TITAN CSR® LIGHTED RETRACTOR BLADE & TITAN CSR® BLADE LIGHT

INSTRUCTIONS FOR USE

02/25

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ASR® SYSTEMS
ADVANCED SURGICAL RETRACTOR SYSTEMS, INC.

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TITAN CSR® LIGHTED RETRACTOR BLADE, TITAN CSR® BLADE LIGHT, INTENDED USE, AND PART NUMBERS

Description

The TITAN CSR® Lighted Retractor Blade is a latex free, reusable device designed to provide surgical retraction. With the addition of the TITAN CSR® Blade Light, a latex free, battery-powered, single-use, disposable LED light, they together are designed to provide retraction and illumination of the surgical field.

Intended Use

The TITAN CSR® Lighted Retractor Blade is intended for use during surgical procedures in order to provide surgical access and exposure. Together with the TITAN CSR® Blade Light, they are designed to provide retraction and illumination of the surgical field.

Part Numbers

TITAN CSR® Lighted Retractor Blade
TSR-106-415SS

TITAN CSR® Tilt Ratchet
TSR-106-400

TITAN CSR® Blade Light
TSR-106-515

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Part Number	Part Number	Part
TITAN CSR® Lighted Retractor Blade	TSR-106-415SS	Light fiber tube affixed to a 2" wide x 3" long Richardson blade for surgical lighting (Reusable/re-sterilizable) **without tilt ratchet**
TITAN CSR® Tilt Ratchet	TSR-106-400	Stainless Steel Tilt Ratchet to connect the TITAN CSR® Lighted Retractor Blade to the TITAN CSR® Retractor
TITAN CSR® Blade Light -Box of Five (5)	TSR-106-515	Box of five (5) sterile, disposable, battery-powered, LED lights

INSPECTION, WARNINGS, PRECAUTIONS, AND CONTRAINDICATIONS

ASR Systems' Instructions for Use are provided to help support the safe and effective reprocessing of the TITAN CSR® Lighted Retractor Blade by healthcare professionals in a healthcare facility.

ASR Systems' TITAN CSR® Lighted Retractor Blade is delivered to the healthcare facility as a non-sterile item that must be inspected, cleaned, and sterilized prior to use. ASR Systems has validated the cleaning and sterilization procedures demonstrating the TITAN CSR® Lighted Retractor Blade can be safely used as intended. These instructions are based on the validation testing conducted by an accredited GLP microbiology lab. Healthcare professionals must take responsibility to ensure appropriate equipment & materials are used to reprocess the TITAN CSR® Lighted Retractor Blade. Healthcare professionals must provide adequate training to staff using or reprocessing the TITAN CSR® Lighted Retractor Blade. If a healthcare professional deviates from ASR Systems' instructions, it is the healthcare facility's responsibility to verify effectiveness of the reprocessing procedure.

Inspection

Inspect the TITAN CSR® Lighted Retractor Blade before and after each use to detect wear, tear, or imperfections. Set aside any damaged or deformed part, do not use, and contact ASR Systems for further instructions. Should you have concerns regarding the operation of the TITAN CSR® Lighted Retractor Blade's proper function, please contact ASR Systems to discuss.

Warnings And Precautions

The following Warnings and Precautions should be reviewed prior to the use of this device:

TITAN CSR® LIGHTED RETRACTOR BLADE

The TITAN CSR® Lighted Retractor Blade is supplied non-sterile

The TITAN CSR® Lighted Retractor Blade must be inspected, cleaned, and sterilized prior to each use, including the initial use. The TITAN CSR® Lighted Retractor Blade 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® Lighted Retractor Blade.

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: Healthcare professionals should read and become familiar with the product materials prior to using this system.

1. The TITAN CSR® Lighted Retractor Blade is an Rx Only medical device and should only be handled and used by healthcare professionals with required training, knowledge, and experience.
2. The healthcare 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. Healthcare professionals 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® Lighted Retractor Blade.
7. U.S. Federal Law restricts this device to sale to or on the order of a physician. Use of the TITAN CSR® Lighted Retractor Blade for any purpose other than their intended use, is not recommended and could result in serious injury or death.

TITAN CSR® BLADE LIGHT/ROVER® SLS - PRODUCT WARNINGS & PRECAUTIONS

NOTE: *This device is provided sterile using the Ethylene Oxide sterilization method.*

The following Warnings and Precautions should be reviewed prior to the use of this device:

- Never dispose of the device while powered on; allow time for device to turn off and cool down before disposal.
- Battery powered equipment is considered unsuitable for use in the presence of flammable anesthetics and/or oxygen rich environments.
- Federal law restricts this device to sale by or on the order of a licensed practitioner.
- Handle damaged or leaking batteries with care.
- Do not modify the device in any manner. Avoid looking directly at the LED beam or pointing it directly at anyone's eyes. The LED can momentarily disorient a person and/or can cause lingering ghost images.
- The device may become warm to the touch and should be monitored during use. **DO NOT** operate unattended.
- If battery removal is necessary for proper disposal, **DO NOT** touch the internal circuit board as it may be hot after use.
- Avoid exposure to liquids. This may cause the device to malfunction.

- Light will turn completely off in device after approximately 1.5 hours of continuous use.
- Dispose of battery and device according to local regulations.

DO NOT ATTEMPT TO STERILIZE OR RESTERILIZE THIS DEVICE IN ANY MANNER.

Storage Temperature: 50°F – 104°F (10°C - 40°C)

Relative Humidity: 0 - 90%

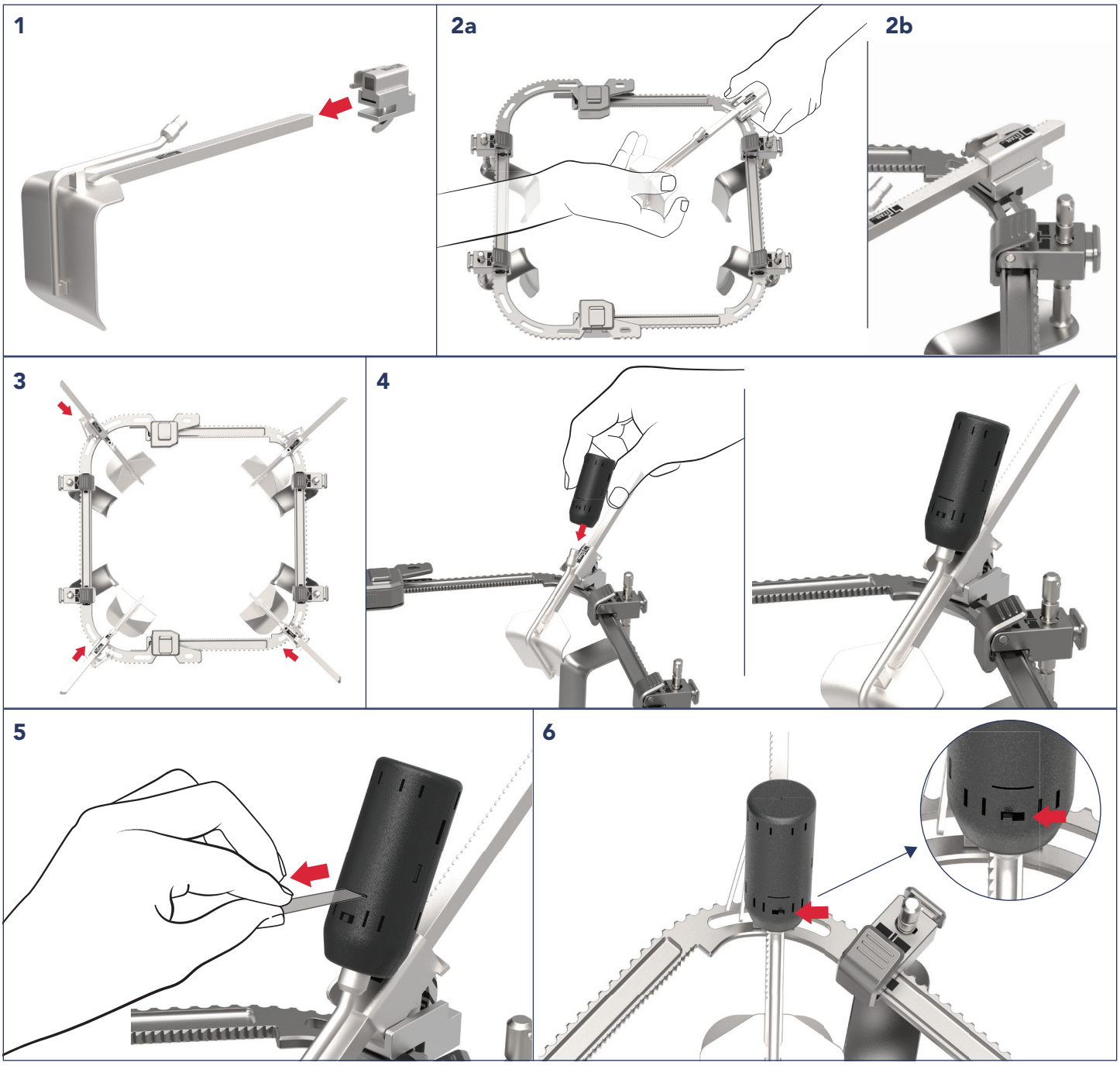
If using components from other retractor kits, follow manufacturer's instruction for use and warnings.

Contraindications

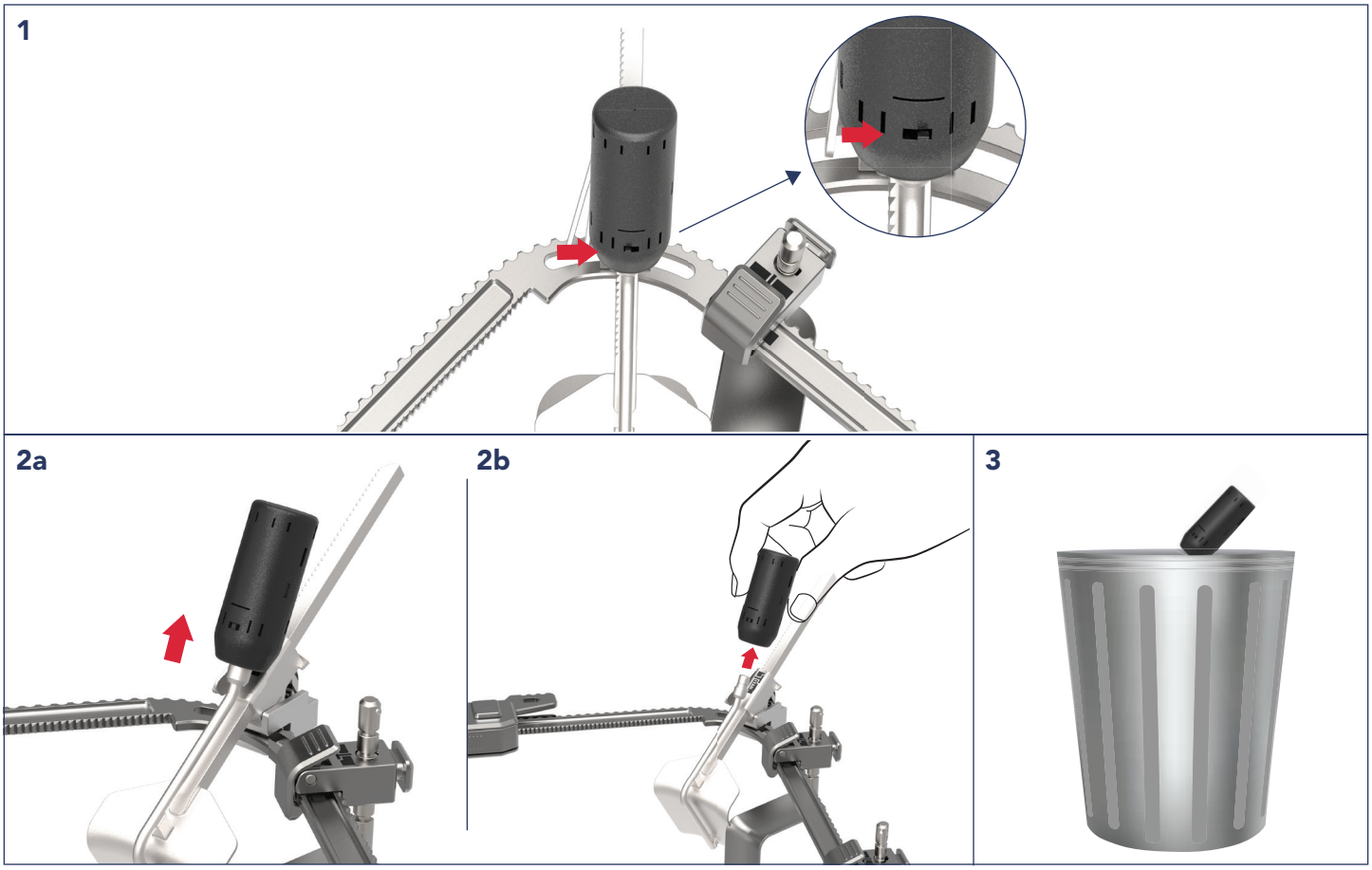
None known.

ASSEMBLY/DISASSEMBLY INSTRUCTIONS

Assembly Instructions



Disassembly Instructions



CLEANING AND STERILIZATION

TITAN CSR® Lighted Retractor Blade

The TITAN CSR® Lighted Retractor Blade is made of stainless steel. We recommend that the facility use the procedures below for cleaning and sterilization of the TITAN CSR® Lighted Retractor Blade unless your facility uses other protocols for stainless-steel surgical retractors.

Do not clean, sterilize, or re-use disposable TITAN CSR® Blade Light or Rover SLS

Point of Use Gross Decontamination

Ensure any connected light source is removed from the TITAN CSR® Lighted Retractor Blade and disposed of in accordance with facility's protocol and local regulations.

Remove the ratchet from the TITAN CSR® Lighted Retractor Blade stem.

Wipe the TITAN CSR® Lighted Retractor Blade with a disposable wipe until the TITAN CSR® Lighted Retractor Blade is free of any visible traces of blood, tissue, body fluids, and debris after use. Do not allow blood, tissue, body fluids, and debris to dry on the TITAN CSR® retractor.

Transportation

To prevent risk of cross contamination, place the TITAN CSR® Lighted Retractor 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

The TITAN CSR® Lighted Retractor Blade cleaning was validated with an enzymatic detergent soak for 20 minutes. Prepare soaking solution and soak the TITAN CSR® Lighted Retractor Blade according to detergent manufacturer's instructions. Inspect the TITAN CSR® Lighted Retractor Blade 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 in any crevice. Remove the TITAN CSR® Lighted Retractor Blade 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® Lighted Retractor Blade. Verify healthcare facility's use of precleaning detergent using manufacturer's instructions.

Automated Wash in Washer/Disinfector

Place the disassembled TITAN CSR® Lighted Retractor Blade in a washer tray. Put the washer tray with the TITAN CSR® Lighted Retractor Blade with other retractor parts, if desired, in a validated automated washer/disinfector using manufacturer's instruction for proper instrument loading. Use the automated washer/

disinfector manufacturer's instructions to select a wash cycle that minimally includes a pre-rinse; 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® Lighted Retractor Blade 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 healthcare 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® Lighted Retractor Blade with a clean non-lint cloth as necessary. Inspect the TITAN CSR® Lighted Retractor Blade for any visible signs of blood, tissue, body fluids, and debris. If the TITAN CSR® Lighted Retractor Blade does not pass visual inspection, return to the decontamination area for cleaning.

Inspect the TITAN CSR® Lighted Retractor Blade to detect wear, tear, or imperfections. Do not use any damaged parts, set them aside and contact ASR Systems for further instructions.

- Examine the scope shaft for any dents in the light fiber tube.
- Inspect the light input and output surfaces of the light tube for any damage
- Hold light tube to a light and ensure light is transmitted through the light fiber tube and that there is less than 30% of the light fibers with black spots which could be a sign of damaged light fibers.

Lubrication

Prior to sterilization, the TITAN CSR® Surgical Retractor's Lighted Retractor Blade 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® Lighted Retractor Blade. Please follow lubricant manufacturer's instructions for use.

Packaging

TITAN CSR® Lighted Retractor Blade was validated in a 510(k) cleared sterilization container. The TITAN CSR® retractor should be packaged in an FDA cleared sterile barrier system. The healthcare facility should refer to sterile barrier system manufacturer's instructions and verify similar results. The TITAN CSR® Lighted Retractor Blade was validated for sterilization in an appropriately sized, FDA cleared sterilization container disassembled from the ratchet.

Sterilization

Load the TITAN CSR® Lighted Retractor Blade in a validated steam sterilizer using the manufacturer's instructions for proper loading and operation. The TITAN CSR® Lighted Retractor Blade has been validated for sterilization in an appropriately sized, FDA cleared sterilization container disassembled from the ratchet:

- 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® Lighted Retractor Blade 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

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Suite 108 - 469
San Antonio, TX 78231

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

TITAN CSR®

TITAN CSR® Retractor System
Literature and Videos

ASR® SYSTEMS
ADVANCED SURGICAL RETRACTOR SYSTEMS, INC.

Part # TSR-106-415SS - DI # G254TSR106100