Manufactured by:
Southern Medical (Pty) Ltd
55 Regency Drive,
Route 21 Corporate Park,
Irene, Centurion, 0062, South Africa
P O Box 17198
Lyttleton, 0140
South Africa
Tel: +27 12 667 6243/4
Email: info@southmed.co.za

IMPORTANT: PLEASE READ
For detailed information on the Southern Surgical Instrumentation, please consult the relevant device Surgeons' Manual.

Description:
Instrumentation provided by Southern Medical are provided in instrument trays. The instruments and trays are manufactured from the following materials: Stainless steel, Titanium, Aluminium, PEEK, Polymers, Composites, Silicone.

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The Caspar distractor is a low profile, sturdy instrument 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.

Recommended Surgical Procedure:
Refer to the surgical procedure provided by Southern Medical (Pty) Ltd.

USAGE WARNING:
Intended duration of use is less than 60 minutes.
Placement of this device is limited to qualified surgeons. Refer to surgical procedure and product brochure for more information.

STERILITY:
Instruments are disinfected and packed onto trays but are not supplied sterile and needs to be sterilized by an ISO 17665 validated moisture sterilization (autoclave) method. It is the responsibility of the hospital to ensure equipment and cycles are validated on site. Personnel responsible for the cleaning and sterilization of the instruments must be a fully trained hospital staff member. All instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Sterilization must be done in time before implanting the prosthesis. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below. If uncertain contact a Southern Medical representative.

Warnings
Aluminium instruments are damaged by alkaline (pH>7) detergents and solutions
Long narrow cannulations and blind holes require particular attention during cleaning
Do not exceed 150°C

Limitations on reprocessing
Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use

Sterilization Instructions
Remove excess soil with disposable cloth/paper wipe.

Point of use
- Thorough cleaning and rinsing should begin as soon as possible after use of the device
- These practices include keeping devices moist after use to prevent soil from drying and removing gross soil from the surfaces, crevices, mating surfaces, joints, and all other hard-to-clean design features

Containment and transportation
No particular requirements

Preparation for cleaning
Devices capable of disassembly must be disassembled prior to cleaning
Dried-on soil is difficult to remove with automatic washing, especially at challenging design features on devices like interfaces, crevices, joint etc. The removal of gross soil from these areas prior to washing in the automatic washer is critical for achieving adequate cleaning

Disinfection:
Disinfectant solution (Thermosept) may be used in accordance with label instructions.
3% hydrogen peroxide may be used on difficult to reach areas

Cleaning: Automated
1. Pre-cleaning should be through soaking in enzymatic detergent for 5 minutes and scrub surfaces including brackets and hinges with cleaning brush
2. Rinse with warm water
3. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations and holes positioned to drain).
4. Run the automatic wash cycle: Minimum cycle parameters:

Phase	Function	Duration (min)
2 Rinse cold + warm water	Rinse, mixed water	2
5 Wash I detergent at 43°C	Wash with detergent	7
13 Rinse warm water 45°C	Rinse, warm water	2
16 Disinfection temperature is set at A0=600; 90˚C (+1˚C)/1 min	Disinfection	1 + heating

5. Check instruments for visible soil
6. Repeat cleaning if soil is visible and re-inspect.

Thermal disinfection Minimum cycle parameters: one (1) minute at 91° C

Cleaning: Manually
1. Immerse instrument and soak for a minimum of ten (10) minutes in enzymatic detergent
2. Blind holes should be repeatedly filled and emptied
3. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features
4. Scrub interfaces several times using a twisting action. If components of the instrument can be disassembled or moved, it is necessary to retract or open the part in order to access and clean these areas.
5. Scrub inside holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached
6. Scrub around hinged surface areas with a brush or pipe cleaner
7. Scrub crevices using a cleaning brush or pipe cleaner
8. Rinse thoroughly with warm water, making sure to wet the challenging design features
9. Check instruments for visible soil

Repeat cleaning if soil is visible

Drying
When drying is achieved as part of a washer disinfector cycle do not exceed 120°C.

Maintenance, Inspection and Testing of Instrumentation
- Visually inspect for damage or wear
- Hinged instruments should be check for smooth movement of hinge without excessive "play."
- Locking mechanisms should be checked for action
- All surfaces should be smooth and free of cracks and deep nicks
- Reamer/drill bits should be inspected for deformities and distortion that might hinder insertion into a drill
- Metal surfaces Inspect for corrosion and major deformation
- Blunt or damaged instruments should be returned to sales representatives

Packaging
Instrument tray should be double wrapped with Steriwrap.

Sterilization Instructions
Instruments and instrument trays:
- It is important that adequate cleaning of instrument cases/trays be performed prior to sterilization. Preparation for Sterilization Single-Use
- Long narrow cannulations and blind holes require particular attention during cleaning.
- Instrument should be placed in Instrument Trays prior to sterilization
- Sterilization trays must be wrapped with an approved autoclave wrap prior to sterilization. The tray by itself does not provide a sterile barrier.
- Do not stack sterilization trays in the sterilizer!

Limitations on reprocessing:
- Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use

Recommended Sterilization Parameters:
- Instrument sets produced by Southern Medical can be sterilized to a sterility assurance level (SAL) of 10E-6 in a pre-vacuum, 4 pulse, 132º-135ºC (270º-275ºF), 3 minute exposure, 15 minute vacuum dry, steam sterilization cycle
- Some health care authorities recommend sterilization according to these parameters to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Storage
- If stored between cleaning and sterilization, dry instruments with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet storage.
- Containment devices can be stacked for storage.

The instructions provided above have been validated by Southern Medical. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.