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VERZA™ HIGH SPEED DRILLS

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IMPORTANT INFORMATION ON VERZA™ HIGH SPEED DRILLS

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WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON VERZA™ HIGH SPEED DRILLS

DESCRIPTION
VERZA™ High Speed Drills include electrical drill attachments and burs powered by a motor with a control unit and foot pedal, and may be navigated using ExcelsiusGPS® or ExcelsiusHub™. Instruments are used to remove tissue and bone in a variety of procedures. When used without navigation, these instruments may be used in a variety of surgical procedures, including but not limited to neuro, orthopedic, spinal, and general surgical procedures. The drill instruments are manufactured from stainless steel per ASTM F899, with a diamond coating on select burs.

INDICATIONS
VERZA™ High Speed Drills are indicated for drilling, burring, removing, and otherwise manipulating hard tissue, bone, bone cement, prosthesis, implant, and other bone related tissue during spinal and orthopedic procedures.

ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

ExcelsiusHub™ is intended for use as an aid for precisely locating 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 scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

WARNINGS
Potential risks which may require surgery includes inaccuracy resulting in misplacement of the implant or screw could lead to neural or vascular structure injury, spinal canal violation, or nerve root compression.

PACKAGING
These instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness 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 soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

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 surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, 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, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain 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 cleaning methods should be observed when cleaning the Power Instruments Array and End Effector Sleeve instruments and instrument trays 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.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.

4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

The VERZA™ Motor and Attachments should be cleaned per the cleaning instructions detailed in the corresponding NSK Primado2 Operating manuals:

- Primado2 Slim Motor G (OM-SE0921EN)
- Primado2 Attachment G (OM-SH0939EN)

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). An ExcelsiusGPS® User Manual may be obtained by contacting Globus Medical.

STERILIZATION

The VERZA™ High Speed Drill Instruments are provided non-sterile, except for the burs which are provided sterile only.

Sterile instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a PETG container/Tyvek heat-sealed pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile instruments that become non-sterile or have expired packaging are considered nonsterile and may be sterilized according to instructions below.

Non-sterile instruments have been validated to ensure an SAL of 10^{-6}, in accordance with ANSI/AAMI/ISO 17665-1. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

Do not stack trays during sterilization. These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER		STERILE BARRIER SYSTEM
	CAUTION	NON STERILE	NON-STERILE
	SINGLE USE ONLY		CONSULT INSTRUCTIONS FOR USE
	DO NOT RESTERILIZE		MANUFACTURER
	DO NOT USE IF PACKAGE IS DAMAGED		USE BY (YYYY-MM-DD)
	PRODUCT QUANTITY	Rx ONLY	PRESCRIPTION USE ONLY
MD	MEDICAL DEVICE		