miniARM™ SYSTEM TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

LSI SOLUTIONS®

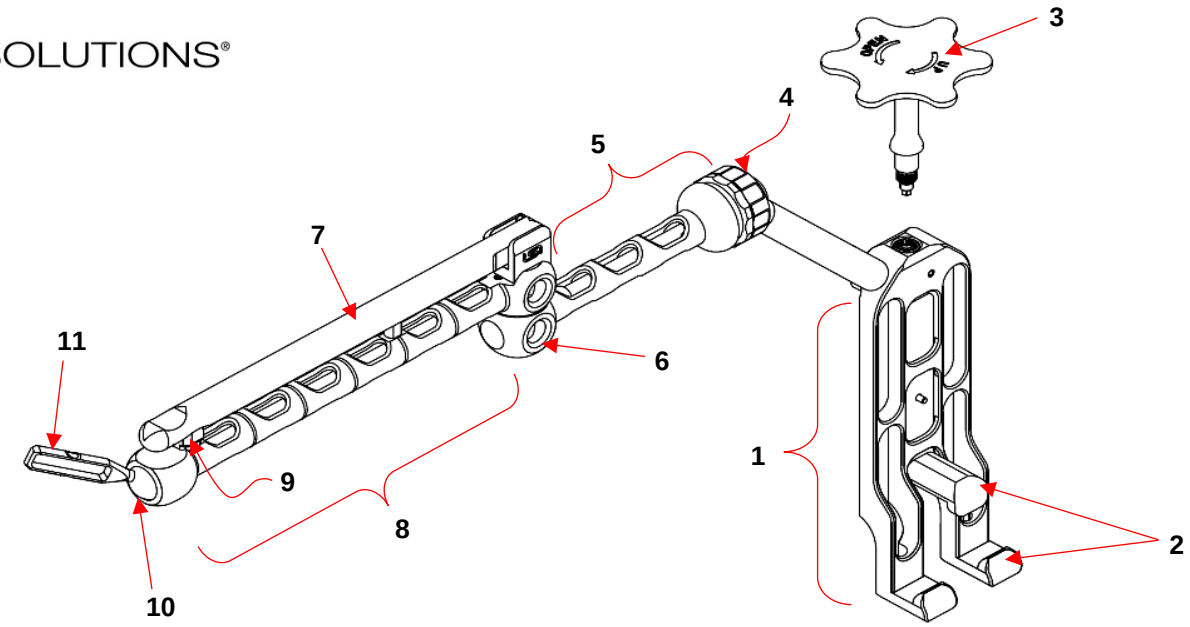


FIG. 1 – miniARM™ Instrument Holder
(Pictured: Patient side view Reorder #080419 Right Version
Also available: Reorder #080418 Left Version)

1- RAIL CLAMP
2- RAIL CLAMP JAW
3- DEPLOYMENT KNOB (Qty. 2)
4- LOWER JOINT
5- LOWER ARM
6- MIDDLE JOINT
7- LOCKING LEVER
8- UPPER ARM
9- LEVER LATCH
10- UPPER JOINT
11- QUICK CONNECT POST

THE miniARM™ SYSTEM DESCRIPTION:

The miniARM™ System is a reusable, sterilizable, repositionable instrument-holding platform which maintains its position relative to an operating room table and does not require continual attention or a dedicated operator. The miniARM™ Instrument Holder (FIG. 1) provides an exceptionally stable base on which interchangeable adapters, such as the one included with the miniARM™ Cannula Adapter Kit (FIG. 2), the miniARM™ Clamping Adapter (FIG. 3) or the miniARM™ Access Adapter (FIG. 5) are attached. The miniARM™ System is easy to setup and disassemble, and the miniARM™ Instrument Holder is available in right and left orientations. The miniARM™ rail clamp **1** has a jaw **2** which is tightened using a removable deployment knob **3** to a standard surgical table accessory rail over sterile drapes. A one-handed locking lever **7** engages a lever latch **9** to lock or release the lower arm **5**, upper arm **8**, and quick connect post **11**. When the locking lever is released, the lower, middle, and upper articulating ball joints **4**, **6**, **10** allow the device to be positioned as desired in all degrees of freedom. The miniARM™ System provides supreme control and maneuverability with easy deployment and single-handed manipulation. The positioning mechanism of the miniARM™ Instrument Holder is entirely mechanical, eliminating the need for external energy sources, such as pneumatic, vacuum, or electric sources.

THE miniARM™ CANNULA ADAPTER KIT (U.S. Only)

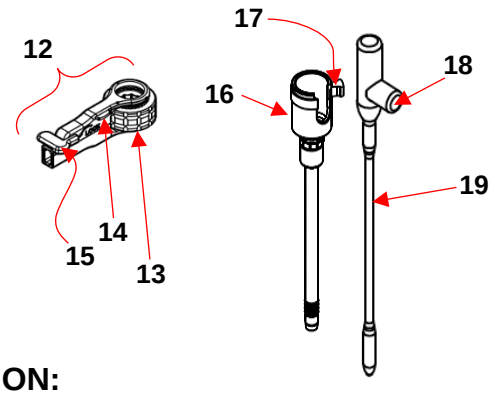


FIG. 2 – miniARM™ Cannula Adapter Kit
(Reorder #080415)

12- miniARM™ CANNULA ADAPTER
13- ROTATION DIAL
14- CANNULA LATCH
15- ADAPTER LOCK
16- miniARM™ CANNULA
17- CANNULA RING
18- OBTURATOR DEPTH STOP
19- miniARM™ OBTURATOR

DESCRIPTION:

The miniARM™ Cannula Adapter Kit may be used with the miniARM™ Instrument Holder. The miniARM™ Cannula Adapter Kit has a miniARM™ Cannula Adapter **12** which slides over the quick connect post of the miniARM™ Instrument Holder, locking into place with the adapter lock **15**. A miniARM™ Cannula **16**, for use with compatible endoscopes, fits into the miniARM™ Cannula Adapter which has a cannula latch **14** for releasably holding the cannula. A miniARM™ Obturator **19** may be placed into the cannula for insertion of the cannula into a patient. After the miniARM™ Obturator is removed, a scope may be placed into the cannula and held in place with the movable cannula ring **17**. A rotation dial **13** enables the cannula (and therefore a scope placed therein) to be rotated as desired. The miniARM™ System also has a fine adjustment feature enabling the position of the miniARM™ Cannula Adapter to be fine-tuned when the remainder of the System is in its rigid locking position.

THE miniARM™ CLAMPING ADAPTER

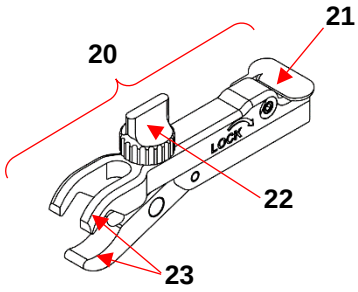


FIG. 3 – miniARM™ Clamping Adapter
(Reorder #080519)

20- miniARM™ CLAMPING ADAPTER
21- ADAPTER LOCK
22- ACTUATION THUMB SCREW
23- JAW

DESCRIPTION:

The miniARM™ Clamping Adapter **20** may also be used with the miniARM™ Instrument Holder. The miniARM™ Clamping Adapter is designed to hold surgical instruments with a diameter of 4-14 mm in the adjustable jaw **23**. The miniARM™ Clamping Adapter slides over the quick connect post of the miniARM™ Instrument Holder and locks into place with the adapter lock **21**. The actuation thumb screw **22** rotates to open and close the jaw in order to secure or release the desired surgical device when in use.

THE miniARM™ LOCKING COUPLER (U.S. Only)

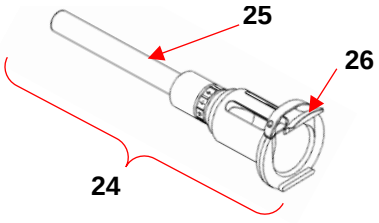


FIG. 4 – miniARM™ Locking Coupler
(Reorder #080555)
(For use with Olympus® ENDOEYE FLEX® 5mm HD surgical video camera, LTF-S190-5)[1]

24- miniARM™ LOCKING COUPLER
25- LOCKING COUPLER SHAFT
26- RELEASE TAB

DESCRIPTION:

The miniARM™ Locking Coupler **24** is designed as an accessory for specific use in holding the Olympus® ENDOEYE FLEX® 5mm HD surgical video camera (LTF-S190-5)[1]. The miniARM™ Locking Coupler is used with either 1) the miniARM™ Cannula Adapter of the separately available miniARM™ Cannula Adapter Kit, or 2) the miniARM™ Clamping Adapter to securely hold the Olympus® ENDOEYE FLEX® surgical video camera in the miniARM™ Instrument Holder.

THE miniARM™ ACCESS ADAPTER (U.S. Only)

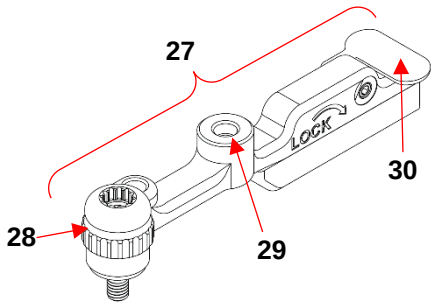


FIG. 5 – miniARM™ ACCESS ADAPTER
(Reorder # 080670)
(For use with LSI SOLUTIONS® 3D® mini Access Portal and RAM® Ring.)

27- miniARM™ ACCESS ADAPTER
28- ATTACHMENT THUMB SCREW
29- RAM® RING RECEIVER
30- ADAPTER LOCK

DESCRIPTION:

The miniARM™ Access Adapter **27** may be used with the miniARM™ Instrument Holder and can be configured to hold the 3D® mini Access Portal and/or the RAM® Ring suture management device (both sold separately by LSI SOLUTIONS®). The attachment thumb screw **28** rotates to secure the miniARM™ Access Adapter to the 3D® mini Access Portal accessory post. (See the 3D® mini Access Portal Technology Guide for more information before using the miniARM™ Access Adapter). The RAM® Ring receiver **29** provides a connection point for the RAM® Ring mounting screw to be attached. (See the RAM® Ring Technology Guide for more information before using the miniARM™ Access Adapter). The miniARM™ Access Adapter slides over the quick connect post of the miniARM™ Instrument Holder and locks into place with the adapter lock **30**.

INDICATIONS FOR USE:
The miniARM™ SYSTEM is indicated for use by surgeons to hold instruments in a fixed position for a period of time.

CONTRAINDICATIONS
- Do not use with non-LSI SOLUTIONS® attachments or adapters.
- These devices are not intended for use except as indicated.

WARNINGS
- Federal (U.S.A.) law restricts these devices to sale, distribution and use by, or on, the order of a physician.
- Read and become familiar with all instructions, warnings, and cautions before using this product.
- Devices shall be used in accordance with these Instructions for Use.
- Improper use of these devices may cause serious injury. In addition, improper care and maintenance of the devices may render the devices non-sterile prior to patient use and may cause serious injury to the health care provider or the patient.
- Patients must be immobilized or anesthetized while using the miniARM™ System.
- Discontinue use of the miniARM™ System when moving patient or when patient is moving.
- Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques and relevant anatomy. Medical literature relative to techniques, complications, and hazards should be consulted prior to use.
- When using the miniARM™ Cannula/Obturator, an insufficient skin incision may cause increased penetration force which may reduce the surgeon's control during entry.
- Do not use the miniARM™ Locking Coupler as a cannula.

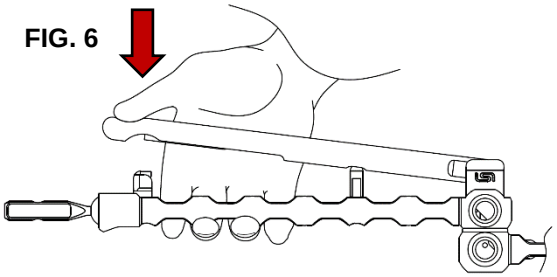
PRECAUTIONS
- **Devices are packaged as non-sterile.** Cleaning and sterilization of devices must occur prior to use.
- If there are any variations between these Instructions for Use and either your facility's policies and/or your cleaning/sterilizing equipment manufacturer's instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your devices.
- Use of a device for a task other than what it is intended for will usually result in a damaged or broken device.
- Prior to use, inspect devices to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or if they have physical damage.
- Surgical instruments may vary from manufacturer to manufacturer. Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure electrical isolation or grounding are not compromised.
- Avoid mechanical shock or overstressing the devices.
- Always use caution when inserting or removing devices through the cannula. Lateral pressure on a device cannulated instrument during removal can damage the working tip and/or shaft of the device. Be sure the tips are closed and the device is pulled straight out until completely clear of the cannula.
- Only the cleaning and sterilization processes which are defined within these Instructions for Use have been validated.
- Check stability of surgical table accessory rails or rail adaptors before table mounting the miniARM™ System. Only table mount to secure, non-moving rails and do not use if movement is evident.
- The miniARM™ System is compatible with USA, EU and Swiss OR table rail sizes 9-10mm wide x 25-30mm tall (0.35-0.39 in. wide x 0.98-1.18 in. tall).
- Be sure to adjust the miniARM™ Clamping Adapter actuation thumb screw enough to hold the device securely without overtightening. Overtightening the miniARM™ Clamping Adapter can result in damage to the held device while insufficient tightening could result in device slippage.
- Be sure to adjust the miniARM™ Access Adapter attachment thumb screw enough to hold the 3D® mini Access Portal and/or the RAM® Ring without overtightening.
- The clamping adapter holds 0.75kg of weight when assembled to the miniARM™ Instrument Holder.
- Store at room temperature.

ADVERSE REACTIONS
- No documented adverse reactions.

INSTRUCTIONS FOR USE

GENERAL SETUP & USE:

NOTE: The following steps may be performed in a different order than shown.

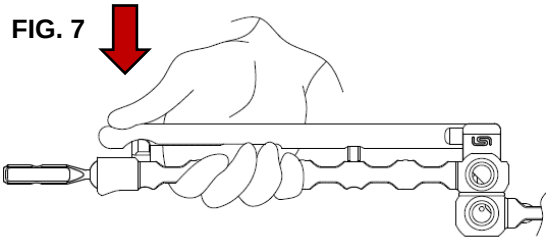


LOCKING AND RELEASING

TEST
the miniARM™ System prior to each use by locking it and confirming that acceptable holding strength is achieved. Discontinue use if holding strength is inadequate.

LOCK
the released miniARM™ System by squeezing the locking lever (FIG. 6) until a SINGLE audible click signals the lever latch is engaged.

RELEASE
the locked miniARM™ System by fully squeezing the locking lever (FIG. 7) until an audible click signals the lever latch is disengaged, and then release the locking lever.



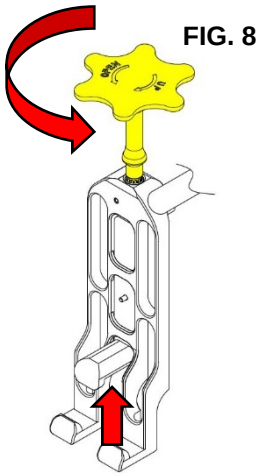
ATTACHMENT TO A SURGICAL TABLE

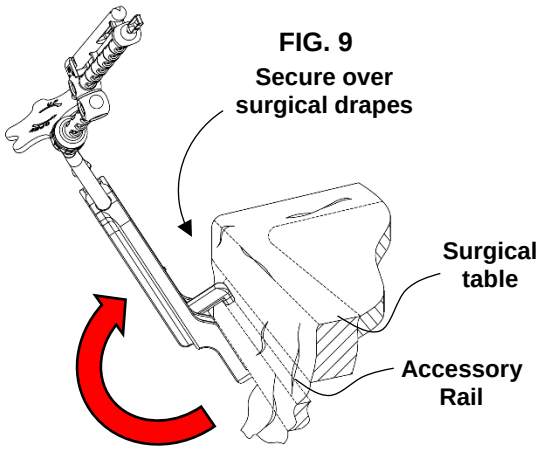
NOTE: The miniARM™ Instrument Holder fits surgical table accessory rails 9-10mm wide x 25-30mm tall (0.35-0.39 in. wide x 0.98-1.18 in. tall).

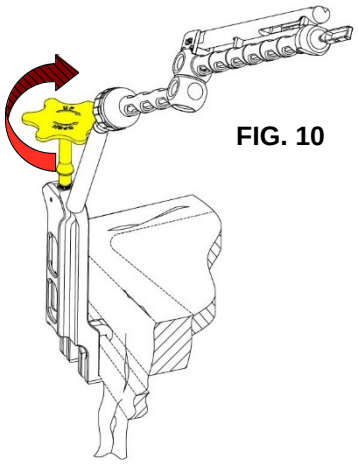
INSERT
the deployment knob into the rail clamp and ROTATE counterclockwise until the rail clamp jaw is completely open (FIG. 8).

PIVOT
the rail clamp jaw onto the surgical table accessory rail over the surgical drapes (FIG. 9). Avoid damaging the drapes.

SECURE
the miniARM™ Instrument Holder by rotating the deployment knob clockwise until the rail clamp jaw is firmly holding onto the table accessory rail (FIG. 10). NOTE: Do not touch below level of sterility described by your hospital's policies.

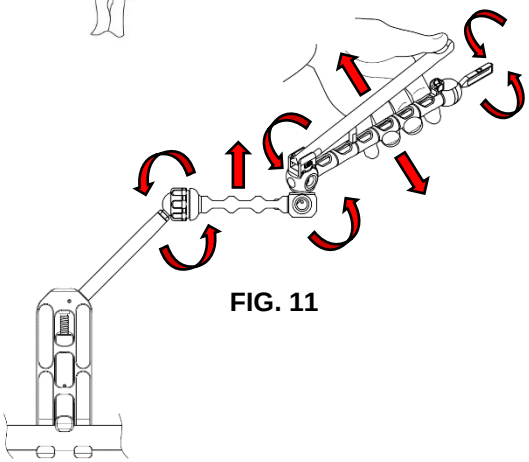






REMOVE
the deployment knob and set it aside in a sterile location.

POSITION
the miniARM™ Instrument Holder when released, by pushing, pulling, or rotating the lower arm, upper arm, and quick connect post about the three joints for adjustability in all directions and precise placement (FIG. 11). When the miniARM™ Instrument Holder has been positioned as desired, lock the system as described above with regard to FIG. 6.



CONFIGURE THE miniARM™ SYSTEM FOR SPECIFIC USE BY ATTACHING AN ADAPTER

SLIDE
the adapter onto the quick connect post while the adapter lock is rotated to the unlocked position (FIG. 12).

ROTATE
the adapter lock to the locked position (FIG. 13) to secure the adapter onto the miniARM™ Instrument Holder.

FINE ADJUST
the upper joint of the miniARM™ Instrument Holder manually for minor positioning without releasing the system lever latch (FIG. 14).

NOTE: FIGS 12-14 show an example miniARM™ Adapter being attached to the miniARM™ System, but other adapters are attached and adjusted in the same manner.

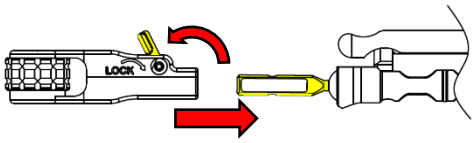


FIG. 12

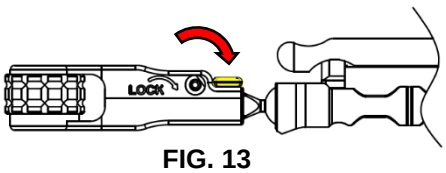


FIG. 13

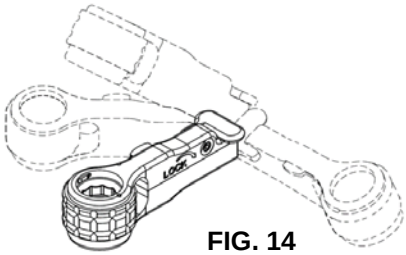


FIG. 14

NOTE: The adapter may either be attached to the miniARM™ Instrument Holder before or after attaching the miniARM™ Instrument Holder to the surgical table accessory rail.

miniARM™ CANNULA SPECIFIC USE: (U.S. Only)

ORIENT
the miniARM™ Cannula Adapter so that the word “SURGEON” is facing the user (FIG. 15).

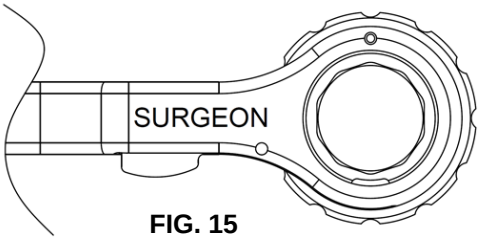


FIG. 15

INSERT
the miniARM™ Cannula from the “SURGEON” side (FIG. 16) until it is fully seated and secured by the cannula latch (FIG. 17).

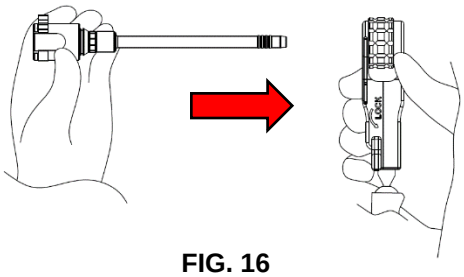


FIG. 16

NOTE: cannula should be fully seated

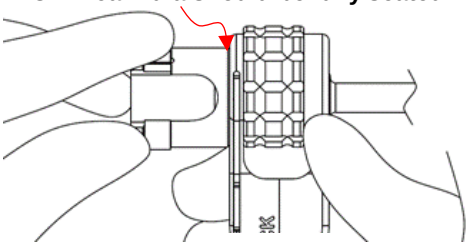


FIG. 17

If a visible gap is present, cannula is NOT fully seated

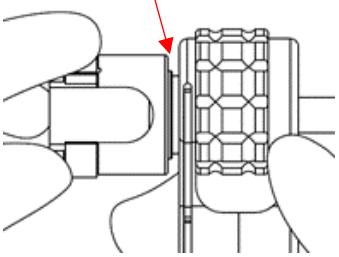


FIG. 18

REMOVAL:

PRESS
the cannula latch (FIG. 19) to remove the miniARM™ Cannula from the miniARM™ Cannula Adapter.

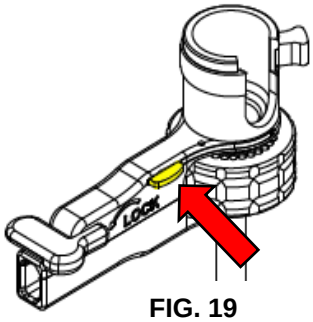


FIG. 19

miniARM™ OBTURATOR SPECIFIC USE: (U.S. Only)

OPEN
the cannula ring by rotating as shown in FIG. 20.

INSERT
the miniARM™ Obturator into the miniARM™ Cannula with the obturator depth stop passing through the gap in the cannula ring (FIG. 21).

CLOSE
the cannula ring over the obturator depth stop (FIG. 22) to secure the obturator in the miniARM™ Cannula.

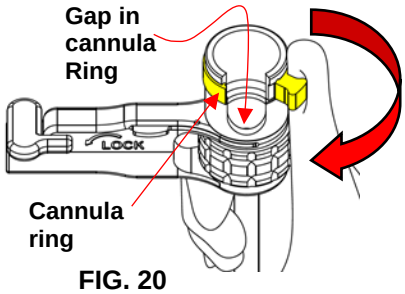


FIG. 20

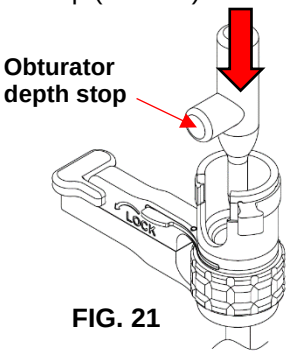


FIG. 21

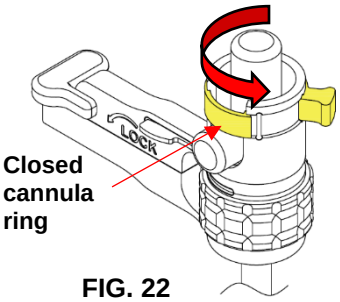


FIG. 22

ENDOSCOPE SPECIFIC USE: (U.S. Only)

NOTE: The miniARM™ Cannula is designed for insertion and retention of endoscopes with a shaft diameter of less than 6mm. It is recommended that any endoscope used with the miniARM™ Cannula be tested for insertion and retention prior to use.

OPEN
the cannula ring by rotating as shown in FIG. 23.

INSERT
the endoscope into the miniARM™ Cannula with endoscope light post through the gap in the cannula ring (FIG. 24).

CLOSE
the cannula ring over the endoscope light post (FIG. 25) to secure the endoscope in the miniARM™ Cannula.

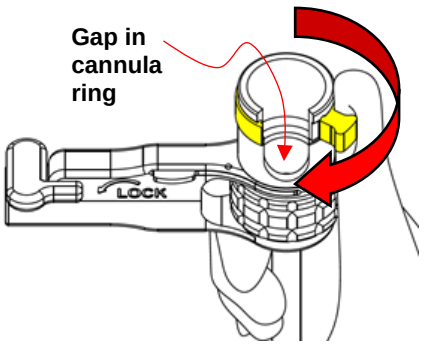


FIG. 23

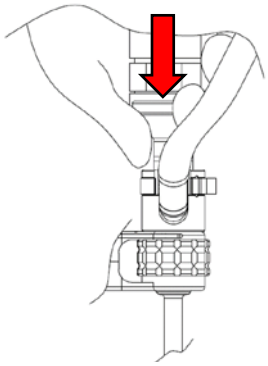


FIG. 24

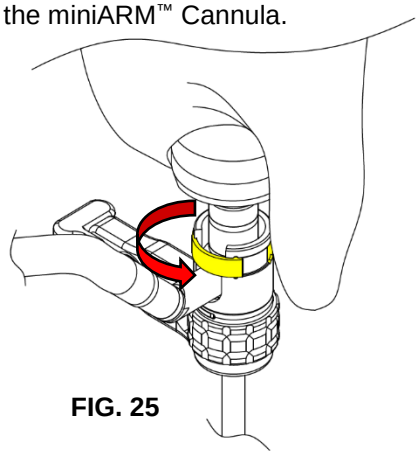


FIG. 25

ROTATE AND SECURE
the endoscope as needed with the cannula rotation dial to achieve desired viewing orientation (FIG. 26). Pull the rotation dial toward surgeon side to lock the rotation dial, and push the rotation dial away from surgeon side to unlock (FIG. 27).

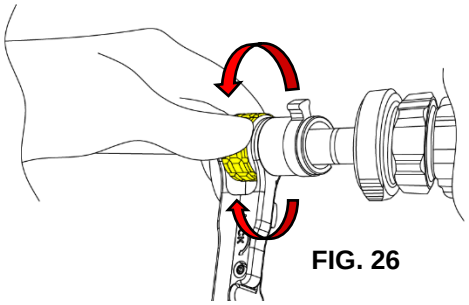


FIG. 26

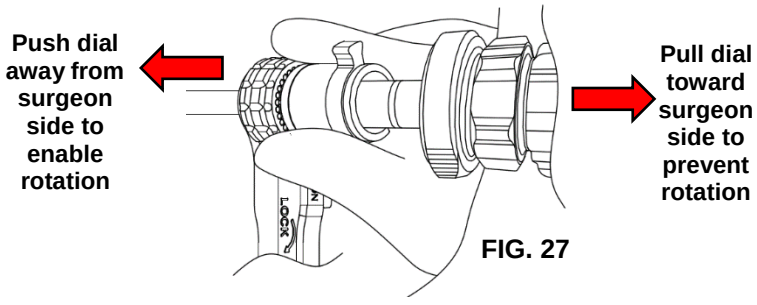


FIG. 27

miniARM™ CLAMPING ADAPTER SPECIFIC USE:

SLIDE
the miniARM™ Clamping Adapter onto the quick connect post while the adapter lock is rotated to the unlocked position (FIG. 28).

ROTATE
the adapter lock to the locked position (FIG. 29) to secure the adapter onto the miniARM™ Instrument Holder.

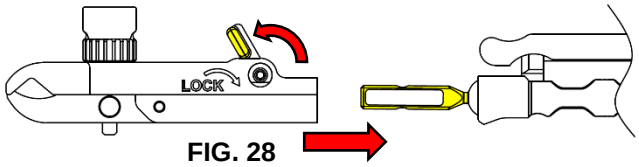


FIG. 28

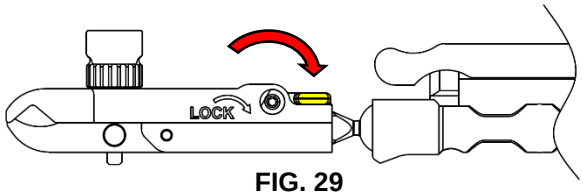


FIG. 29

OPEN
the miniARM™ Clamping Adapter jaw by rotating the actuation thumb screw counterclockwise (FIG. 30).

SECURE
a surgical device in the miniARM™ Clamping Adapter by twisting the actuation thumb screw clockwise to close the jaw (FIG. 31).

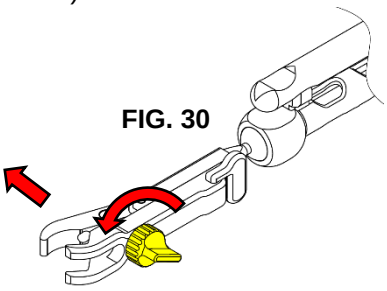


FIG. 30

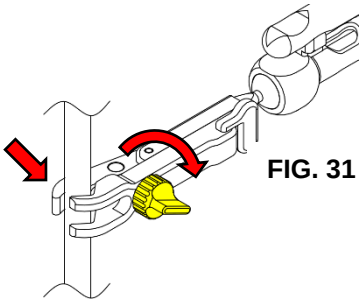


FIG. 31

NOTE: Using excessive force when closing the miniARM™ Clamping Adapter jaw could damage the held instrument. Similarly, failing to fully close the jaw around the instrument could result in the device slipping or changing position.

miniARM™ LOCKING COUPLER SPECIFIC USE: (U.S. Only)

NOTE 1: The miniARM™ Locking Coupler is an attachment for specific use with the Olympus® ENDOEYE FLEX® (LTF-S190-5), 5mm HD surgical video camera only.[1]

NOTE 2: The miniARM™ Locking Coupler must be used with either 1) the miniARM™ Cannula Adapter from the miniARM™ Cannula Adapter Kit or 2) the miniARM™ Clamping Adapter.

IF USING THE LOCKING COUPLER WITH THE CLAMPING ADAPTER:

OPEN
the miniARM™ Clamping Adapter jaw by rotating the actuation thumb screw counterclockwise (FIG. 32).

SECURE
the miniARM™ Locking Coupler in the miniARM™ Clamping Adapter by twisting the actuation thumb screw clockwise to close the jaw around the miniARM™ Locking Coupler shaft (FIG. 33).

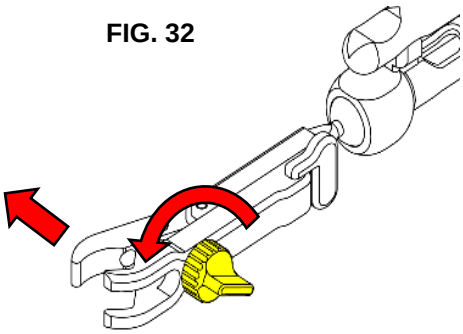


FIG. 32

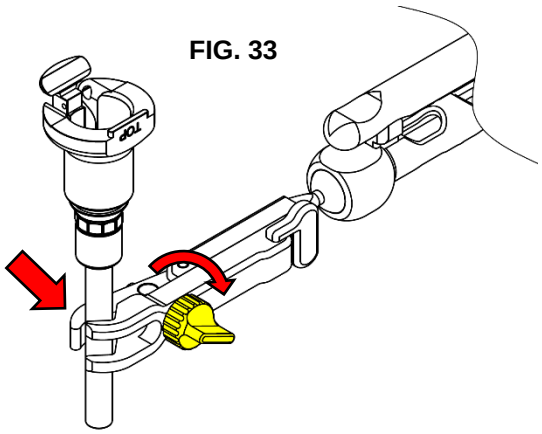


FIG. 33

IF USING THE LOCKING COUPLER WITH THE CANNULA ADAPTER:

ORIENT

the miniARM™ Cannula Adapter so that the word “SURGEON” is facing the user (FIG. 34).

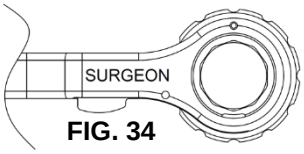


FIG. 34

INSERT

the miniARM™ Locking Coupler from the “SURGEON” side (FIG. 35) until it is fully seated (FIG. 36).

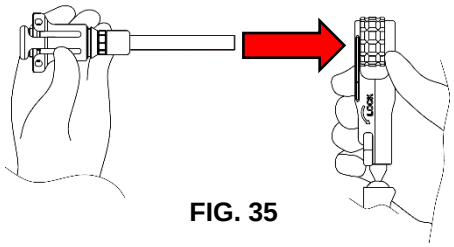


FIG. 35

NOTE: locking coupler should be fully seated

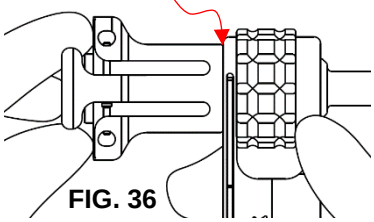


FIG. 36

If a visible gap is present, the locking coupler is NOT fully seated

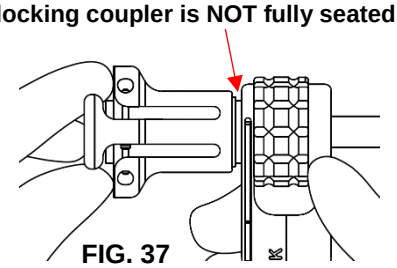


FIG. 37

NOTE: After insertion, the locking coupler can be rotated and secured as desired. See “Rotate and Secure” instructions on Page 7, FIGS. 26 & 27.

INSERTING THE OLYMPUS® ENDOEYE FLEX® SURGICAL VIDEO CAMERA:

ORIENT

the miniARM™ Locking Coupler so that the word “TOP” is facing the user (FIG. 38).

ENSURE

the Olympus® ENDOEYE FLEX® surgical video camera is not flexed before insertion to avoid damage to the camera’s distal tip.

INSERT

the Olympus® ENDOEYE FLEX® surgical video camera into the miniARM™ Locking Coupler making sure that the flat portion of the camera as shown (FIG. 39) aligns with the flat portion of the coupler labeled “TOP”.

FIG. 38

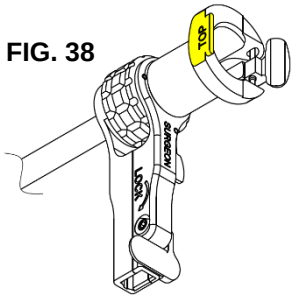
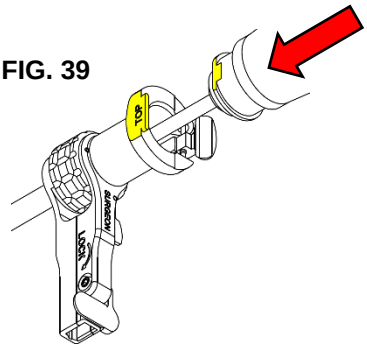


FIG. 39

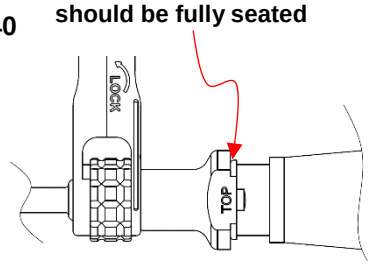


ENSURE

the Olympus® ENDOEYE FLEX® surgical video camera is fully seated and secured in the locking coupler (FIG. 40).

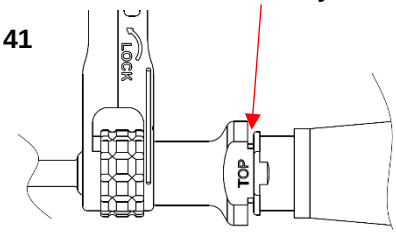
FIG. 40

NOTE: the video camera should be fully seated



If a visible gap is present, the video camera is NOT fully seated

FIG. 41



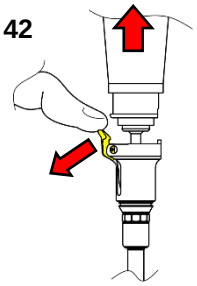
NOTE: FIGS 38 & 39 show the miniARM™ Cannula Adapter holding the Locking Coupler but the miniARM™ Clamping Adapter can also hold the Locking Coupler during the Olympus® ENDOEYE FLEX® video camera insertion.

REMOVING THE ENDOEYE FLEX® SURGICAL VIDEO CAMERA:

ENSURE
the Olympus® ENDOEYE FLEX® surgical video camera is not flexed before removal to avoid damage to the camera's distal tip.

PULL
the release tab (FIG. 42) to disengage the Olympus® ENDOEYE FLEX® from the miniARM™ Locking Coupler, then carefully remove the video camera.

FIG. 42



DISASSEMBLY:

IF USING THE CANNULA ADAPTER:

PRESS
the cannula latch (FIG. 43) to release the locking coupler from the miniARM™ Cannula Adapter.

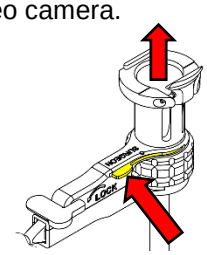
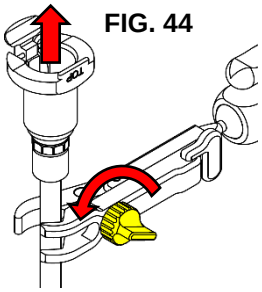


FIG. 43

FIG. 44



IF USING THE CLAMPING ADAPTER:

OPEN
the miniARM™ Clamping Adapter jaw by rotating the actuation thumb screw counterclockwise (FIG. 44) to release the miniARM™ Locking Coupler.

miniARM™ ACCESS ADAPTER SPECIFIC USE: (U.S. Only)

NOTE 1: The miniARM™ Access Adapter is an attachment for specific use with the 3D® mini Access Portal and the RAM® Ring Suture Management Device (sold separately by LSI SOLUTIONS®). The miniARM™ Access Adapter can be configured to hold either the 3D® mini Access Portal or the RAM® Ring Suture Management Device or both at the same time.
NOTE 2: The 3D® mini Access Portal should be attached to the miniARM™ Access Adapter before the RAM® Ring Suture Management Device when the two devices are used together.

OPTION A

IF USING THE miniARM™ ACCESS ADAPTER WITH ONLY THE 3D® mini ACCESS PORTAL:

NOTE: See the 3D® mini Access Portal Technology Guide for complete use and adjustment instructions for the 3D® mini Access Portal.

POSITION
the soft cradles of the 3D® mini Access Portal through an incision and around the ribs and/or soft tissue. Laterally spread the ribs to desired expansion width (FIG. 45). Do not use the 3D® mini Access Portal height adjustment screws to adjust the expansion arms anteriorly or posteriorly yet.

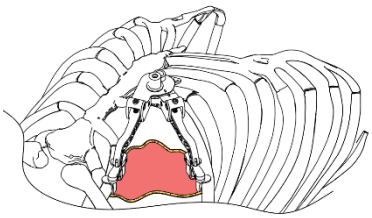


FIG. 45

ATTACH
the miniARM™ Instrument Holder to a surgical table rail on the opposite side of the patient from where the 3D® mini Access Portal is positioned. (See "Attachment to a Surgical Table" instructions on Page 5).

SECURE
the miniARM™ Access Adapter to the miniARM™ Instrument Holder (see Page 6, FIGS. 12-13).

CONNECT
the miniARM™ Access Adapter to the accessory post of the 3D® mini Access Portal using the attachment thumbscrew (FIG. 46).
NOTE: Ensure the miniARM™ Access Adapter and the 3D® mini Access Portal are sufficiently secured to each other with the attachment thumbscrew.

LOCK
the miniARM™ Instrument Holder following the locking instructions on Page 5.
NOTE: Check again to make sure the miniARM™ Access Adapter attachment thumbscrew is sufficiently tightened.

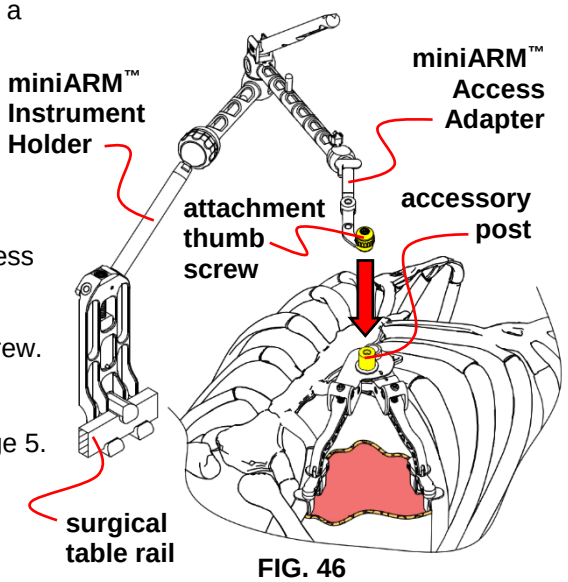


FIG. 46

ADJUST
the 3D® mini Access Portal expansion arms with the height adjustment screws to achieve surgeon's preferred anterior or posterior orientation.
NOTE: Make sure the miniARM™ Access Adapter attachment thumbscrew is sufficiently tightened.

OPTION B
IF USING THE miniARM™ ACCESS ADAPTER WITH ONLY THE RAM® RING:
NOTE 1: See the RAM® Ring Technology Guide for complete instructions for use of the RAM® Ring.

ATTACH
the miniARM™ Instrument Holder to a surgical table rail on the opposite side of the patient from where the 3D® mini Access Portal is positioned. (See "Attachment to a Surgical Table" instructions on Page 5).

SECURE
the miniARM™ Access Adapter to the miniARM™ Instrument Holder. (See Page 6, FIGS. 12-13).

CONNECT
the RAM® Ring mounting screw to the RAM® Ring receiver of the miniARM™ Access Adapter using the miniARM™ Deployment Knob (FIG. 47).

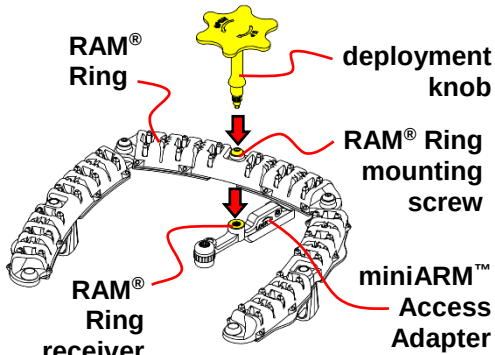


FIG. 47

OPTION C
IF USING THE miniARM™ ACCESS ADAPTER WITH BOTH THE 3D® mini ACCESS PORTAL & THE RAM® RING:

FIRST
follow the instructions for OPTION A above to attach the miniARM™ Access Adapter to the 3D® mini Access Portal.

SECOND
follow the instructions for OPTION B above to attach the RAM® Ring to the Access Adapter, resulting in the combined assembly show in FIG. 48.

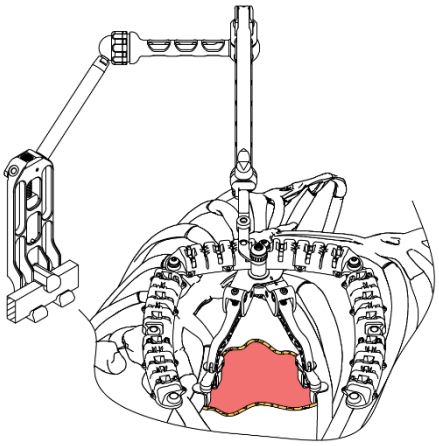


FIG. 48

DISASSEMBLY
IF USING THE RAM® RING, TO DISASSEMBLE:

INSERT
the miniARM™ Deployment Knob into the RAM® Ring mounting screw (FIG. 49) and rotate counterclockwise until the RAM® Ring mounting screw releases from the miniARM™ Access Adapter.

NOTE 1: The RAM® Ring is a single use device that should be disposed of in accordance with local regulations and hospital procedures.

NOTE 2: The miniARM™ Access Adapter can be reprocessed with the miniARM™ System using the instructions in this Technology Guide.

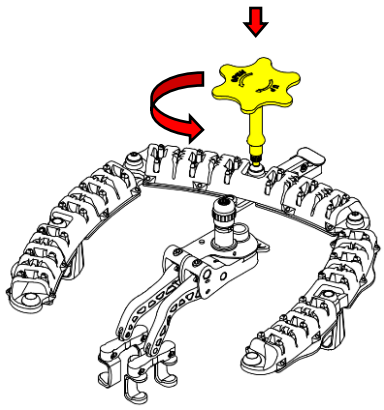


FIG. 49

IF USING THE 3D® mini ACCESS PORTAL, TO DISASSEMBLE:

ROTATE
the attachment thumb screw counterclockwise (FIG. 50) until the miniARM™ Access Adapter releases from the 3D® mini Access Portal.

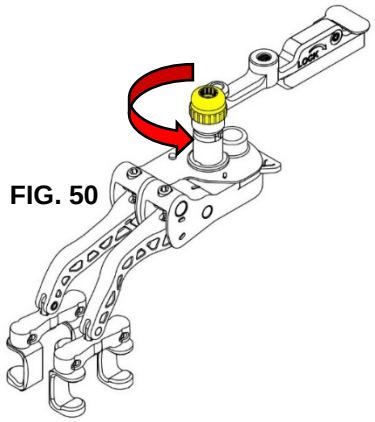


FIG. 50

NOTE 1: During use the attachment thumb screw may tighten. If unable to loosen by hand, the miniARM™ Deployment Knob may be used to loosen the attachment thumb screw.
NOTE 2: As shown in FIG. 50, the 3D® mini Access Portal is not shown engaging ribs. If the 3D® mini Access Portal is still engaging ribs after the miniARM™ Access Adapter is removed, be sure to remove the 3D® mini Access Portal from the patient when done, per the 3D® mini Access Portal Technology Guide.
NOTE 3: The 3D® mini Access Portal is a single use device that should be disposed of in accordance with local regulations and hospital procedures.
NOTE 4: The miniARM™ Access Adapter can be reprocessed with the miniARM™ System using the instructions in this Technology Guide.

REMOVAL & CLEANUP:

The following steps may be made easier by having the miniARM™ System locked while handling.

REMOVE
the adapter by rotating the adapter lock and sliding the adapter off the quick connect post (FIG. 51).

DISASSEMBLE
all previously assembled adapter parts, including the miniARM™ Cannula, miniARM™ Obturator, miniARM™ Locking Coupler, any devices held in the miniARM™ Clamping Adapter or any devices attached to the miniARM™ Access Adapter using the instructions in this Technology Guide.

DETACH
the miniARM™ Instrument Holder from the surgical table accessory rail by inserting and rotating the deployment knob counterclockwise while securely holding the system (FIG. 52).

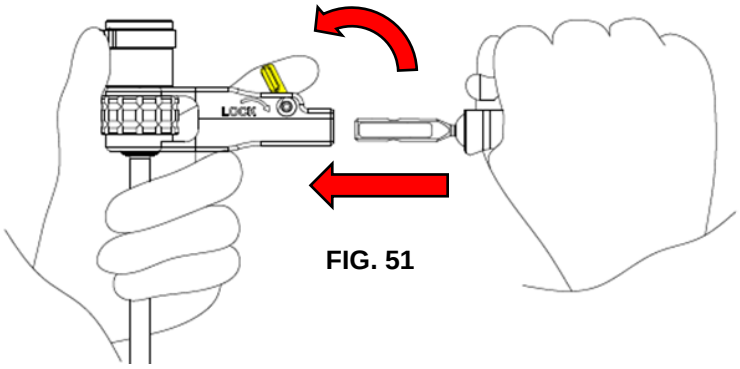


FIG. 51

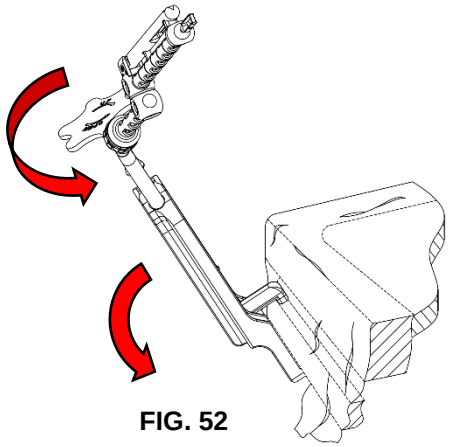


FIG. 52

miniARM™ SYSTEM REPROCESSING

- Disassemble and clean devices immediately after use. Do not allow soiled devices to dry.
- The miniARM™ System is not validated to be cleaned or sterilized in the fully assembled state. It should be disassembled into the components as shown on pages 1 - 3 FIGS. 1-5.
- Cleaning agent used in validation: Steris Prolystica 2X (Enzymatic, Neutral pH)
- Final rinse using only freshly prepared purified water/highly purified water.
- Never use metal brushes or steel wool for cleaning.

POINT OF USE

1. Disassemble and clean devices immediately after use.
2. Do not allow soiled devices to dry.

PREPARATION

1. Insert the deployment knob into the top center hole on the rail clamp and then rotate the deployment knob clockwise until all threads (shown in the red circle) are exposed and the deployment knob stops turning (FIG. 53).

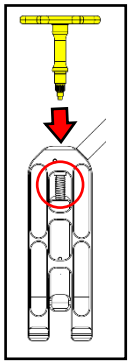


FIG. 53

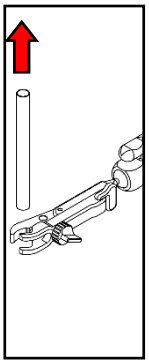


FIG. 55

2. If present, remove the obturator from the cannula (FIG. 54).

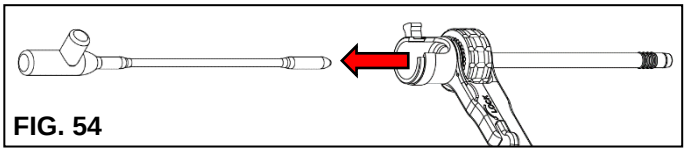


FIG. 54

3. If present, remove any devices from the miniARM™ Clamping Adapter (FIG. 55).

4. Remove the adapter from the miniARM™ Instrument Holder by rotating the adapter lock and sliding the adapter off the quick connect post (FIG. 56).
NOTE: FIG. 56 shows cannula adapter being removed but other adapters are removed in the same manner.

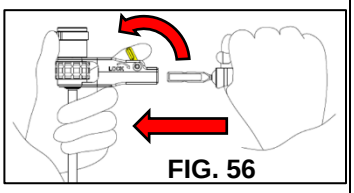


FIG. 56

5. If present, remove the cannula or miniARM™ Locking Coupler from the adapter by pressing the cannula latch while pulling the cannula or miniARM™ Locking Coupler out of the adapter (FIG. 57).

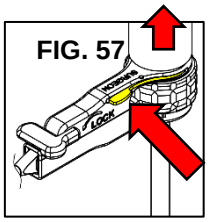


FIG. 57

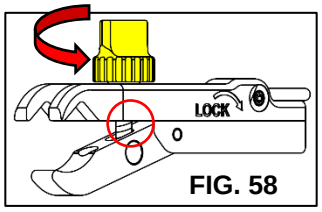


FIG. 58

6. If the miniARM™ Clamping Adapter is present, rotate the actuation thumb screw counterclockwise until all threads (shown in the red circle) are exposed and the actuation thumb screw stops turning. (FIG. 58)

7. If present, remove the RAM® Ring from the miniARM™ Access Adapter by inserting a miniARM™ deployment knob and rotating it counterclockwise to disengage. (FIG. 59)

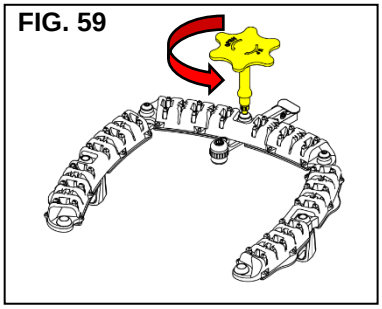


FIG. 59

NOTE 1: The RAM® Ring is a single use device that should be disposed of in accordance with local regulations and hospital procedures.

NOTE 2: The miniARM™ Access Adapter can be reprocessed with the miniARM™ System using the instructions in this Technology Guide.

PREPARATION (CONTINUED)

8. If present, remove the 3D® mini Access Portal from the miniARM™ Access Adapter by rotating the attachment thumb screw counterclockwise (FIG. 60). If hand loosening is not possible a deployment knob can be used for assistance.

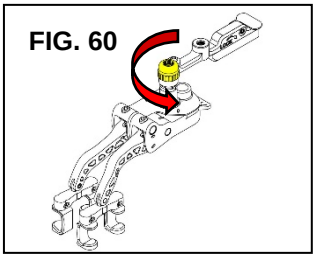


FIG. 60

NOTE 1: The 3D® mini Access Portal is a single use device that should be disposed of in accordance with local regulations and hospital procedures.

NOTE 2: The miniARM™ Access Adapter can be reprocessed with the miniARM™ System using the instructions in this Technology Guide.

9. If the miniARM™ lever is in the locked position (FIG. 61), release the lock by fully squeezing the locking lever (FIG. 62) until an audible click signals the lever latch is disengaged, then release the locking lever.

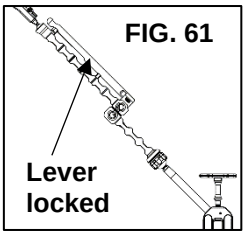


FIG. 61

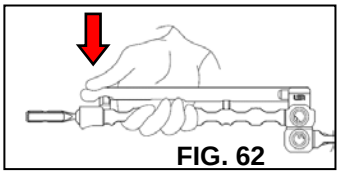


FIG. 62

10. Raise the lever completely to ensure the miniARM™ system is fully open and in the reprocessing position (FIG. 63).

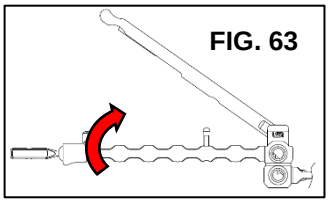


FIG. 63

11. If using the miniARM™ sterilization tray, clean the tray separately according to the sterilization tray instructions for use.

MANUAL PRE-CLEANING

1. Soak in enzymatic, neutral pH cleaning solution for 5 minutes minimum. Refer to detergent manufacturer's instructions for temperature and concentration.
2. Use a plastic bristled brush to thoroughly scrub the device's exterior surfaces, paying special attention to the following "Soil Traps":
   a. Locking lever pivot point (FIG. 64)
   b. Lever latch & catch (FIG. 65)
   c. Cannula Adapter attachment opening (FIG. 66)
   d. Length of cannula lumen (FIG. 67) use round brush 1mm larger than cannula (e.g. use 7mm brush for 6mm lumen)
   e. Clamping Adapter attachment opening (FIG. 68)
   f. Lower Jaw threading shaft (FIG. 68)
   g. Threading and jaw cavity (FIG. 68)

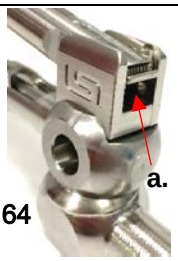


FIG. 64

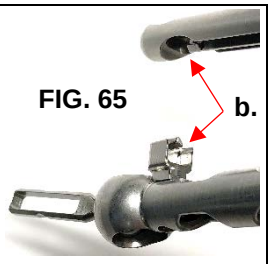


FIG. 65

FIG. 66

FIG. 67

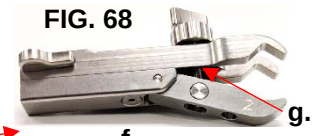


FIG. 68

   h. Release tab pin pocket (FIG. 69)
   i. Length of locking coupler lumen (FIG. 69) use round brush 1mm larger than lumen (e.g. use 7mm brush for 6mm lumen)

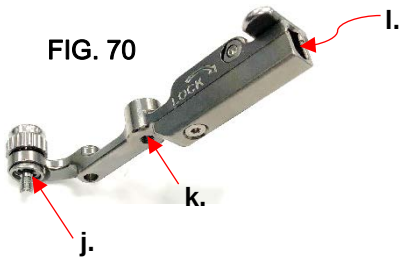
FIG. 69

MANUAL PRE-CLEANING (CONTINUED)

j. Attachment thumb screw threads (FIG. 70)
k. RAM® Ring receiver threads (FIG. 70)
l. Access Portal attachment opening (FIG. 70)

3. Rinse with warm water for 2 minutes minimum.

4. Proceed with one of the two required cleaning options (ultrasonic or automated).



ULTRASONIC CLEANING

1. Clean in ultrasonic bath with enzymatic, neutral pH cleaning solution for 15 minutes minimum. Refer to detergent manufacturer's instructions for temperature and concentration.

2. Rinse with warm water for 4 minutes minimum. To ensure a complete rinse, use a clean brush to scrub all the various components i.e.: cannula, obturator and adapters.

OR

AUTOMATED CLEANING

1. A washer-disinfector is required with fundamentally approved efficiency (e.g. FDA approval according to ISO 15883) and must be properly installed, qualified, and regularly subjected to maintenance and testing.

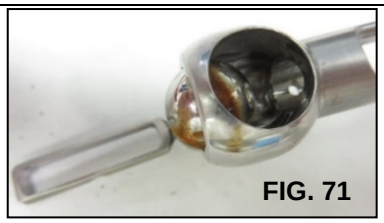
2. The miniARM™ sterilization tray is NOT designed for cleaning the miniARM™ System, it must be processed separately. The tray is only intended for sterilization, transport, and storage of re-usable instruments. For more tray information see the sterilization tray instructions for use.

3. Load the device(s) into the washer-disinfector. Avoid contact between devices and arrange to allow for proper drainage.

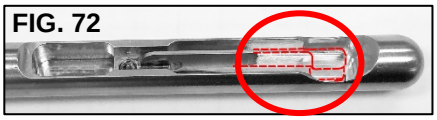
4. Operate the washer-disinfector cycle with an additional rinse cycle.

INSPECTION

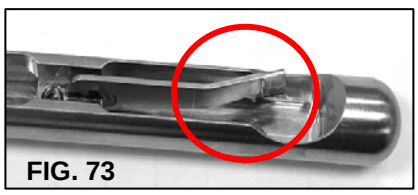
1. Carefully inspect the device to assure that all visible soil has been removed. Generally un-magnified visual inspection under good light conditions is sufficient. Particular attention should be paid to the "Soil Traps" in FIGS 64-70. Repeat cleaning process if soil is detected.



2. Visually inspect the device for mild or excessive corrosion. For example, see the corrosion example FIG. 71. If corrosion is present, complete the reprocessing, but discontinue use of the device in surgery.



3. Visually inspect the device for damaged latches or other affected parts. For example, see the broken lever latch outline of FIG. 72 and the bent lever latch of FIG. 73. If parts are damaged, complete reprocessing, but discontinue use of the device in surgery.



4. Perform a functional check for adequate device locking and release (see page 5, FIGS. 6 and 7).

5. Application of instrument lubricant can aid in prolonging instrument life. Entire device may be submerged in solution mixed to manufacturer's recommendations.

PACKAGING

1. Ensure Locking Lever is in the fully open reprocessing position (see FIG. 63).
2. Confirm all instruments are present. If using sterilization pouches place each instrument in its own individual pouch. If using the miniARM™ sterilization tray, Part Number 100028, read the sterilization tray instructions for use before proceeding. Ensure the sterilization tray has been cleaned according to the sterilization tray instructions for use and load the tray bottom according to FIG. 74.

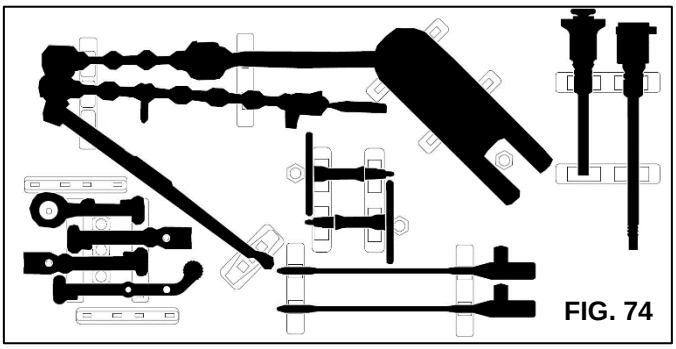


FIG. 74

NOTE: The tray lid only fits the tray bottom in one direction. If the side locks cannot both be securely latched, it may be necessary to reorient the lid to achieve a secure fit.

For more tray information see the sterilization tray instructions for use.

3. Package the miniARM™ System according to TABLE 1. The barrier system for sterilized re-usable instruments should meet the following requirements.

- ISO 11607-1
- Suitable for Pre-Vacuum steam sterilization
- Appropriate for medical use
- Grade appropriate for weight of loaded tray per sterilization tray IFU and facility procedures

STERILIZATION

1. The device must be properly cleaned prior to sterilization.
2. Perform sterilization cycle according to TABLE 1:

TABLE 1: miniARM™ System Sterile Packaging and Processing

Method	Moist heat (steam) sterilization according to ANSI/AAMI ST 79	Moist heat (steam) sterilization according to ANSI/AAMI ST 79	Immediate Use Steam Sterilization according to ANSI/AAMI ST 79
Container	miniARM™ Sterilization Tray Part Number 100028	No Tray	No Tray
Cycle	Pre-Vacuum (Pre-Vac)	Pre-Vacuum (Pre-Vac)	Pre-Vacuum (Pre-Vac)
Packaging	2-layer polypropylene wrap	Pouch	No Packaging
Temperature	132°C (270°F)	132°C (270°F)	132°C (270°F)
Exposure Time	4 minutes (minimum)	4 minutes (minimum)	4 minutes (minimum)
Dry Time	55 minutes (minimum)	15 minutes (minimum)	N/A

Device(s) processed by Immediate Use Sterilization should be transferred immediately, using aseptic technique, from the sterilizer to the point of use. Refer to ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.

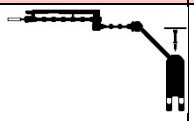
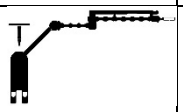
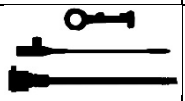
The miniARM™ Instrument Holder and miniARM™ accessories have been validated to twenty (20) reprocessing cycles. The useful lifespan of a surgical instrument is largely dependent on the care and handling of the instrument. Careful inspection and functional testing of the instrument should be used to determine the end of its serviceable life.

STORAGE

1. During storage, ensure devices remain in a sterile condition ready for reuse.
2. Shelf life is dependent on the sterile barrier employed, storage manner, and environmental and handling conditions

Ordering Information

TABLE 2: miniARM™ System Product Ordering

	REORDER	PRODUCT	DESCRIPTION	AVAILABILITY
	080418	miniARM™ Instrument Holder, 30cm, Adjustable, Left	1 Shelf Box	US, EU
	080419	miniARM™ Instrument Holder, 30cm, Adjustable, Right	1 Shelf Box	US, EU
	080415	miniARM™ Cannula Adapter Kit	1 Shelf Box	US ONLY
	100028	miniARM™ Sterilization Tray*	1 Shelf Box	US ONLY
	080519	miniARM™ Clamping Adapter	1 Shelf Box	US, EU
	080555	miniARM™ Locking Coupler- For Use with the Olympus® ENDOEYE FLEX® 5mm HD surgical video camera (LTF-S190-5)[1] (NOTE: the miniARM™ Locking Coupler requires either 1) the miniARM™ Cannula Adapter Kit (#080415) OR 2) the miniARM™ Clamping Adapter (#080519) in order to be attached to the miniARM™ Instrument Holder)	1 Shelf Box	US ONLY
	080670	miniARM™ Access Adapter- For Use with 1) the 3D® mini Access Portal (#110300) AND/OR 2) the RAM® Ring (#080215)	1 Shelf Box	US ONLY

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**The miniARM™ Sterilization Tray is manufactured by: Summit Medical, 815 Vikings Parkway, Suite 100 St. Paul, MN 55121 U.S.A.*

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