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## FOR OUTSIDE THE US ONLY

## ENGLISH IMPORTANT INFORMATION ON ExcelsiusGPS® INSTRUMENTS

**DESCRIPTION**  
ExcelsiusGPS® instruments consist of navigation instruments, surgical instruments, and end effectors. Navigation instruments incorporate arrays of reflective markers, and are used to track patient anatomy and surgical instruments and implants; components include the verification probe, surveillance marker, surgical instrument arms, intra-op registration, and dynamic reference base. Patient reference instruments are either clamped or driven into any rigid anatomical structures using a robotic arm. The navigation system includes a camera mounted on the device, and includes arms, drives, drivers, taps, and probes. End effectors are wirelessly powered guide blades that attach to the distal end of the robotic arm and provide a rigid structure for insertion of implants or a rigid arm to a surgical retractor. Navigation instruments are cleared for use with CRED®, REVERSE®, REVOLVE®, QUARTEX®, ULLI™, CAPTIVATE™, and SUSTAIN™. Surgical instruments are cleared for use with CRED®, REVERSE®, REVOLVE®, QUARTEX®, ULLI™, CAPTIVATE™, and AUTOBAHN™ surgical instruments.

ExcelsiusHub™ is a navigation system that includes hardware and software that enables real-time surgical visualization using radiological patient images (preoperative CT, fluoroscopy), a dynamic reference base, and a camera tracking system. ExcelsiusHub™ may be used in conjunction with ExcelsiusGPS® for guidance of navigated instruments along a planned trajectory using a robotic arm. When connected to ExcelsiusGPS®, ExcelsiusHub™ software is responsible for both navigation and guidance.

## INDICATIONS

The ExcelsiusGPS® is intended for use as aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used for surgery for navigating and/or guiding procedures in open or percutaneous procedures. The system is indicated for the placement of spinal and orthopedic bone screws and intramedullary spinal instrumentation.

The ExcelsiusGPS® is intended for use to precisely locate anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scan or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and intramedullary fusion devices.

## WARNINGS

Attention: A product which may require surgery includes inaccuracy resulting in misplacement of the implant or screw that could lead to neural or vascular structure injury, spinal canal violation, or nerve root compression.

## PACKAGING

These instruments are supplied in a padded outer packaging including a generic unit. The integrity of the generic packaging should be checked to make sure that the contents are not compromised. Packaging should be carefully checked to comprehend all and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

Instruments may be provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to use, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

Instruments identified with the "do not re-use" symbol are intended for one use, or for use on a single patient during a single procedure.

## HANDLING

All instruments, instrument trays, and cases should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to use. All products should be respected to make sure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, discoloration, nonstickiness, residual debris, cracking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

## CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process. Sterile instruments should be cleaned for sterilization. Nonsterile instruments should be cleaned for cleaning before being detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field (if applicable) return of the product to Globus Medical.

Cleaning and decontamination can be performed with alcohol-free solvents at higher temperatures. Cleaning and decontamination must not exceed 176 °F (79 °C). Some cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following instructions should be observed when cleaning instruments and instrument tray and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.

Disassemble all instruments that can be disassembled.

Do not clean all instruments that are not reusable.

Do not use water to clean the instruments.

Do not use detergents or soaps to clean the instruments.

Do not use abrasive materials to clean the instruments.

Do not use sharp objects to clean the instruments.

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