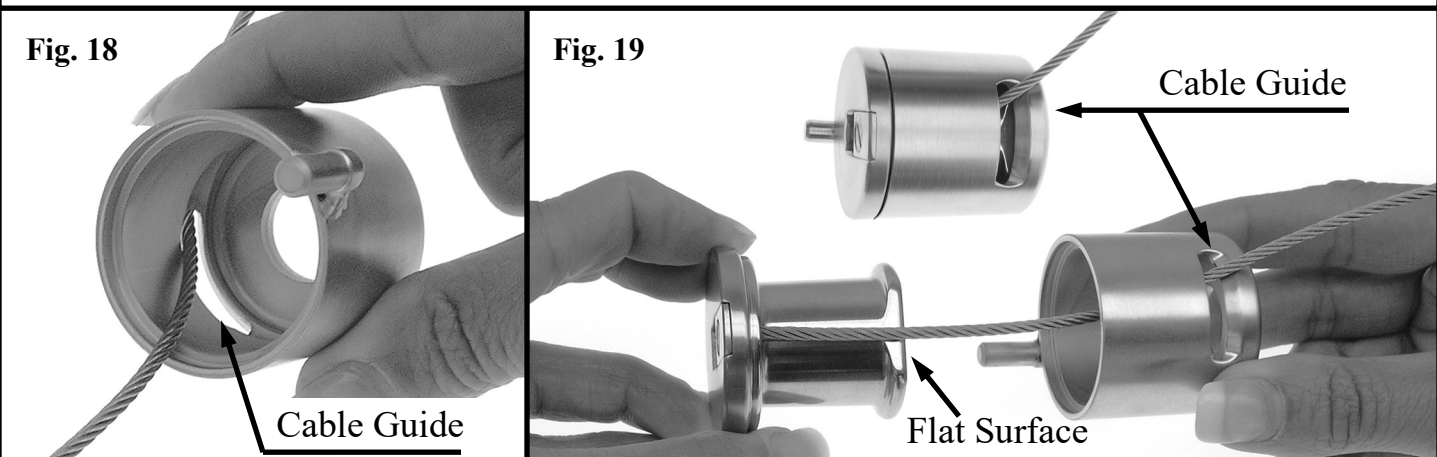
STEP 6 INSTALL CABLE:

Insert tip of a **new Rultract® cable** through the same hole (Fig. 15). Assure the Cable Bushing is properly seated. Replace the Cable Access Plate (**recess side up**) and loosely insert Cable Access Plate Screw. Push outer edge of Cable Access Plate inward when tightening screw (Fig. 16). This will assure the edge of the Cable Access Plate is flush with the edge of the Spool. Note: After Cable Access Plate is tightened, cable must spin freely (Fig. 17).



STEP 7 REASSEMBLE SPOOL CAP AND SPOOL:

Insert **new Rultract® Cable** into largest opening of Spool Cap® and through the Cable Guide (Fig. 18). Align the Cable Guide with the flat surface of the Spool and slide the two pieces together (Fig. 19).



STEP 8 INSTALL CRANK HANDLE ASSEMBLY, SPOOL CAP AND SPOOL CAP NUT:

Slide the shaft of the Crank Handle Assembly into Gearbox by inserting the squared end into the square hole located above the Ratchet Lever (Fig. 20). **Note:** Both squared sections of the shaft must be completely inserted and **flush**. 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. 21). 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. 22).**

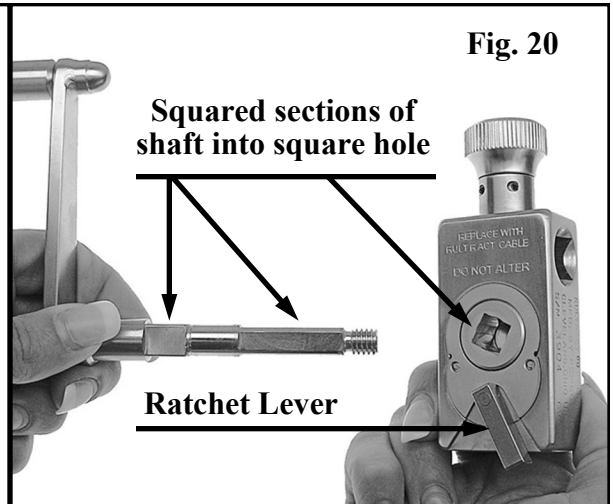


Fig. 20

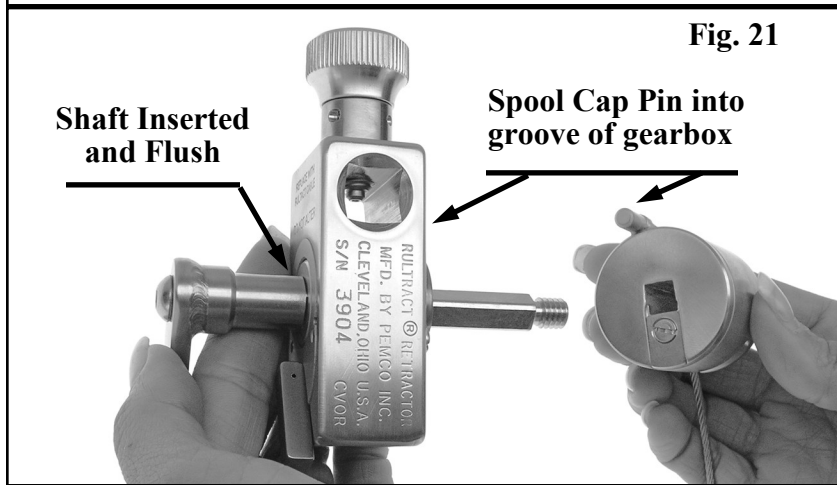


Fig. 21

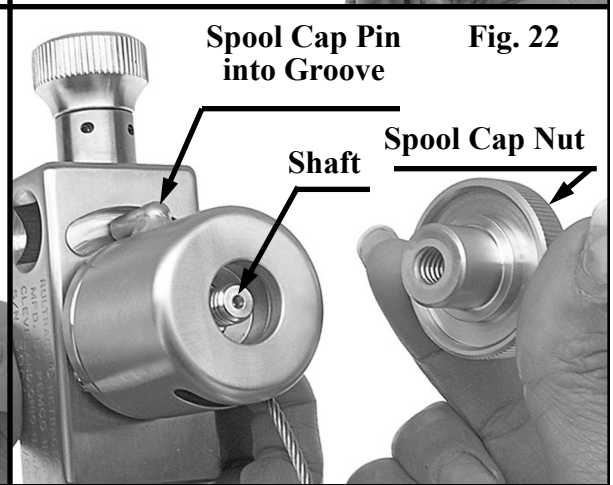


Fig. 22

STEP 9 CABLE INSERTION INTO SNAP CLIP OR PIVOT HUB:

Insert the **new Rultract® cable** completely into the hole until it stops, approximately 1/2" deep. **Make sure set screw is not blocking cable (Fig 23).** Proper tightening of the cable will require some force to compress the cable. Holding the rake plate securely will give the correct amount of leverage. Turn set screw until it makes contact with the cable. **Note** position of allen wrench and tighten set screw 1 to 1 1/2 turns (Fig. 24). Proper tightening of the set screw creates an **upset**, which properly retains the cable. Once the set screw has been tightened do not reposition cable.

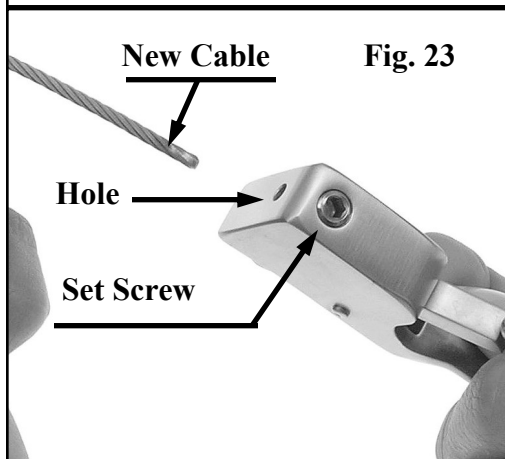


Fig. 23

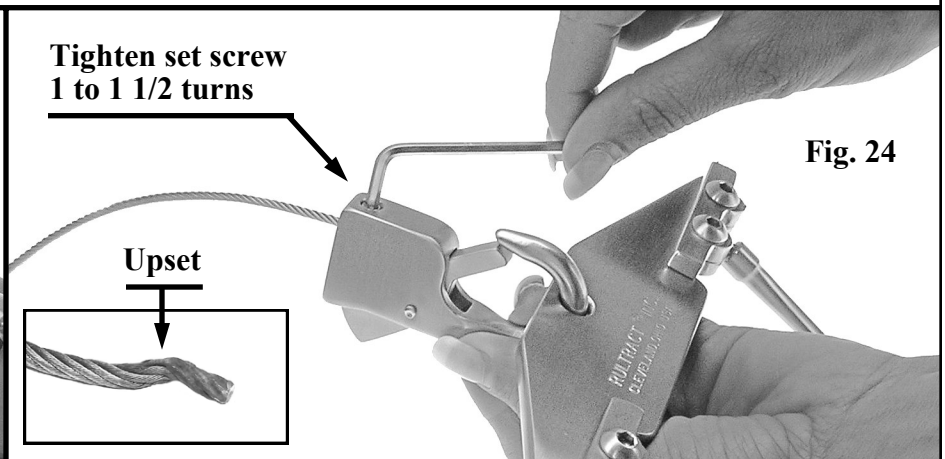


Fig. 24

STEP 11 TEST WINDING FUNCTION:

Allow Rake Plate or Snap Clip to hang freely. Weight of Rake Plate or Snap Clip allows for proper alignment of Cable on Spool. Total length of exposed, unwound Cable is approximately 18 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.

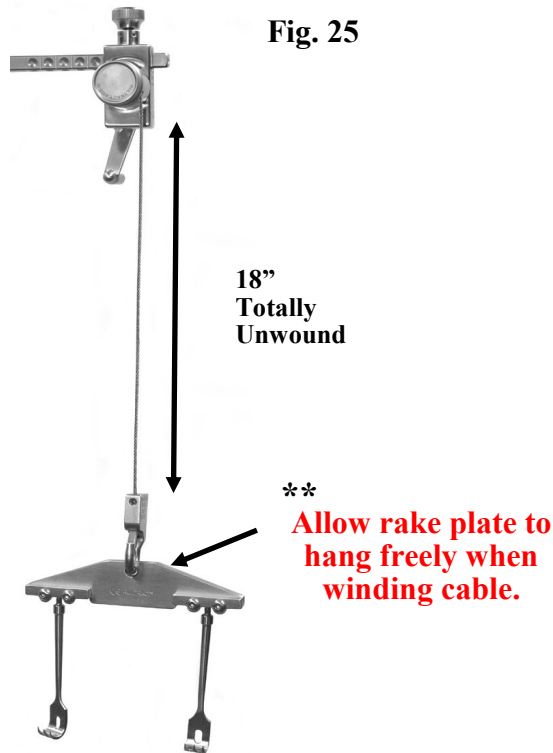


Fig. 25

18"
Totally
Unwound

**
**Allow rake plate to
hang freely when
winding cable.**

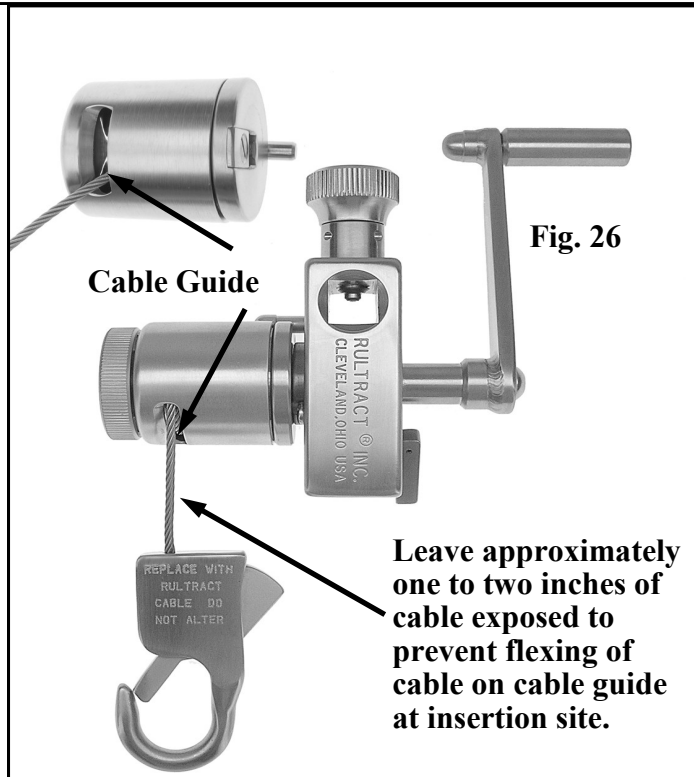


Fig. 26

Cable Guide

Leave approximately
one to two inches of
cable exposed to
prevent flexing of
cable on cable guide
at insertion site.

The Rultract Cable Replacement is now complete

HANDLING OF RULTRACT® RETRACTOR CABLE

WARNING: Cables worn or damaged through mishandling *prior to the factory service interval*, must be replaced with a new Rultract® cable. Do not attempt to repair, cut, alter or modify the cable in any way. **Cutting and reattaching the cable will cause it to weaken and fray. This can result in failure during use and can lead to serious injury or death.**

CAUTION:

****Always allow rake plate to hang freely when winding Cable.** The weight of Rake Plate allows for proper alignment of Cable on Spool. Failure to allow the Rake Plate to hang freely may cause the Cable to kink during winding. Leave approximately one to two inches of Cable exposed to prevent flexing of Cable on Cable Guide at insertion site.

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.

REPLACEMENT PARTS

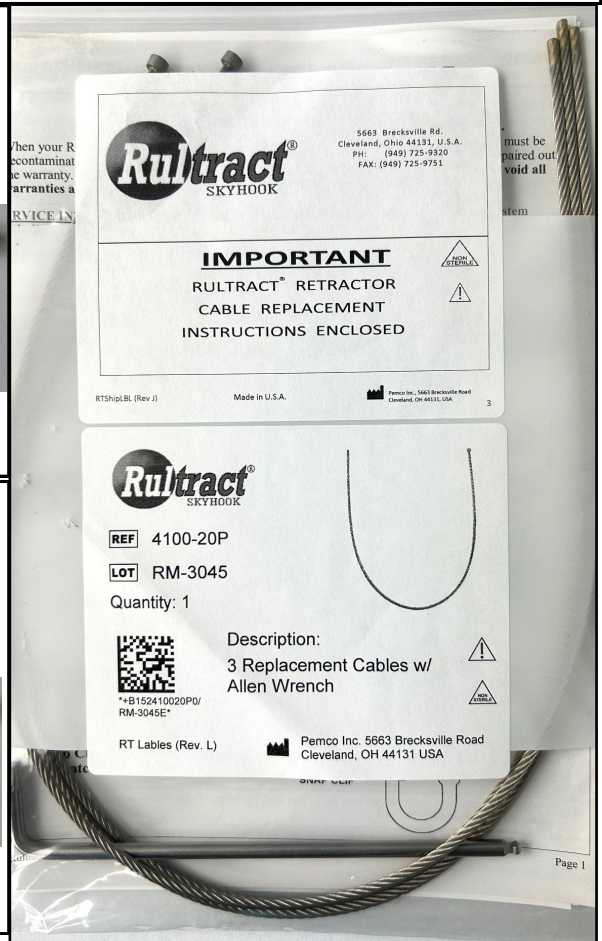
- 4100P-12 Large Allen Wrench - 5/32"
- 4100P-13 Small Allen Wrench - 1/8"
- 4100-20P Cable Replacement Pack, 3 each (Allen wrench included)

NOTE:
ALL REPLACEMENT CABLES ARE 20" LONG.
INSTALLED AND UNWOUND THE EXPOSED CABLE IS 18" LONG.

4100P-12
Large Allen Wrench
One per pack



4100P-13
Small Allen Wrench
One per pack



REPLACEMENT PARTS

4100-341P Snap Clip Pack

Includes:

- (1) Snap Clip
- (1) Rultract Cable
- (1) Large Allen Wrench - 5/32"
- (1) Small Allen Wrench - 1/8"

NOTE:
ALL REPLACEMENT CABLES ARE 20" LONG.
INSTALLED AND UNWOUND THE EXPOSED
CABLE IS 18" LONG.



CONTACT INFORMATION

Rultract Inc. 5663 Brecksville Rd. Cleveland, Ohio 44131 U.S.A.

Website: www.rultract.com

Email: rultract@rultract.com

Phone: 888-550-5695

Rultract, Inc. is the ONLY authorized service center in the U.S.A.

When your Rultract[®] instrument needs repair or service, contact Rultract Inc. or Rultract[®] distributor for the location of an authorized service center. All instruments must be decontaminated before being returned for service. **Proof of decontamination must be included with device being returned for service. See the website for the Rultract Service Request Form.** Repair charges will apply to instruments repaired outside the warranty.

Use only Rultract OEM parts and service as provided at the factory authorized Rultract OEM service center. The use of any other replacement parts is potentially dangerous, could put the hospital, operating room staff and patient at risk, **and can lead to serious injury or death.**

USING OUTSIDE SERVICE VENDORS TO SERVICE/REPAIR YOUR RULTRACT RETRACTOR: Rultract is the only authorized service center for the Rultract Retractor System. Outside service vendors are not authorized to service or repair the Rultract Retractor System and do not have access to all Rultract OEM replacement parts. Using outside service vendors to service/repair your Rultract retractor system is potentially dangerous, could put the hospital, operating room staff and patient at risk, **and can lead to serious injury or death.**

SERVICE INTERVAL: Complete factory service of your Rultract Skyhook Retractor System: (including a cable change)

****If using a surgical device tracking system to track cases, i.e. Censitrac: 400 cases.**

****If not using a surgical device tracking system to track cases, i.e. Censitrac: Every 12-24 months dependent on frequency of use.**

WARNING: Cables worn or damaged through mishandling *prior to the factory service interval*, must be replaced with a new Rultract[®] cable. Do not attempt to repair, cut, alter or modify the cable in any way. Cutting and reattaching the cable will cause it to weaken and fray. This can result in failure during use **and can lead to serious injury or death.**

REPLACEMENT: Rultract Ratchet Assemblies and Rake Plate Assemblies purchased prior to 2000, with no OEM maintenance history or relevant product update history, require replacement.

Rultract FDA Information

FDA Establishment:
RULTRACT INC
5663 Brecksville Road
Independence, OH 44131
Registration #: 1530504
FEI Number*: 3000717741
Owner Operator # 10060024



RULTRACT WARNINGS INDEX:

Standards of Safe Use Compliance

PROPER SERVICING AND REPAIR OF YOUR RULTRACT RETRACTOR SYSTEM

Rultract, Inc. is the ONLY authorized service center in the U.S.A. Contact Rultract at service@rultract.com or 888-550-5695 to schedule service/repair or with questions concerning routine maintenance and service.

SERVICE INTERVAL: Complete factory service of your Rultract Skyhook Retractor System: (including a cable change)

****If using a surgical device tracking system to track cases, i.e. Censitrac: 400 cases.**

****If not using a surgical device tracking system to track cases, i.e. Censitrac: Every 12-24 months dependent on frequency of use.**

WARNING: Cables worn or damaged through mishandling prior to the factory service interval, must be replaced with a new Rultract® cable. Do not attempt to repair, cut, alter or modify the cable in any way. **Cutting and reattaching the cable will cause it to weaken and fray. This can result in failure during use and can lead to serious injury or death.**

Use only Rultract OEM parts and service as provided at the factory authorized Rultract OEM service center. The use of any other replacement parts is potentially dangerous, could put the hospital, operating room **staff and patient at risk, and can lead to serious injury or death.**

USING OUTSIDE SERVICE VENDORS TO SERVICE/REPAIR YOUR RULTRACT RETRACTOR:

Rultract is the only authorized service center for the Rultract Retractor System. Outside service vendors are not authorized to service or repair the Rultract Retractor System and do not have access to all Rultract OEM replacement parts. Using outside service vendors to service/repair your Rultract retractor system is potentially dangerous, could put the hospital, operating room staff and patient at risk, **and can lead to serious injury or death.**

REPLACEMENT: Rultract Ratchet Assemblies and Rake Plate Assemblies purchased prior to 2000, with no OEM maintenance history or relevant product update history, require replacement.

WARNING:

Any modification or alteration to a Rultract® product by user is dangerous, could put the hospital, operating room staff and patient at risk, **and can lead to serious injury or death.** This action will also void all warranties and release Rultract® from any liability.

HANDLING OF RULTRACT® RETRACTOR

The Rultract Retractor System uses An OEM specific cable which holds the Snap Clip and Rake Plate. If the proper OEM pieces are not used and the pieces are not serviced in regular intervals by a factory trained technician, **they could separate during surgery possibly causing serious injury or death.**

CAUTION:

**** Always allow rake plate to hang freely when winding Cable (pages 25 & 33).** The weight of Rake Plate allows for proper alignment of Cable on Spool. Failure to allow the Rake Plate to hang freely may cause the Cable to kink during winding. Leave approximately one to two inches of Cable exposed to prevent flexing of Cable on Cable Guide at insertion site.

CAUTION:

Always insert spool cap pin into the groove of the gearbox (pages 24 & 32). Failure to do so may result in disassembly or damage to the unit.



SERVICE REQUEST FORM

Please complete this form and send with items for service/repair to
5663 Brecksville Road, Cleveland, OH 44131

Items sent for repair will NOT be serviced without documentation of proper decontamination and cleaning. Complete the verification of decontamination section below to ensure service begins.

- Upon receipt and inspection, a service representative will contact you with a quote
- Please check one box here if you would like RUSH service: RUSH \$95.00 SUPER RUSH \$165.00

Item(s) Description	Quantity
_____	_____
_____	_____
_____	_____

Description of Service Requested

Sterilization Status: (Must be verified for service/repair to be completed)

The enclosed medical device(s) **have** been thoroughly cleaned/brushed and decontaminated in autoclave equipment according to the manufacturer's instructions.

RETURNED / UNUSED EQUIPMENT ONLY: The enclosed medical device(s) **have NEVER** been in contact with blood, tissue, body substances or other body fluids and thus is hygienically safe.

**** Complete the information below & include this form in the box with equipment to be repaired.**

Customer/Company Name and Billing Address

Shipping Address (if different)

_____	_____
_____	_____
_____	_____

Signature _____ Date _____ Phone _____ (Mobile **OR** FAX)

Print Name _____ Title _____

Email _____

PURCHASE ORDER # (if applicable): _____

Rultract Service Questions? Call 888-550-5695

Form 6.4.2.2 Rev. D

DO NOT REMOVE PAGE

Rultract® Skyhook Retractor Parts List

Part #	Part Description	Part #	Part Description
4100-IMR-6	Ratchet/Rake Assembly with Snap Clip	4100-59-07	Coupler Assembly
4100-IMR-41	Ratchet Assembly with Snap Clip	4100-59-07B	Coupler Bar
4100-02	Rake Plate Clamp	4100-59-08	Coupler Assembly
4100-341P	Snap Clip Pack w/ Cable	4100-59-08B	Coupler Bar
4100-03A	Cable Set Screw	4100-59-11	Coupler Assembly
4100-04	Ratchet Shaft	4100-59-11B	Coupler Bar
4100-06A	Take Up Spool	4100-59-03	Coupler Tube Assembly
4100-07B	Gearbox	4100-60	Minimally Invasive Rake Set
4100-08	One Piece Post	4100-60A	Minimally Invasive Rake
4100-11	Crank Arm	4100-60B	Minimally Invasive Rake
4100-12	Sternal Rake, Sharp Tip	4100-60C	Minimally Invasive Rake
4100-12D	Sternal Rake, Dull Tip	4100-60D	Minimally Invasive Rake
4100-12R	Sternal Ring Rake, Sharp Tip	4100-60AS	Pediatric Rake
4100-12RD	Sternal Ring Rake, Dull Tip	4100-60P-01	Pediatric Rake
4100-15	Spool Cap Nut	4100-60P-02	Pediatric Rake
4100-15A	Spool Cap	4100-60P-03	Pediatric Rake
4100-17	Crank Handle Sleeve	4100-60P-04	Pediatric Rake
4100-18	Crank Handle Screw	4100-60P-05	Pediatric Rake
4100-19	Cable Access Plate	4100-60P-06	Pediatric Rake
4100-20	Cable	4100-70	Xiphoid Rake
4100-20SP	Cable Replacement Single Pack	4100-71	Xiphoid Rake
4100-20P	Cable Replacement 3 Pack	4100-72	Xiphoid Rake
4100-28C	Square Tip Double Bend Bottom Post	4100-73	Xiphoid Rake
4100-28CP	Square Tip Offset Bottom Post	4100-74	Xiphoid Rake
4100-28CS	Spline Tip Double Bend Bottom Post	4100-75	Xiphoid Rake
4100-32A	Square Top Post, Standard Length	4100-77L	Sternal Rake, Large
4100-32AL	Square Top Post, Extended Length	4100-77M	Sternal Rake, Medium
4100-32ALS	Spline Top Post, Extended Length	4100-77S	Sternal Rake, Small
4100-32AP	Square Offset Top Post	4100P-05	Ratchet Cover Plate Screw
4100-32AS	Spline Top Post, Standard Length	4100P-08	Crank Arm Screw
4100-32AST	Spline Tilting Top Post	4100P-11	Cable Access Plate Screw
4100-32AT	Square Tilting Top Post	4100P-12	Large Allen Wrench
4100-32C	Square Tip Bottom Post with Collar (Round Base)	4100P-13	Small Allen Wrench
4100-32CS	Spline Tip Bottom Post with Collar (Square Base)	4100P-25	Rotating Extender Bar Spring
4100-32ST-06A	Knob Assembly	4100P-26	Tilting Post Spring
4100-33	Rake Clamp Screw	4110	Round Base Combination Clamp
4100-33P	Rake Clamp Screw Pack	4110-03A	Cross Handle Assembly
4100-39R	Riser Extender Bar with Cross Square	4110-04A	Wing Handle Assembly
4100-39S	Extender Bar with Cross Square	4110-17	Lower Jaw Assembly
4100-39TS	Rotating Extender Bar with Cross Square	4110P-05	Clamp Spring
4100-39TS-07A	Knob Assembly	4110P-12	Handle Retaining Screw
4100-50	Gearbox Assembly	4110P-14	Combination Clamp Spring (2019 and newer)
4100-51	Spool Cap Assembly	4110P-15	Combination Clamp Shoulder Bolt
4100-52	Sternal Rake Plate Assembly, Sharp Tip	4110S	Square Base Combination Clamp
4100-52D	Sternal Rake Plate Assembly, Dull Tip	4150	Square Tip, Double Bend Post/Clamp, Scrub Applied
4100-52RDH	Lift Spreader Plate Assembly, Hook	4150S	Spline Tip, Double Bend Post/Clamp, Scrub Applied
4100-52RDL	Lift Spreader Plate Assembly, Large	4160	Square Tip, Double Bend Post/Clamp, Circulator Applied
4100-52RDM	Lift Spreader Plate Assembly, Medium	4160-09A	5 Point Handle Assembly 10-TPI
4100-52RDS	Lift Spreader Plate Assembly, Small	4160-09B	5 Point Handle Assembly 8-TPI
4100-53	Crank Handle Assembly with Shaft	4160S	Spline Tip, Double Bend Post/Clamp, Circulator Applied
4100-54	Ratchet Cover Plate Assembly		

PROPER SERVICING AND REPAIR OF YOUR RULTRACT RETRACTOR SYSTEM

WARNING: -

USING OUTSIDE SERVICE VENDORS TO SERVICE/REPAIR YOUR RULTRACT RETRACTOR SYSTEM:

USING OUTSIDE SERVICE VENDORS TO SERVICE/REPAIR YOUR RULTRACT RETRACTOR:

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Use only Rultract OEM parts and service as provided at the factory authorized Rultract OEM service center. The use of any other replacement parts is potentially dangerous, could put the hospital, operating room staff and patient at risk, **and can lead to serious injury or death.**

Using outside service vendors to service/repair your Rultract retractor system is potentially dangerous, could put the hospital, operating room staff and patient at risk, **and can lead to serious injury or death.**

HANDLING OF RULTRACT® RETRACTOR CABLE

The Rultract Retractor System uses a specific cable which holds the Snap Clip and Rake Plate. If the proper OEM pieces are not used and the pieces are not serviced in regular intervals by a factory trained technician, they could separate during surgery **potentially causing serious injury or death.**

CAUTION:

****Always allow rake plate to hang freely when winding Cable.** The weight of Rake Plate allows for proper alignment of Cable on Spool. Failure to allow the Rake Plate to hang freely may cause the Cable to kink during winding. Leave approximately one to two inches of Cable exposed to prevent flexing of Cable on Cable Guide at insertion site.

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.

Contact Rultract at service@rultract.com or 888-550-5695 to schedule service/repair or with questions concerning routine maintenance and service.

Rultract FDA Information

FDA Establishment:
RULTRACT INC
5663 Brecksville Road
Independence, OH 44131
Registration #: 1530504
FEI Number*: 3000717741
Owner Operator # 10060024
Listing # D345513



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