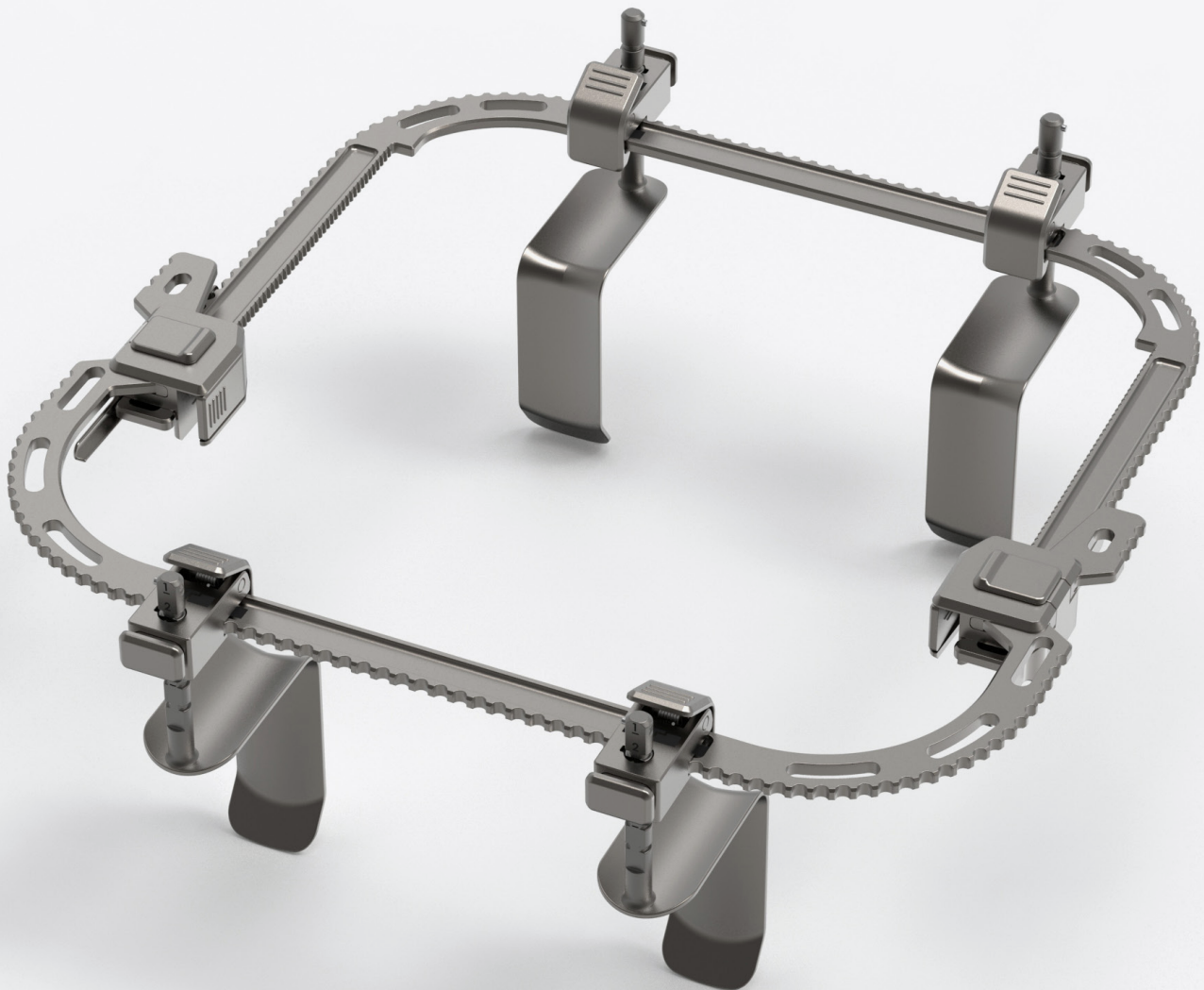




TITAN CSR®

SURGICAL RETRACTOR

INSTRUCTIONS FOR USE



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TITAN CSR® RETRACTOR SYSTEM AND BLADE ACCESSORIES DESCRIPTION, INTENDED USE AND PART NUMBERS

Description

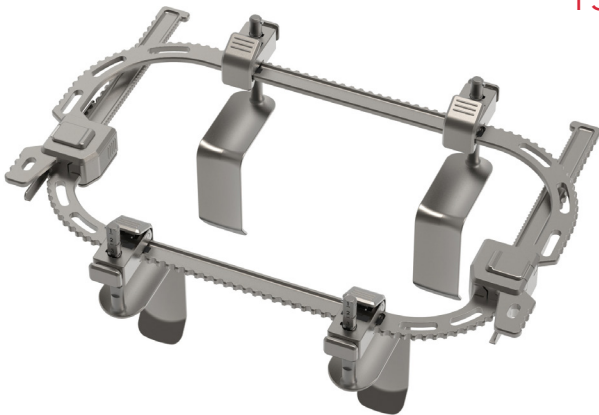
The TITAN CSR® self-retaining retractor system is a latex-free, reusable device designed to provide access and exposure for a variety of surgical procedures. The TITAN CSR® self retaining retractor system is designed with accessories to meet a variety of patient anatomies and procedures.

Intended Use

The TITAN CSR® self-retaining retractor is intended for use during surgical procedures in order to provide surgical access and exposure.

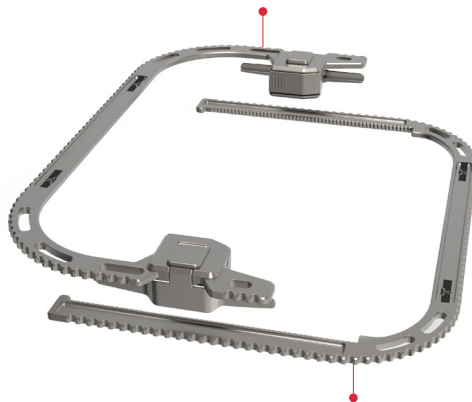
Part Numbers

TITAN CSR® Surgical Retractor System TSR-106-100



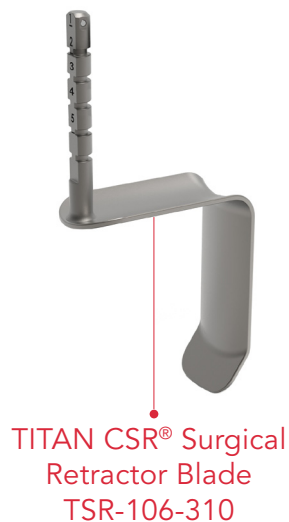
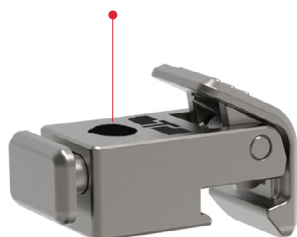
- One (1) Modular Frame Arm with Locking Mechanism
- One (1) Modular Frame Arm without Locking Mechanism
- Four (4) Blade Clamps
- Four (4) Retractor Blades

TITAN CSR® Surgical Retractor Modular Frame Arm with Locking Mechanism TSR-106-110



TITAN CSR® Surgical Retractor Modular Frame Arm without Locking Mechanism TSR-106-120

TITAN CSR® Surgical
Retractor Blade Clamp
TSR-106-210



Blade Accessories

Part Number	Part
TSR 106-400	Stainless Steel Tilt Ratchets
TSR 106-410T	Titanium Richardson 2" wide x 3" long
TSR 106-411T	Titanium Richardson 2" wide x 4" long
TSR 106-420T	Titanium Malleable 3" wide x 6" long
TSR 106-410SS	Stainless-steel Richardson 2" wide x 3" long
TSR 106-411SS	Stainless-steel Richardson 2" wide x 4" long
TSR 106-420SS	Stainless-steel Malleable 3" wide x 6" long

INSPECTION, WARNINGS AND PRECAUTIONS, AND CONTRAINDICATIONS

ASR Systems' Instructions for Use are provided to help support the safe and effective reprocessing of the TITAN CSR® Surgical Retractor system and blade accessories by health care professionals in a health care facility. .

ASR Systems' TITAN CSR retractor system and blade accessories are delivered to the health care facility as non-sterile items that must be inspected, cleaned, and sterilized prior to use. The TITAN CSR retractor system and blade accessories are substantially equivalent to commercially available table mounted retractors. ASR Systems has validated the cleaning and sterilization procedures demonstrating the TITAN CSR retractor system can be safely used as intended. These instructions are based on the validation testing conducted by an accredited GLP microbiology lab. Health care professionals must take care responsibility to ensure appropriate equipment & materials are used to reprocess the TITAN CSR retractor system. Health care professionals must provide adequate training to staff using or reprocessing the TITAN CSR retractor system. If a health care professional deviates from ASR Systems' instructions, it is the health care facility's responsibility to verify effectiveness of the reprocessing procedure. .

Inspection

Inspect the TITAN CSR® surgical retractor system and blade accessory parts before and after each use to detect wear, tear, or imperfections. Set aside any damaged or deformed parts, do not use, and contact ASR Systems for further instructions. Should you have concerns regarding the operation of the TITAN CSR retractor system and blade accessories' proper function, please contact ASR Systems to discuss.

Warnings And Precautions

The TITAN CSR® self-retaining surgical retractor system and blade accessories are supplied non-sterile.

All instruments must be inspected, cleaned, and sterilized prior to each use, including the initial use.

The TITAN CSR retractor modular frame, blades, blade clamps and blade accessories may have sharp edges and require careful handling while inspecting, wiping, cleaning, and packaging.

Personal Protective Equipment (PPE): PPE should be worn, per individual facility protocol, when handling or working with a contaminated or potentially contaminated TITAN CSR retractor system and blade accessories.

Creutzfeldt-Jakob Disease (CJD): Discard or destroy instruments in contact or exposed to patients with CJD, or those suspected of CJD.

Cross-Contamination Issues: Care should be taken in accordance with facility protocol for any cross-contamination issues.

Proper Use of the TITAN CSR® surgical retractor system and blade accessories: Health care professionals should read and become familiar with the product materials prior to using this system.

1. The TITAN CSR retractor system and blade accessories are an Rx Only medical device and should only be handled and used by health care professionals with required training, knowledge, and experience.

2. The health care professionals are responsible for assessing the patient, patient anatomy and pathology to determine surgical techniques and retractors for desired outcomes.
3. Retractor blades apply significant tension and force to incision edges and tissues. Only use as much retraction as necessary for adequate exposure and access. It is recommended to occasionally release the retractor tension and/or change retractor blade position to relieve constant pressure to any one location.
4. Retractor blades may compress nerves. Health care professional must evaluate the need to use free running EMG to monitor for retractor nerve compression outside the visual field.
5. Care should be taken to prevent any occurrence of a nerve palsy, especially on the iliopsoas muscle.
6. Consult manufacturer instructions if using electrosurgical equipment while retracting with the TITAN CSR retractor system and blade accessories.
7. U.S. Federal Law restricts this device to sale to or on the order of a physician. Use of the TITAN CSR retractor system and blade accessories for any purpose other than their intended use, is not recommended and could result in serious injury or death.

If using components from other retractor kits, follow manufacturer's instruction for use and warnings.

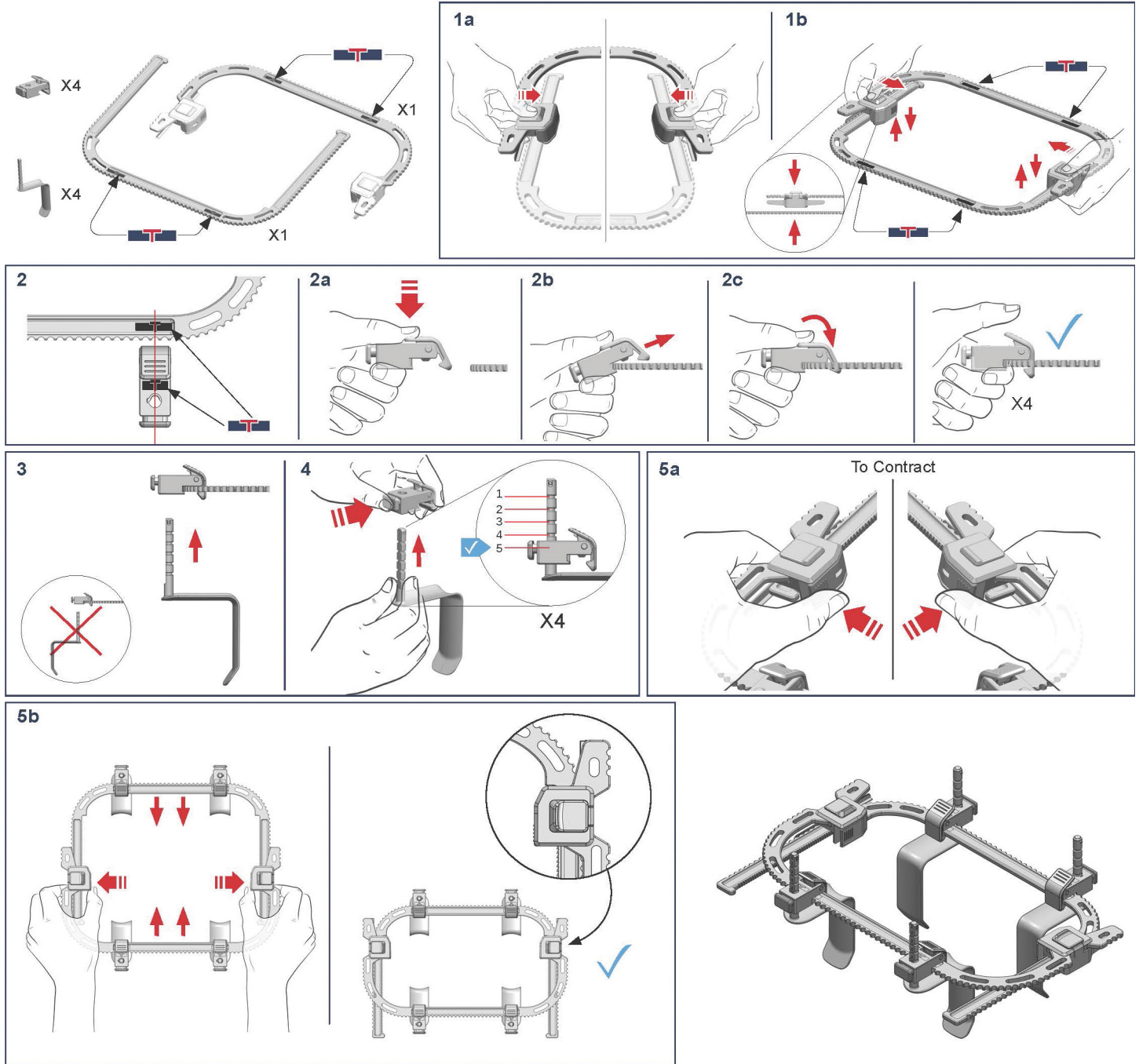
Contraindications

None known.



ASSEMBLY/DISASSEMBLY INSTRUCTIONS

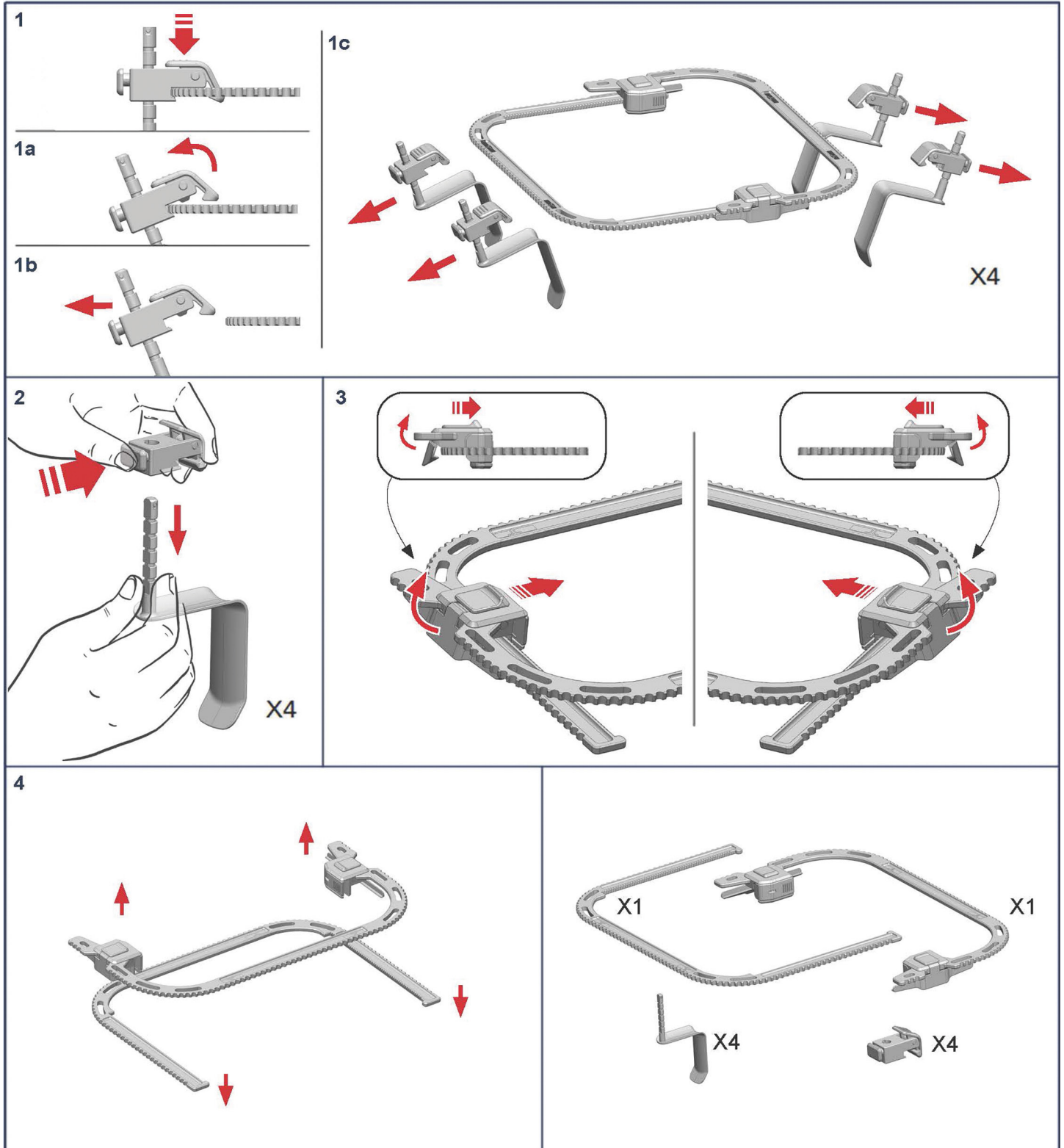
Assembly Instructions



The TITAN CSR® Surgical Retractor is compatible with Bookwalter® retractor blades and attachments. For Customer Service Please Call 855-415-7471. For Assembly Videos, Scan QR Code.

The Bookwalter® trademark is a registered trademark of Symmetry Surgical, Inc., and ASR Systems makes no claim to it. ASR Systems is not an authorized seller of Bookwalter® branded products.

Disassembly Instructions



CLEANING AND STERILIZATION

TITAN CSR® Retractor System and Blade Accessories

The TITAN CSR® retractor system and blade accessories are substantially equivalent to commercially available table mounted retractors. The TITAN CSR retractor system and blade accessories are made of stainless steel and/or titanium and supplied by ASR Systems. We recommend that the facility use the procedures below for cleaning and sterilization of the TITAN CSR® retractor system and blade accessories unless your facility uses other protocols for table mounted surgical retractors.

Point of Use Gross Decontamination

Wipe the TITAN CSR® Surgical Retractor frame arms, blades, and blade clamps with a disposable wipe until TITAN CSR retractor is free of any visible traces of blood, tissue, body fluids, and debris after use. Do not allow blood, tissue, body fluids, and debris dry on the TITAN CSR retractor.

Transportation

To prevent risk of cross contamination, place the TITAN CSR® Surgical Retractor system and blade accessories in a closed tray, container, and/or case cart and transport to the decontamination area of the Sterile Processing Department as soon as possible.

Pre-cleaning

Disassemble the TITAN CSR® Surgical Retractor into its 10 separate parts for cleaning. The TITAN CSR retractor cleaning was validated with an enzymatic detergent soak for 20 minutes. Prepare soaking solution and soak TITAN CSR retractor according to detergent manufacturer's instructions. While soaking in the solution, actuate blade clamps, thumb activated slide buttons, and release levers of the locking mechanisms of the upper frame arm. Inspect blade post at each blade post height location, and check grooves of the TITAN CSR retractor for visual signs of blood, tissue, body fluids, and debris. While in the soaking solution, use a firm bristled cleaning brush to remove all visible signs of blood, tissue, body fluids, and debris. Pay particular attention to debris that may be between the coils of the springs in the blade clamps, and any crevice of any part. Remove the TITAN CSR retractor from the soaking solution and rinse under incoming warm running water allowing water to drip off. Do not use hard water for soaking or rinsing the TITAN CSR retractor. Verify health care facility's use of pre-cleaning detergent using manufacturer's instructions.

Ultrasonic Washing

The TITAN CSR® Surgical Retractor can be cleaned in an ultrasonic washer prior to washing in an automated washer/disinfector. Please follow all ultrasonic washer's manufacturer instructions for appropriate time, temperature, and frequency.

Automated Wash in Washer/Disinfector

Place the disassembled TITAN CSR® Surgical Retractor in a washer tray, taking care to keep all the parts together. Put washer tray with the TITAN CSR retractor in a validated automated washer/disinfector using manufacturer's instruction for proper instrument loading. Use automated washer/disinfector manufacturer's instructions to select a wash cycle that minimally includes a pre-wash; detergent wash cycle; rinse; thermal disinfection rinse; and dry cycle using the following parameters:

Automated Washer Phase	Time	Temperature
Pre-Rinse	Minimum of 2 minutes	Cold water, not to exceed 40°C/104°F
Detergent Wash	Minimum of 6 minutes	Set water temp, as per detergent IFU
Rinse	Minimum of 4 minutes	Incoming hot water
Thermal Disinfection	Minimum of 1 minute	90°C/194°F
Dry	Minimum of 5 minutes	No temp max or requirement

The TITAN CSR retractor validation testing was performed using Renuzyme Plus Enzymatic detergent manufactured by Getinge Group. Other manufacturer detergents may provide similar results. Mechanical cleaning equipment should be inspected daily and tested weekly (preferably daily) during routine use. Verify health care facility's washer/disinfector and washer/disinfector detergents use according to manufacturer's instructions.

Inspection

Upon completion of the automated washer/disinfector process, dry the TITAN CSR® Surgical Retractor with a clean non-lint cloth as necessary. Compressed air may be used to help dry springs, locking mechanisms, and around thumb activated buttons. Inspect TITAN CSR retractor for any visible signs of blood, tissue, body fluids, and debris. If TITAN CSR retractor does not pass visual inspection, return to the decontamination area for cleaning.

Assemble the TITAN CSR retractor and check for proper functions of locking mechanisms (slide lock and side clamp of the main ratchets on the upper frame arm), expansion/contraction, blade clamps, and post height adjustments. Inspect the TITAN CSR retractor to detect wear, tear, or imperfections. Do not use any damaged parts, set them aside and contact ASR Systems for further instructions.

Lubrication

Prior to sterilization, TITAN CSR® Surgical Retractor's locking mechanisms and blade clamps may be lubricated with a water-soluble lubricant compatible with the subsequent sterilization process. Do not use oil or silicone lubricants on the TITAN CSR retractor. Please follow lubricant manufacturer's instructions for use.

Packaging

TITAN CSR® Surgical Retractor was validated in a 510(k) cleared sterilization container. The TITAN CSR retractor should be packaged in an FDA cleared sterile barrier system. The health care facility should refer to sterile barrier system manufacturer's instructions and verify similar results. The TITAN CSR surgical retractor has been validated for sterilization in an appropriately sized, FDA cleared sterilization container disassembled in 10 separate parts, and fully assembled.

Sterilization

Load the TITAN CSR® Surgical Retractor in a validated steam sterilizer using the manufacturer's instructions for proper loading and operation. The TITAN CSR retractor has been validated for sterilization in an appropriately sized, FDA cleared sterilization container disassembled in 10 separate parts, and fully assembled using:

- Pre-vacuum/ vacuum pulse cycle
- Minimum temperature of 132°C/270°F
- Minimum exposure time of 4 minutes
- Dry time of 30 minutes

ASR Systems does not recommend ETO sterilization.

Storage

Store the TITAN CSR® Surgical Retractor in a temperature-controlled sterile area of the Sterile Processing Department protected from dust, moisture, and other contaminants.

The results of ASR Systems' Cleaning and Sterilization Validation are on file and available upon request.

WARRANTY

ASR Systems, Inc. warrants only to the original purchaser of the instrument that this medical device is free from defects in material and workmanship for 1 year from the date of purchase (herein referenced as the “Warranty”). Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. There are no warranties that extend beyond the description of the Warranty provided herein.

The Warranty shall be void in the event any ASR Systems® instrument: (i) is used for purposes other than abdominal surgical retraction performed by a trained surgeon; (ii) is not maintained or cleaned properly; (iii) is damaged as a result of misuse or accident, including but not limited to, if the instrument is dropped; or (iv) is repaired or altered by persons not specifically authorized for such repair in writing by ASR Systems.

The above is a limited warranty, and it is the only warranty made by ASR Systems. ASR Systems makes no other warranty, express or implied, including any warranty of merchantability or fitness for a particular purpose, as well as any warranty, whether express or implied, to patients. ASR Systems shall have no liability for consequential, exemplary or incidental damages even if it may be aware of the possibility of such damage. No warranty or guarantee may be created by any act or statement nor may the Warranty be modified in any way. These limitations on the creation or modification of the Warranty may not be waived or modified orally or by any conduct by ASR Systems, its agents or representatives. The stated express Warranty is in lieu of all liabilities or obligations of ASR Systems arising out of, or in connection with, the delivery, use or performance of any ASR Systems instrument. ASR Systems neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with ASR Systems instruments.

SERVICE, REPAIR, QUESTIONS/COMMENTS, OR COMPLAINTS

For service, repair, questions/comments please send an email to Service@asrsystemsinc.com

For product complaints, please send an email to Complaints@asrsystemsinc.com

ASR Systems, Inc.
14439 NW Military Hwy.
Suite 108 - 469
San Antonio, TX 78231

Always include the serial number of each part returned and a written description of the problem.



Model # TSR 106-100 - UDI # G254TSR106100