SEGI®

Shoulder-Side Entry Glenosphere Inserter
33-38 mm (SEGI-3338) and 39-44 mm (SEGI-3944)

Instructions for Use

⚠ Read these Instructions for Use prior to using this device.
Federal law restricts this device to sale by, or on the order of, a physician.

Indications for Use

Tullo SEGI™ Shoulder-Side Entry Glenosphere Inserters are instruments used in shoulder surgical procedures and are for use by, or as directed by, a trained medical professional. The instruments should be used only for the purpose for which they are designed. The proper technique for the use of the instrument is the responsibility of the medical professional.

Sterility

SEGI™ Shoulder-Side Entry Glenosphere Inserters are supplied non-sterile and must be cleaned and sterilized before first use and after each reuse.

Recommended Cleaning and Sterilization Instructions

Rinsing

Directly after surgery, rinse instruments under hot running water.

Cleaning

Instruments should be submerged in a solution of water and neutral pH (7) detergents.

Ultrasonic Cleaning

Completely submerge instruments in an open position in the ultrasonic cleaner. All instruments should be processed in the cleaner for the full recommended cycle time, which is normally about 5-10 minutes. A lid should cover the ultrasonic cleaner during the operation to prevent splashing. Never place different metals – such as stainless steel and copper – in the same cleaning cycle. Change the solution as frequently as the manufacturer recommends. After ultrasonic cleaning, rinse all instruments with water to remove excess cleaning solution.

Manual Cleaning

Most instrument manufacturers recommend ultrasonic cleaning as the best way to clean instruments, especially those with hinges, locks and other moving parts. If ultrasonic cleaning is not available, follow the instructions below.

a) Use stiff nylon cleaning brushes. Do not use steel, wool or wire brushes except specially recommended brushes for serrated areas of instruments or on bone files, burs or stained areas in knurled handles.

b) Use only neutral pH (7) detergents.

c) Make sure all instrument surfaces are visibly clean and free from stains and tissue. At this point it is a good time to inspect individual instruments for proper function and condition.

d) After scrubbing, rinse all instruments thoroughly under running water.

e) Dry the instruments thoroughly using filtered medical-grade air or a soft, clean, low-linting cloth.

Sterilization

Sterilizers vary in design and performance characteristics. Cycle parameters and load configuration should always be verified against the sterilizer manufacturer's instructions.

The following steam sterilization cycles may be used for instruments:

Sterilization Method	Instrument Configuration	Temperature	Exposure Time (minimum)	Drying Time (minimum)
Pre-vacuum	Wrapped	270°F (132°C)	4 minutes	10 minutes
Pre-vacuum	Wrapped	273°F (134°C) to 279°F (137°C)	3 minutes	10 minutes
Gravity Displacement	Wrapped	270°F (132°C) to 275°F (135°C)	10 minutes	10 minutes

Storage

Instruments must be stored in a dry, clean, chemical-free and dust-free environment. Instruments must remain wrapped or enclosed within the sterilization container to maintain sterility.

Symbols

							
Manufacturer	Catalogue number	Caution	Consult instructions for use	Prescription Use Only	Non-sterile	Unique Device Identifier	Visit tullomed.com/use for product education and resources

Caution

Federal law restricts the sale of this device to or on the order of a licensed clinician. Treatment planning and clinical use of the SEGI™ Shoulder-Side Entry Glenosphere Inserters are the responsibility of each individual clinician's judgement. Clinician judgement and experience should be applied in conjunction with this suggestive use protocol. Tullo is not responsible for incidental or consequential damages or liability relating to the use of SEGI™ Shoulder-Side Entry Glenosphere Inserters alone or in conjunction with other products other than replacement under warranty. SEGI™ Shoulder-Side Entry Glenosphere Inserters are warranted for a period of 365 days from the date of initial invoice.

Notice

Report any serious incident resulting from the use of SEGI™ Shoulder-Side Entry Glenosphere Inserters to Tullo and the local health competent authority of the state in which the user and/or patient is established.

Tullo, LLC
22701 Hall Road, Suite 100, Macomb, MI 48042
tullomed.com