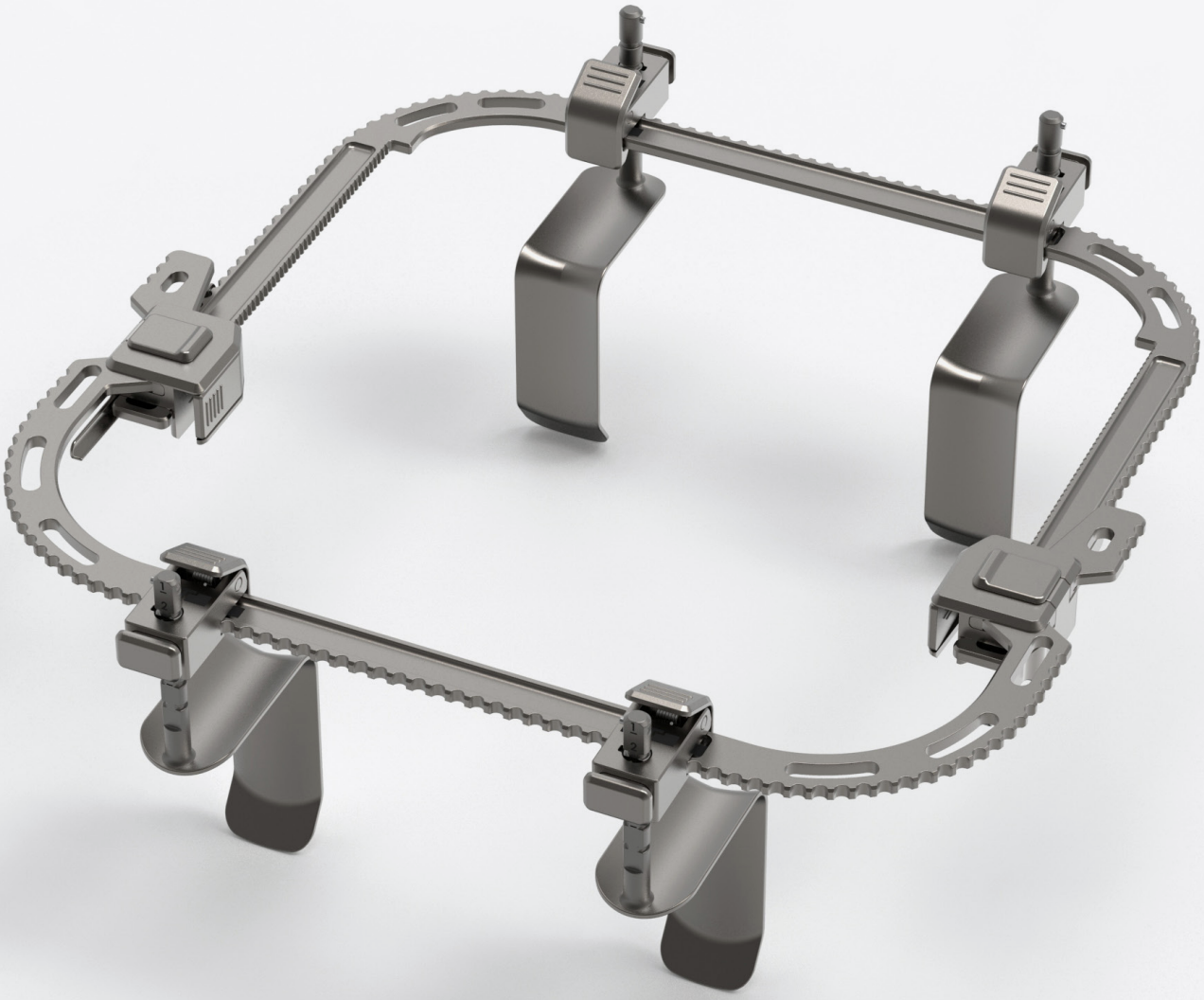
TITAN CSR™

INSTRUCTIONS FOR USE



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ASR SYSTEMS
ADVANCED SURGICAL RETRACTOR SYSTEMS, INC.

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TITAN CSR™ DESCRIPTION, INTENDED USE AND PART NUMBERS

Description

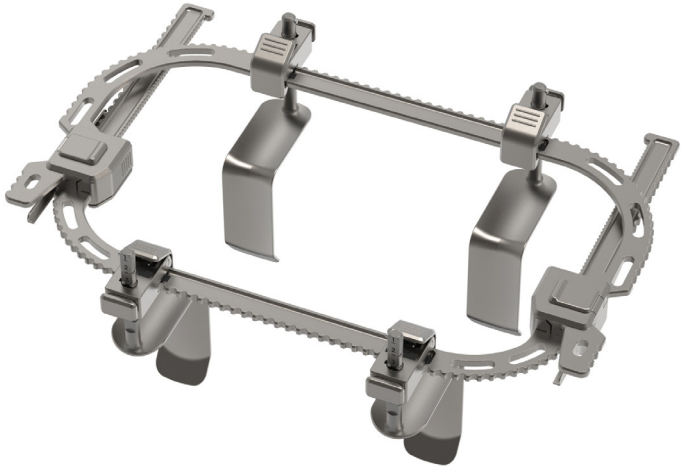
The TITAN CSR™ self-retaining retractor system is a latex-free, reusable system designed to provide access and exposure for surgical procedures.

Intended Use

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

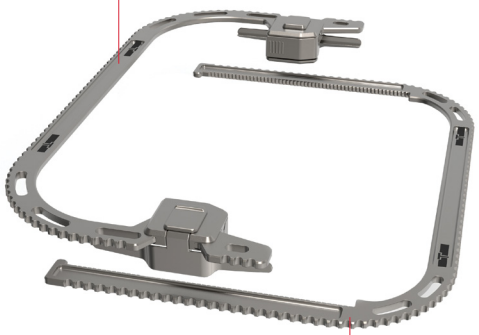
Part Numbers

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*

TSR-106-110



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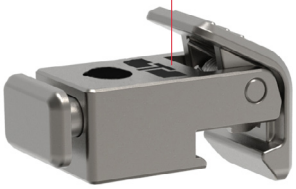
TSR-106-210



TSR-106-310

INSPECTION, WARNINGS AND PRECAUTIONS, AND CONTRAINDICATIONS

Inspection

Inspect the TITAN CSR™ parts before and after each use to detect wear, tear, or imperfections, if any. Should you have concerns regarding the operation of the TITAN CSR's proper function, please contact ASR Systems to discuss the device issue. Set aside any damaged parts and contact ASR Systems for further instructions.

Warnings And Precautions

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

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

Personal Protective Equipment (PPE): PPE should be worn, per individual hospital protocol, when handling or working with a contaminated (or potentially contaminated) TITAN CSR.

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 hospital protocol for any cross contamination issues.

Medical professionals using this system should be familiar with all product support materials to perform procedures with this system before use.

1. Many variables such as patient anatomy, pathology, and surgical techniques may influence the procedure's outcome. Patient, product, and procedure selection is the responsibility of the medical professional.
2. Only use as much retraction as necessary to provide adequate exposure and access to the needed area.
3. Retractor blades may compress nerves. User must evaluate the need to use free running EMG to monitor events such as retractor nerve compression outside of the visual field.
4. It is important to realize that a great amount of force can be exerted on the wound edges and on tissues that are retracted with this retractor system. Release the retractor for short periods of time or shift the blades to avoid having unrelieved pressure on any one point for more than two hours.
5. As with any self-retaining retractor, caution should be taken not to exert undue retraction pressure on the iliopsoas muscle to prevent possible femoral nerve palsy.
6. Product should be inspected before each use according to this IFU. Do not use products that show signs of damage such as cracking, deformation, or sharp edges.

7. Use of the TITAN CSR self-retaining retractor for any purpose other than what is described herein, is not recommended and may cause damage or failure of the device which could result in serious patient injury or death.
8. If using electrosurgical equipment while using the TITAN CSR, consult the manufacturer's instructions for use.
9. U.S. Federal Law restricts this device to sale to or on the order of a physician.

If using components from other retractor kits, follow instructions for use and warnings provided by those manufacturers.

Contraindications:

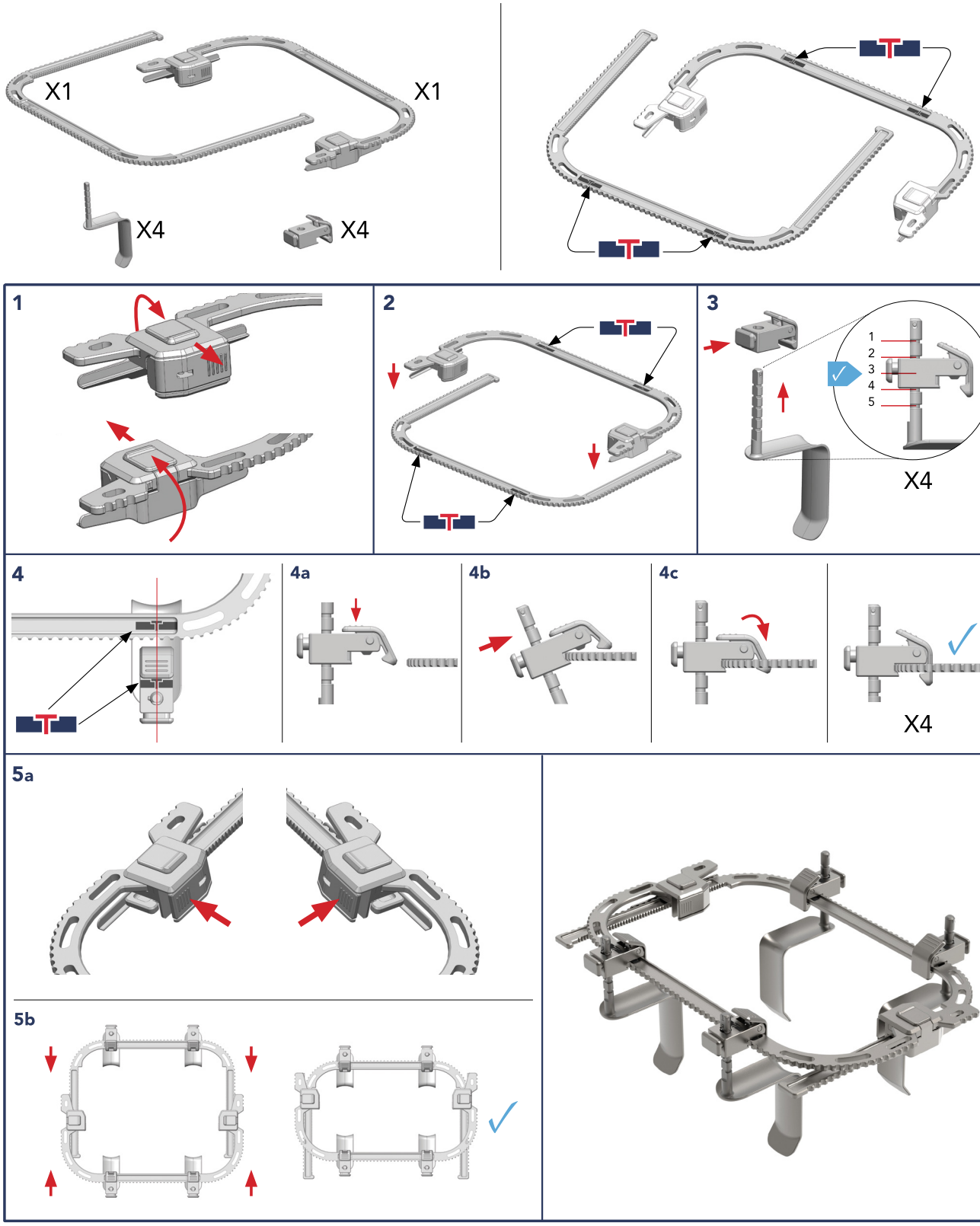
None known

NON STERILE

Rx only

ASSEMBLY/DISASSEMBLY INSTRUCTIONS

Assembly Instructions



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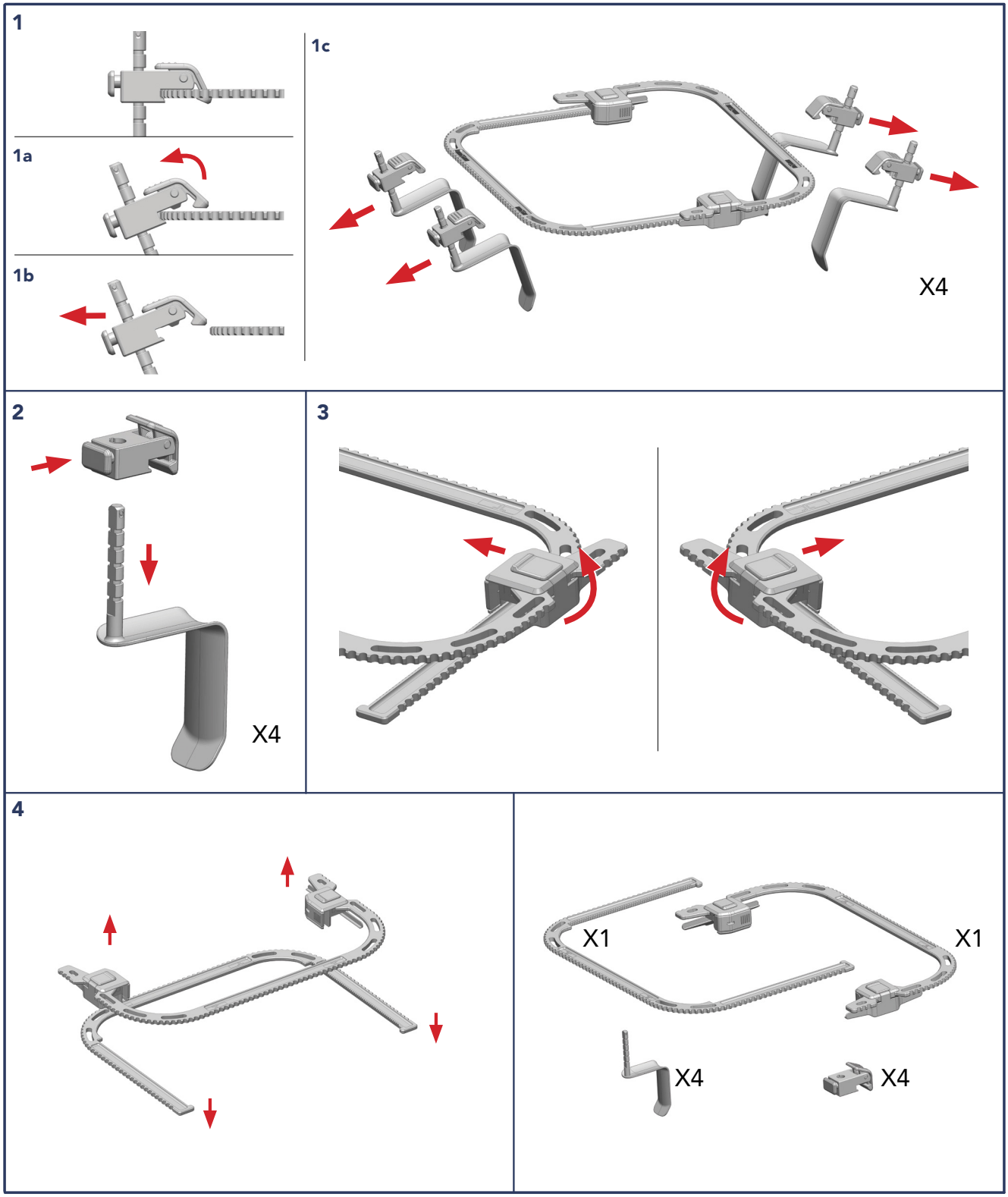
Disassembly Instructions:



TITAN CSR™ is compatible with Bookwalter® retractor components except for oval, round, and segmented rings.

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CLEANING AND STERILIZATION

Cleaning

Disassemble the device and scrub the parts thoroughly using a medium to firm brush and an enzymatic detergent. Remove all traces of blood and debris. Make sure all moveable parts are cleaned thoroughly to prevent debris from interfering with movement. It is recommended that the parts be ultrasonically cleaned prior to washing in a washer disinfector.

It is recommended that the end user validate the cleaning procedure before use of this device.

Sterilization

The device parts may be steam sterilized. Refer to the sterilizer manufacturer's instructions for correct times, temperatures, and pressure settings.

It is recommended that the end user validate the sterilization procedure before use of this device.

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 AND REPAIR

Send all parts for service or repair to:

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

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