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IMPORTANT: PLEASE READ

DESCRIPTION
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The **Caspar Distractors (CD-ASM & CD-RVN)** and **pins** are surgically invasive medical devices. The pins are provided sterile while all other items, including the distractors, are provided non-sterile.

The Caspar Distractors, Pinion Keys and Drivers are manufactured from SS 431 (ASTM F899)., while the **pins** are manufactured from Titanium Grade 23 (ASTM F136).

Instrumentation provided by Southern Medical is provided in **Instrument trays**. The instruments and trays are manufactured from the following materials: Stainless steel, Titanium, Aluminum, PEEK, Polymers, Composites, Silicone.

INDICATIONS FOR USE

The distractors are a low profile, sturdy instruments that can be used to distract the cervical vertebrae. Caspar pins anchor into the vertebra while a linear ratchet is able to distract open the disc space. This provides the space to perform discectomies or temporarily restoring disc height. The pins are easily locked and unlocked into the distractor to ensure slippage cannot occur. The distractor allows for any preferential orientation to be easily obtained for left-handed and right-handed surgeons. both locking and non-locking pins of varied lengths, including an extended length are available.

CONTRAINDICATIONS

Contraindications include but are not limited to**:**

- Allergy/Hypersensitivity to raw materials
- Use for any purpose other than tissue distraction.

RISKS & UNDESIRABLE SIDE-EFFECTS

Include but are not limited to**:**

- Small parts can be lost

Caution must be taken whilst instrument is in use – moving parts

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

STERILE R

The pins are sterilized via gamma irradiation and are provided **STERILE**. Do not re-sterilize the device. Re-sterilization could cause material degradation and could result in mechanical failure of the device, host rejection and/or post-operative infection. Distractors are provided **NON-STERILE**.

Do not use pins if the packaging has been damaged or previously opened, or if the expiration date on the label has been exceeded.

The devices are **SINGLE-USE**. Do not re-use pins. Devices in this range may not be implanted. Re-use or re-implantation of pins may result in failed surgery, cross-contamination, or infection.

WARNINGS & PRECAUTIONS: CORRECT & SAFE USE

The device should only be used by qualified surgeons with knowledge of the correct and safe use of the device and associated instrumentation, if uncertain, please contact a Southern Medical Representative.

The pins are intended to be used in combination with a cervical distractor. Failure to use a cervical distractor may lead to failure of the device, or inadequate distraction.

INSTRUMENTS
Only the instruments provided by the manufacturer should be used. Instruments are provided non-sterile and should be cleaned and sterilized before use in accordance with the instructions provided in IFU-100.

STORAGE
There are no special storage instructions. Storage conditions must not lead to degradation or contamination of the packaging or its contents. Handle with care.

POST-OPERATIVE CARE INSTRUCTIONS
The surgeon/physician should provide appropriate postoperative care instructions to the patient and should ensure that the patient understands the potential consequences of non-compliance. To achieve the desired clinical outcome, the patient should be instructed to minimize physical activity as far as possible and avoid activities that require lifting, bending, twisting or excessive movement. Follow-up consultations should be arranged with the patient at appropriate intervals, as deemed necessary by the physician. The patient should only resume their normal activities once cleared to do so by their physician.

MRI SAFETY INFORMATION
The devices have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement “The device presents a projectile hazard in the MR environment. The safety of the devices in the MR environment is unknown. Performing an MR exam on a person during use of this medical device may result in injury or device malfunction.

DEVICE REMOVAL & USAGE
The intended duration of use of the pins is less than 60 minutes. Surgical removal of the pins is possible. The pins may not be implanted.

DISPOSAL
Single-use devices that have been in contact with blood or bodily fluids/tissues should be disposed of in accordance with the hospital’s procedure for disposal of hazardous and/or biological waste. Users must wear surgical gloves and take care to avoid sharp edges.

REPORTING
Any device-related adverse events must be reported to the manufacturer as soon as possible.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING

MANUFACTURER		USE BY	
CONSULT INSTRUCTIONS FOR USE		CATALOGUE NUMBER	REF
DO NOT RE-USE		CAUTION	
DO NOT RE-STERILIZE		LOT NUMBER	LOT
DATE OF MANUFACTURE		STERILIZED USING IRRADIATION	STERILE R

DO NOT USE IF PACKAGING IS DAMAGED

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

℞ ONLY