



#### CERVICAL SPINE TRUSS SYSTEM - STAND ALONE (CSTS-SA) INTERBODY FUSION DEVICE

#### INSTRUCTIONS FOR USE (ENGLISH)

#### PLEASE READ CAREFULLY

#### CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.

#### INTENDED USE:

The Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device is designed to provide mechanical support to the cervical spine while biologic fusion takes place.

#### DEVICE DESCRIPTION:

The device is an open architecture device design mathematically formulated to provide structural support with open space through the implant for bone growth and fusion. The 4WEB additive manufacturing process provides a hierarchical surface topology. The implant is made from Ti6Al4V alloy. The device is available in a variety of sizes and indications available to accommodate the patient's anatomy. Screws are inserted through the anterior portion of the implant and secured with washers and nuts for bony fusion.

#### INDICATIONS FOR USE:

The Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level or two contiguous disc levels with a minimum of 10mm of disc height. The device is designed for use in minimally invasive minimally disruptive and minimally disruptive minimally disruptive procedures. For use of this product outside the United States, consult WHO and local regulations for further information.

#### CONTRAINDICATIONS:

The CSTS-SA Interbody Fusion Device should not be implanted in patients with:

- An active infection of the operative site or other active systemic infections
- Tumor involvement at the operative site
- Phor fusion at the level(s) to be treated
- Known sensitivity to the material

#### WARNINGS AND PRECAUTIONS:

Safety and effectiveness have not been established in the following conditions:

- Gross obesity
- Severe osteoporosis
- Three or more levels to be fused
- Symptomatic cardiac disease
- Aspleny
- Previous fusion attempts at the involved level(s)
- Spondyloarthrosis or osteoarthritis in the vertebral bodies
- Significant loss of bone stock as seen with osteoporosis or osteostomia
- Conditions requiring chronic corticosteroid use
- Other conditions as determined by the physician

The CSTS-SA Interbody Fusion Device is for single use only.

Breaking or fracture of the implants or instruments can occur if not handled properly.

All sizes and instruments are provided non-sterile and must be steam sterilized prior to use. The 4WEB Spine Truss System instruments are intended to be used together with the 4WEB Spine Truss System instrumentation during spinal fusion instrumentation.

No implant should be reused if it has come in contact with blood or other bodily fluids.

All implants, sizes and instrumentation should be inspected prior to use for possible damage or defects. Any damaged or defective instruments should be discarded and should be returned to 4WEB.

Interbody Fusion Devices are intended to provide mechanical support while biologic fusion occurs. In the event of pseudoarthrosis or delayed fusion, the risk of implant migration, loosening or breakage increases. The physician/surgeon should consider the risks of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.

Only surgeons trained in cervical spine fusion procedures should implant this device.

For disposal of a product that has come in contact with body fluids, follow standard hospital procedures for disposing of biologically hazardous material. For disposal of a product that has not been in contact with body fluids, follow procedures for removal of hospital waste in force within the institution.

#### OPERATIVE PRECAUTIONS:

The surgeon is to be thoroughly familiar with the CSTS-SA Interbody Fusion Device, methods of application, instruments and surgical technique. Correct positioning of the CSTS-SA Interbody Fusion Device relative to the vertebral body should be checked intraoperatively with the use of a more particularly (weight) of the CSTS-SA Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction. Implantation of the CSTS-SA Interbody Fusion Device must be used in accordance with the instructions provided in this manual.

Each CSTS-SA Interbody Fusion Device is to be filled with autologous and/or allograft bone to promote bone fusion (See Surgical Technique for complete details). The implants are for single-implant use only. An explant implant must never be re-implanted. Stresses and fracture, even though not noticeable by visual inspection, may have been created during initial implantation.

Upon implantation, the product number and manufacturing lot number of the device that has been implanted must be recorded in the patient's surgical file.

#### POTENTIAL ADVERSE EVENTS:

Potential adverse events may be related to surgery in general, spine surgery specifically or the device. These may include, but are not limited to the following:

- Complications associated to anesthesia, the anesthetic or other medications: bleeding, infection, ileus, blood vessel damage, nerve or soft tissue damage, atelectasis, pneumonia, hematoma, seroma, wound dehiscence or incisional hernia, urticaria, pruritus, embolism; anemia, colitis, thrombophlebitis, hair attack, stroke, or death.
- Adverse events related specifically to surgery: Atrial tear and CSF leak, nerve damage leading to radiculopathy, myelopathy, paraparesis, parasthesia or paralysis, meningitis, vertebral body damage or fracture, ligament damage, retrograde sacrum, or retrograde disc.
- Adverse events related to the device: implant crack or fracture, failure to achieve fusion, implant migration, dislodgement, or metal stentility to a foreign body, implant causing possible tumor formation. Additional surgery may be necessary for implant removal, repositioning or replacement at the implantation site. Additional surgery or surgery at another disc level may be necessary if non-union or anatomic change at an adjacent level develops.

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#### POSTOPERATIVE CARE:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are described in detail in the patient's instruction manual.

Detailed instructions for use and limitations of the device must be given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive activity and return to sports.

The patient must be advised not to smoke or consume alcohol during period of the bone fusion process.

Patients must be advised to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

It is critical that immobilization of urine is established and confirmed by roentgenographic examination. If a non-voiding status or if the components loosen, migrate, and/ or break, the devices must be revised and / or removed immediately before serious injury occurs.

\* Any retrieved devices are not to be used in another surgical procedure.

#### MRI SAFETY INFORMATION:

The following information is illustrated the CSTS-SA Interbody Fusion Device is MR Conditional. A patient with this device can be safely scanned in an MRI system meeting the following conditions:

- Staic magnetic field of 1 or 1.5 T
- Maximum spatial field gradient of 1900 Gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the CSTS-SA Interbody Fusion Device produces a maximum temperature rise of no more than 1.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact gradient by the device extends approximately 28 mm from the CSTS-SA Interbody Fusion Device. The condition for MRI safety is that the MRI system is set to the following conditions:

- Maximum SAR of 1.5 W/kg
- Maximum spatial field gradient of 1900 Gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

#### PACKAGING:

CSTS-SA Interbody Fusion Device is provided sterile and is clearly labeled as such in an unopened sterile package provided by 4WEB. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised.

#### Implants supplied sterilized from 4WEB must not be re-sterilized.

CSTS-SA ancillary instrumentation is provided non-sterile and is supplied in a tray that is used for steam sterilization prior to use in the operating room. In the case of instrument restock, auxiliary items will be sent in a plastic bag, labeled for that device.

Storage conditions must maintain the integrity of the implants, associated ancillary instruments and their respective packaging. The condition for use of the implants and instruments must be checked before use. Damaged products must not be used and should be returned to 4WEB.

#### INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS:

CAUTION: THESE INSTRUCTIONS DO NOT APPLY TO SINGLE-USE DEVICES.

The instruments used to implant the CSTS-SA Interbody Fusion Device do not have an indefinite functional life. All reusable instruments are subjected to repeated sterilization and cleaning cycles. The cleaning, rinsing, and sterilization processes. Instruments should be carefully inspected before use to ensure that they are fully functional.

All ancillary instruments of the CSTS-SA Interbody Fusion Device are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use. Decontamination reduces the population of microorganisms and prevents the subsequent cleaning stage. Strict compliance with the instructions concerning the packaging, cleaning and cleaning is mandatory, particularly the concentration and exposure time requirements. Thorough rinsing with water must be conducted following decontamination and cleaning.

\* Decontamination: Each hospital must use their own validated decontamination procedures. The decontamination procedure is equivalent to the instructions in ANSI Z379.1 and ISO 15883-1 compliant washing machine with the appropriate cleaning products, rinsing and dry. Any product which may alter the material is prohibited. I.e. bleach, formalin, hypochlorite solutions, saline solution, etc.

The reprocessing instructions provided have been validated as being capable of preparing reusable 4WEB instruments. It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and persons to achieve the desired results. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

#### WARNINGS:

Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equip-

ment.

- Do not exceed 140° C (284° F) during processing steps.

- Highly alkaline conditions can damage products with aluminum parts.
- Avoid exposure to hypochlorite solutions to prevent corrosion. Hypochlorite solutions will promote corrosion.
- Scrapes or dents can result in breakage.
- For instruments produced by another manufacturer, reference the manufacturer's instructions for use.
- Care should be taken to remove any debris, tissue or frame fragments that may collect on the instrument.

#### LIMITATIONS ON REPROCESSING:

- End of useful life is generally determined by wear or damage in surgical use.
- Use of reprocessed instruments between users to verify proper functioning and configuration.
- Damaged instruments must be replaced to prevent potential patient injury such as loss of metal fragments into the surgical site.

#### DECONTAMINATION CONSIDERATIONS – CREUTZFELDT-JAKOB DISEASE (CJD):

- Under certain classifications of risk, the World Health Organization (WHO) or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation procedures. For use of this product outside the United States, consult WHO and local regulations for further information.

#### REPROCESSING INSTRUCTIONS

#### CARE AT THE POINT OF USE:

- Use purified water obtained via ultra-filtration, RO, DI and/or distilled.
- Thoroughly clean instruments for 5 minutes as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible pH neutral detergent solution and purified water to prevent drying and encrustation of surgical steel.
- Avoid prolonged exposure to saline to minimize the chance of corrosion.
- Remove excessive sputal with a disposable low lint wipe.

#### CLEANING:

- All INSTRUMENTS
- No instruments provided with the CSTS-SA Interbody Fusion Device require disassembly prior to cleaning.
- Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions (1oz Enzol, or equivalent, per gallon of purified water). **Note:** the enzyme solution must be changed on a regular basis.
- Soak loaded instruments for 5 minutes in the enzymatic solution.

- Use a soft bristle brush to remove all traces of blood and debris, pay close attention to any hard-to-reach areas, tired surfaces, grooves, or crevices.
- Rinse the instrument thoroughly with purified water.
- Dry the instrument immediately after rinsing.

- When using the 4WEB instrument, a validated washer disinfectant and a pH neutral cleaning agent intended for use in an automated cleaner. The cleaning cycle should incorporate enzymatic pre-wash, wash, rinse, thermal rinse, and drying steps.
- Place heavier instruments on the bottom of containers. Do not place heavy instruments on top of delicate instruments.

- For instruments with concave surfaces, such as currettes, place instrument with the concave surface facing downward to facilitate draining.

#### CLEANING INSTRUMENTS:

Inspect all instruments to verify that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process.

#### MAINTENANCE INSPECTION AND ANNUAL TESTING:

- Visually inspect all instruments to ensure no bending and wear.
- Ensure there are no cracked handles and/or connection casettes) that are visible in handles.
- Ensure long instruments are free of any damage and distortion.
- Ensure instrument tips are free of defects or burrs.
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#### WRAPPING:

CSTS-SA Interbody Fusion Device is for single use only.

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**OPERATIVE PRECAUTIONS:**

- The surgeon is to be thoroughly familiar with the CSTS-SA Interbody Fusion Device, methods of application, instruments and surgical technique. Correct positioning of the CSTS-SA Interbody Fusion Device relative to the vertebral body should be checked intraoperatively with the use of a more particularly (weight) of the CSTS-SA Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction. Implantation of the CSTS-SA Interbody Fusion Device must be used in accordance with the instructions provided in this manual.

#### STERILIZATION:

Effective steam sterilization can be achieved using the following cycle to achieve an SAL of 10<sup>-6</sup>:

| Cycle     | Temperature     | Duration | Dry Time |
|-----------|-----------------|----------|----------|
| Gravity   | 121° C (250° F) | 30 min   | 45 min   |
| Prevacuum | 132° C (270° F) | 4 min    | 45 min   |
| Prevacuum | 134° C (273° F) | 3 min    | 45 min   |

\* The Prevacuum 134° C Sterilization Cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use any sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the cycle specifications (time and temperature).

#### NOTE: STERILIZATION DOES NOT REPLACE DECONTAMINATION OR CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

#### PRODUCT COMPLAINTS:

















Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction with the product should contact the manufacturer. If the complaint concerns a 4WEB product, please notify 4WEB, or, where applicable, their distributor, and the competent authority of the Member State in which the user and/or patient is established.

#### SURGICAL TECHNIQUE MANUAL:

To receive additional copies of the Surgical Technique Manual (ST-CSTS-SA-01), contact your local sales representative or contact us at the following address:

|  |   |  |
|--|---|--|
| <b>USA:</b><br>4WEB Medical<br>2801 Network Blvd., Suite 620<br>Frisco, TX USA 75034<br>T +1(800) 285-7090<br>F +1(972) 488-1816 | <b>OUTSIDE USA:</b><br>4WEB EU BV<br>Industrieweg 13b<br>1564JN Assendelft, The Netherlands<br>T +31 20 708 45 45<br>F +31 20 708 45 45 |  0344 |
|--|---|--|

|  |  |  |  |
|--|--|--|--|
| <b>Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied.</b> |  |  |  |
|--|--|--|--|

| Symbol  | Ref. Number    | Title                         | Description of Symbol   |
|---|----------------|-------------------------------|---|
|  | 5.4.4          | Caution                       | Indicates the need for user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
|  | 5.4.2          | Do not re-use                 | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.  |
|  | 5.4.3          | Consult instructions for use  | Indicates the need for user to consult the instructions for use.  |
|  | 5.1.5          | Lot number                    | Indicates the manufacturer's lot number so that a specific medical device can be identified.  |
|  | 5.1.6          | Catalog number                | Indicates the manufacturer's catalog number so that the medical device can be identified.   |
|  | 5.1.1          | Manufacturer                  | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42 EEC, and 98/79 EC.   |
|  | 5.1.3          | Date of manufacture           | Indicates the date when the medical device was manufactured.  |
|  | 5.1.4          | Use-by date                   | Indicates the date after which the medical device is not to be used.  |
|  | 5.2.4          | Sterile                       | Sterilized using irradiation. Indicates a medical device that has been sterilized using irradiation.  |
|  | 5.2.6          | Do not resterilize            | Indicates a medical device that is not to be resterilized.  |
|  | 5.2.8          | Do not use if damaged         | Indicates a medical device that should not be used if the package has been damaged or opened.   |
|  | 5.2.12         | Double Sterile Barrier System | Indicates two sterile barrier systems.  |
|  | 5.7.7          | Medical Device                | Indicates the item is a medical device.   |
|  | 5.7.10         | Unique Device Identifier      | Indicates a carrier that contains unique device identifier information.   |
|  | 5.7.13         | MR Conditional                | Medical device that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.  |
|  | 21 CFR 801.109 | Prescription only             | Requires prescription in the United States.   |

#### 4WEB MEDICAL (GERMAN)

**HALSWIRBELSÄULEN-VERBINDUNGSSYSTEM – EIGENSTÄNDLICH (CSTS-SA) GERÄT FÜR HALSWIRBELKÖRPERFUSIONEN**

- Produkte mit Aluminiumteilen können unter stark alkalischen Bedingungen beschädigt werden.
- Vermeiden Sie die Exposition gegenüber Hydrochloridsäuren, die dazu Korrosion fördern.
- Kratzer oder Dellen können zu Brüchen führen.
- Wenden Sie Instrumente eines anderen Herstellers nie verwenden, lesen Sie die Gebrauchsanweisung des Herstellers.
- Bei der Entfernung jeglicher Ablagerungen, Gewebe oder Knocherfragmente, die sich auf dem Instrument angesammelt haben, mit Vorsicht umzugehen.

#### WICHTIGENHINWEISE – BITTE SORGFÄLTIG LESEN

#### ANWENDUNG: GEMÄSS DER RUNDVERSCHÜBZUGEBUNG DER USA DÜRFEN DIESE PRODUKTE NUR AN ÄRZTE ODER AUF DEREN ANWEISUNG VERWENDET WERDEN

#### VERWENDUNGSSZUKAUF:

Das Halswirbelsäulen-Verbindungssystem – Eigenständiges (CSTS-SA) Gerät für Halswirbelkörperfusionen ist darauf ausgelegt, die Halswirbelsäule mechanisch zu unterstützen, während gleichzeitig eine biologische Fusion stattfindet.

#### BESCHREIBUNG DES GERÄTS:

Das Gerät ist mathematisch formuliert, um eine Verbindungskonstruktion mit offener Architektur zur strukturellen Unterstützung durch ein vollständiges Gefüge für Knochenwachstum und -fusion. Das additive Herstellungsverfahren von 4WEB Spine Truss System (4WEB) ermöglicht die Herstellung von Instrumenten, die in verschiedenen Größen und unterschiedlichen Längenworken erhältlich, um der Anatomie des Patienten zu entsprechen. Die Schrauben werden für eine kinematische Verankerung durch den vorderen Teil des Implantats in die bearbeiteten Wirbelkörper eingesetzt.

#### ANWENDUNGSGEBIETE:

Das Halswirbelsäulen-Verbindungssystem – Eigenständiges (CSTS-SA) Gerät für Halswirbelkörperfusionen ist indiziert für den Einsatz bei:

- Therapie von bis zu 3 (dreieiniges) Wirbelsäulen- und einer degenerativen Bandscheibenverknüpfung (DDD) der Halswirbelsäule für eine Höhe von zwei angrenzenden Höhen und zwei Schrauben mit Trailführung zu verwenden, die dem Gerät beiliegen. DDD wird definiert als diskogener Rückenschmerz mit einer Degeneration der Bandscheibe, die durch die CTS-SA Interbody Fusion Device behandelt werden kann.
- Die CTS-SA Interbody Fusion Device wird als Ergänzung bei Fusionen der Halswirbelsäule verwendet und über einen anterioren Zugang in der Höhe C2 bis C7 eingesetzt werden kann.
- Die CTS-SA Interbody Fusion Device ist für ein- oder korpuskopspezifisch Knochentransplantat bestimt. Vor der Behandlung mit den Geräten sollten Patienten eine nichtoperative Behandlung über 4 Wochen erhalten haben.

**ANWENDUNGSSCHREITWEISE:**

- Die CTS-SA Interbody Fusion Device ist für die Überwachung der Leistung von Sterilisationsverfahren verwendet werden, sollten in unentwickelten Schulen in den mittleren Ständen platziert werden. Sie sollten gemäß den Anweisungen der Hersteller zu verwenden.
- Umwickeln Sie Instrumente gemäß lokalen Verfahren unter Anwendung von Standardwickeltechniken, wie den in ANSI/AAMI ST7 beschrieben, doppelt.
- Verwenden Sie nur ein für die DKA zugelassene Verpackung.
- Kenntnisse über den Inhalt der unentwickelten Schule müssen eines nicht behalteneren Markiers oder einem anderen, das die Anweisungen des Herstellers enthält, versehen sein.
- Lassen Sie zwischen der Instrumenterschale und der Innenseite des Behälterdeckels 2,5 cm Platz, um eine effektive Verankerung zu ermöglichen.

**KONTRADIKATIONEN:**

- Keines der mit dem CSTS-SA Gerät für Halswirbelkörperfusionen gelieferten Instrumente muss vor der Reinigung demontiert werden.
- Bereiten Sie eine enzymatische Reinigungslösung entsprechend den Anweisungen des Herstellers vor (2,5l mit Enzoz oder equivalent, pro Gallon gereinigtes Wasser). **Hinweis:** Enzyme sind Enzyme, die die enzymatische Lösung.
- Tauchen Sie verschmutzte Instrumente für 5 Minuten in die enzymatische Lösung.
- Verwenden Sie eine weiche Bürste, um alle Blut- und Ablagerungen sorgfältig zu entfernen; achten Sie insbesondere auf schwer erreichbare Stellen, strukturierte Oberflächen oder Spalten.
- Spülen Sie das Instrument gründlich mit gereinigtem Wasser.
- Reinigen Sie das Gerät unmittelbar nach der abschließenden Spülung ab.
- Führen Sie die Reinigung unter Verwendung des „INSTRUMENTE“-Zyklus auf einem validierten Reinigungs- und Desinfektionsprozess mit einem pH-neutralen Reinigungsmodell durch, das für die Verwendung der automatischen Reinigungs bestirmt ist. Der Reinigungszyklus sollte die Schritte enzymatisches Vorwaschen, Waschen, Abspülen und Trocknen umfassen.
- Platzieren Sie schwere Instrumente auf dem Boden der Behälter. Legen Sie schwere Instrumente nicht auf empfindliche Oberflächen.
- Legen Sie Instrumente mit konkaven Oberflächen, wie Küretten, mit der konkaven Seite nach unten, um das Abtrocknen zu erleichtern.

**WARNUNGEN UND VORSICHTSMASSNAHMEN:**

- Schwere Adipositas
- Diabetes mellitus
- Überwiegend mehr zu fusionaleren Höhen
- Symptomatische Herzkrankheit
- Schwergewicht
- Frühere Fusionenversuche an den betroffenen Höhen
- Spinalarthrose oder Osteoarthritis in den Wirbelkörpern
- Signifikanter Verlust von Knochenmasse, wie bei Osteoporose oder Osteomalazie
- Erkrankungen, die die chirurgische Anwendung eines Corticosteroids erfordern
- Aktiver Drogenmissbrauch

Das CSTS-SA Gerät für Halswirbelkörperfusionen ist für den einmaligen Gebrauch bestimmt.

Beim nicht ordnungsgemäßen Handhabung kann es zu Verbiegungen oder Brüchen der Implantate kommen.

Alle Size- und Instrumente werden unsteril geliefert und müssen vor der Verwendung dampfsterilisiert werden. Die Implantate sind für die Verwendung mit dem Instrumenten des Herstellers 4WEB Spine Truss Systems während Spindelzyklus-Entfernung bestimmt.

Implantate, die mit Blut oder anderen Körperflüssigkeiten in Kontakt gekommen sind, dürfen nicht wiederverwendet werden.

Alle Implantate, Size- und Instrumente müssen vor der Verwendung auf eventuelle Schäden oder Defekte geprüft werden. Jede beschädigte oder defekte Komponente darf nicht verwendet werden und muss an 4WEB zurückgeschickt werden.

Geräte für Halswirbelkörperfusionen sind darauf ausgelegt, für mechanische Unterstützung bei gleichzeitiger biologischer Fusion zu sorgen. Im Falle einer Pseudoarthrose oder verzögerten Fusion steigt das Risiko für Implantatlokalisation, Spinalarthrose oder Osteoarthritis in den Wirbelkörpern, einschließlich Bandscheibenverknüpfung, an.

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