

IFU-101-03

Date Issued:2023/06/13

INSTRUCTIONS FOR USE

Caspar Distractors & Pins

MANUFACTURED BY: Southern Medical (Pty) Ltd.

distractors, are provided non-sterile

INDICATIONS FOR USE

extended length are available.

Include but are not limited to:

Contraindications include but are not limited to:

Small parts can be lost

RISKS & UNDESIRABLE SIDE-EFFECTS

CONTRAINDICATIONS

55 Regency Drive Route 21 Corporate Park Irene, 0062 South Africa

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DESCRIPTION

Description:

P O Box 17198 Lyttelton, 0140 South Africa

IMPORTANT: PLEASE READ

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

The Caspar Distractors, Pinion Keys and Drivers are manufactured from SS 431

(ASTM F899)., while the pins are manufactured from Titanium Grade 23 (ASTM

Instrumentation provided by Southern Medical is provided in Instrument trays. The

instruments and trays are manufactured from the following materials: Stainless steel.

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

discectomies or temporarily restoring disc height. The pins are easily locked and

for any preferential orientation to be easily obtained for left-handed and right-

unlocked into the distractor to ensure slippage cannot occur. The distractor allows

handed surgeons, both locking and non-locking pins of varied lengths, including an

able to distract open the disc space. This provides the space to perform

Allergy/Hypersensitivity to raw materials

Use for any purpose other than tissue distraction.

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

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

Titanium, Aluminum, PEEK, Polymers, Composites, Silicone.

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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.

The device should only be used by qualified surgeons with knowledge of the

correct and safe use of the device and associated instrumentation, if

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

STORAGE

There are no special storage instructions. Storage conditions must not lead to

POST-OPERATIVE CARE INSTRUCTIONS

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



malfunction.

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.

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

REPORTING

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

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING

MANUFACTURER





CAUTION



CONSULT INSTRUCTIONS



CATALOGUE NUMBER



DO NOT RE-USE

DO NOT RE-STERILIZE

DATE OF MANUFACTURE





STERILE R

LOT NUMBER



STERILE R

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.

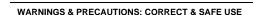
The pins are sterilized via gamma irradiation and are provided

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

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



provided NON-STERILE.



DO NOT USE IF

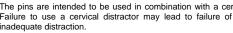
PACKAGING IS DAMAGED

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



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uncertain, please contact a Southern Medical Representative.

INSTRUMENTS

with the instructions provided in IFU-100.

degradation or contamination of the packaging or its contents. Handle with care.

The surgeon/physician should provide appropriate postoperative care instructions to



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

DEVICE REMOVAL & USAGE

DISPOSAL

to avoid sharp edges.