Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Disimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will form corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. 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POSSIBLE ADVERSE EFFECTS
1. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including radiculopathy, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Vascular damage could result in catastrophic or fatal bleeding. Mal-positioned implants adjacent to large arteries or veins could erode those vessels and cause catastrophic bleeding in the late postoperative period.
9. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
11. Paralysis.
12. Esophageal perforation, erosion or irritation.
13. Screw back-out, possibly leading to esophageal erosion, implant loosening, and/or reoperation for device removal.
14. Damage to lymphatic vessels and/or lymphatic fluid exudation.
15. Spinal cord impingement or damage.
16. Fracture of bony structures.
17. Degenerative changes or instability in segments adjacent to fused vertebral levels.
18. Death.

CLEANING OF INSTRUMENTS:
Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If correct hand must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Disassemble instruments with re-movable parts. Methods of cleaning VANCOGH™ re-useable instruments are provided in these instructions, a manual method and a method using an automated washer disinfector. Whenever possible the automated method should be used. The automated cleaning process is more reproducible and, therefore, more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used. Whichever method is used, staff should use suitable protective clothing and equipment at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product. The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient. CTL Medical does not recommend any specific cleaning and/or disinfection agent. For cleaning or disinfecting reusable instruments, only specifically formulated cleaning agents and/or disinfectants should be used. Do not alter the concentrations specified by the detergent manufacturer. The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing reusable instruments should be carefully considered. Application of freshly pre-purred purified water/highly purified water or sterile water for rinsing purposes with less than 100 cfu/ml and Minerals residues from hard water, as well as higher contamination with microorganisms and endotoxins, can result in failure of the device or prevent effective cleaning and decontamination.

Cleaning and Decontamination
• All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field.
• CAUTION: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
• Implants removed from a patient or that contact bodily fluids or fluids should never be reused.
• In a clean metal pan, prepare an enzymatic detergent bath according to the detergent manufacturer’s instructions.
• Allow the devices to soak in enzymatic detergent bath for 20 minutes.
• While in detergent bath, using a soft bristled brush, gently clean the devices, paying attention to pivots, threads, recesses, crevices, cannnulas and other difficult to clean areas, until all visible debris is removed.
• Remove the devices from the enzymatic detergent bath and rinse with tap water for a minimum of 1 minute.
• Prepare an enzymatic detergent bath in a sonicator.
• Ultrasonically clean the individual devices in the enzymatic bath for ten (10) minutes.
• Remove from sonicator and rinse the devices in DI water for a minimum of 1 minute.
• Using a clean, soft cloth, dry the devices.
• Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
• Verify that the instruments are in operation condition. Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and they must not be used.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Cleaning Instructions:
Point of Use
• Remove excess body fluids and tissue from instruments with a disinfectant suitable for cleaning/sterilization.
• Place devices in a tray of distilled water or cover with damp towels.
• Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
• Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning
• Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
• Where applicable, multi-use re-usable instruments should be disassembled for appropriate cleaning.
• Disassembly, where necessary is generally self-evident.
• Care should be exercised to avoid losing small screws and components.
• All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
• Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloodied and/or turbid).

Cleaning/Disinfection Options:
2. Combination Manual/Automated - Enzymatic soak and scrub followed by an automated washer/disinfector cycle.
3. Automated cycle - Not recommended without manual pre-cleaning.

Manual Cleaning Steps:
1. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Scrub using a soft-bristled brush to gently clean the device until all visible soil has been removed. Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the device from the enzyme solution and rinse in purified water for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in a sonication unit.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Combination Manual/Automated Cleaning Steps:
1. Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush.
2. Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector instrument cycle.
4. Rinse 3 times using tap water for 30 seconds after wash using the enzymatic detergent in the ultrasound cleaner at 35-45°C for 3 minutes.
5. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45°C.
6. Dry at 100°C (±5°C) for 30 minutes.

Note: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

CLEANING AND STERILIZATION
Implants are supplied non-sterile and are for single use only. So all implants used in surgery must be sterilized by the hospital prior to use. Otherwise, instruments are supplied non-sterile and may be re-used. Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Unless just removed from an unopened CTL Medical package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to CTL Medical.

STORAGE AND HANDLING
CTL Medical VANCOGH™ Anterior Cervical Plate System should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

manual cleaning steps:
1. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Scrub using a soft-bristled brush to gently clean the device until all visible soil has been removed. Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the device from the enzyme solution and rinse in purified water for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in a sonication unit.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat the sonication and rinse steps above.
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Combination Manual/Automated Cleaning Steps:
1. Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush.
2. Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
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6. Dry at 100°C (±5°C) for 30 minutes.

Note: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.
INSPECTION
1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage.
   Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your CTL Medical representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your CTL Medical representative for a replacement.

CAUTION:
• Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
• Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
• Verify that the instruments are in operation condition.

Sterilization
All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Sterilization: recommended method to achieve a degree of sterility equal to at least 10⁻⁶. The gravity displacement sterilization parameters we suggested comply with AAMI ST79. CTL Medical recommends the following parameters:

<table>
<thead>
<tr>
<th>METHOD</th>
<th>Steam</th>
<th>Steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Gravity Pre-Vacuum</td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>132°C (270°F)</td>
<td>132°C (270°F)</td>
</tr>
<tr>
<td>Exposure</td>
<td>15 minutes</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Dry time</td>
<td>45 minutes*</td>
<td>45 minutes*</td>
</tr>
</tbody>
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(15 Min Open Door Time + 30 Min Cool-Down Time)

It is important to note that an FDA-cleared sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility. Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be resterilized. Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical implants and instruments.

PRODUCT COMPLAINTS
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or CTL Medical. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any CTL Medical product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence.

When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION
Recommended directions for use or surgical technique manual of this system are available at no charge upon request. If further information is needed or required, please contact CTL Medical.