Snowden Pencer™ Articulating Pretzel Retractor

Catalog Numbers
89-6132 – 5mm Articulating Pretzel Retractor
89-6133 – 3mm Articulating Pretzel Retractor
89-6232 – 5mm Sterilization Sleeve
89-6233 – 3mm Sterilization Sleeve

3mm Articulating Pretzel Retractor (89-6132)
5mm Articulating Pretzel Retractor (89-6133)

Device Components
(a) Handle
(b) Diameter 5mm Shaft
(c) Flexible Segments
(d) 3mm Sterilization Sleeve (89-6232)
(e) Actuation Knob
(f) Flush Port
(g) Diameter 3mm Clamp Area
(h) Diameter 3mm Shaft
(i) 3mm Sterilization Sleeve (89-6233)

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Made in the United Kingdom

Distributed by CareFusion
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Indications for Use
Articulating Pretzel Retractor is designed as an organ and tissue retractor for the use in minimally invasive surgical procedures to elevate or retract organs and tissues to provide better access as well as visualization of surgical sites.

How Supplied
Snowden Pencer™ devices are packaged non-sterile. Cleaning and sterilization must occur prior to use.

Limitations on Reprocessing
Repeated reprocessing has minimal effect on these devices. End of life is normally determined by wear and damage due to misuse.

Cautions
If there are any variations between these instructions and either your facility’s policies and/or your cleaning/sterilization equipment manufacturer’s instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your devices.

Improper use of the device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.

Avoid mechanical shock or over-stressing the device. It is important when using the retractor to move organs to ensure that the shape and load is supported evenly by the shaft and predefined shape of the device. Place the load in the orientation and shape as shown in the diagram. Incorrect orientation could result in instrument damage and patient injury.

When clamping the 3mm device (89-6133) to a bench clamping system, ensure the device is clamped in the clamp area shown in (Figure 1 and Figure 16). Incorrect clamping in any other area could result in instrument damage and patient injury.

Always use caution when inserting or removing devices through cannula. Lateral pressure on the device during removal can damage the working tip, shaft of the device.

Use only a neutral pH (6-8) solution when cleaning the instrument. Use of highly acidic or alkaline detergents will cause pitting or breakage of the instruments.

The retractor is not entirely gas tight. To minimize gas leakage through the instrument, always ensure the luer fitting is covered and that the instrument is not left un-actuated in the patient.

The warranty may be void if the instrument is continually exposed to high acid or high alkaline solutions, detergents, stain removers etc. Do not use instruments if they do not perform satisfactorily in an operational test. Avoid mechanical shock or over-stressing the instruments which will cause damage.

When sterilizing or storing this device, always use the protective/stereilizing sleeve provided. Failure to use the sleeve may result in premature device failure. This device should never be folded or bent to fit into a small sterilization tray.

Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.

Figure 1

3mm Articulating Pretzel Retractor (89-6133)
5mm Articulating Pretzel Retractor (89-6132)

Figure 2

3mm Sterilization Sleeve (89-6233)
5mm Sterilization Sleeve (89-6232)

Proofed by: _________________________________ Date: ____________ __
Dimensions checked: ________________ __ Copy checked: ________________ __
Examples of misuse
1. Sterilization using any other method than stated may damage the instrument.
2. Do not place the instrument in direct contact with live electrical instruments.
3. During use it is possible to generate considerable load on the instrument which can under extreme circumstances break. Do not over tighten the actuation knob, once the retractor has assumed its actuated shape only rotate the knob a maximum of 1/4 turn (90°) in clockwise direction.
4. In the event of a breakage it is important to examine the instrument carefully to ensure that all components, specifically the actuating segments are accounted for.

Pre-processing Instructions
1. Initiate cleaning of the device immediately after use or within a maximum of 2 hours.
2. Transport devices via the institutions established transport procedure.
3. Remove excess gross soil as soon as possible after use by rinsing the device in 6 gallons of tap water for a minimum of 3 minutes. Flush the device through lumen via flush port until fluid runs clear. All devices must be processed in the relaxed straight configuration. All flush ports shall remain in the fully open position. (Figure 2)

Manual Cleaning
1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic / neutral pH detergent solution, per manufacturer’s instructions, utilizing tap water with a minimum temperature of 36°C (97°F). Note: This detergent preparation shall be used to complete cleaning stages 3, 4 and 5. It is recommended that the detergent solution is changed when it becomes grossly contaminated (bloody and/or turbid).
3. Place device in the open/relaxed position, with flush port open, and completely immerse in the detergent solution and allow device to soak for a minimum of 20 minutes. Actuate all movable parts during the initiation of the soak time. (Figure 3)

4. Using a small firm bristled brush, remove all visible soil from the device. Actuate device while brushing, paying particular attention to hinges, crevices and other difficult to clean areas. (Figure 4)

5. Suck or flush the internal lumen of the instrument with neutral pH detergent by using the flushing port located on the handle. A minimum of 3 complete flushes with 50ml of neutral pH detergent or a sufficient volume of detergent and number of flushes should be used until all fluid exiting the instrument is clear of particulate matter. (Figure 5)

6. If visible soil is detected during the final lumen flush, re-perform brushing and flushing of the lumen.
7. Rinse the device by completely immersing in 4 gallons of tap water with a temperature range of 27°C to 44°C (81°F to 111°F), for a minimum of 2 minutes to remove any residual detergent or debris. (Figure 6)

8. Place the device in an ultrasonic wash with enzymatic / neutral pH detergent solution (prepared as per the manufacturer’s instruction) for a minimum of 10 minutes, at a minimum temperature of 38°C (100°F). Ensure sufficient volume of detergent solution is prepared to fully submerge the device. (Figure 7)

9. Following the ultrasonic wash, the device shall be thoroughly rinsed internally and externally with a minimum of 4 gallons of reverse osmosis/deionized (ROD) water at room or ambient temperature for a minimum of 2 minutes. The internal flushing of the lumen should be through the flushing port located on the handle/shaft. In both instances internal and external flushing of the device should be repeated a minimum of 3 times ensuring all fluid exiting the device runs clear. (Figure 8)

10. Dry the device with a clean, lint-free towel.
11. For lumen devices, manipulate the device to allow rinse water to drain from the lumen.
12. Visually examine each device for cleanliness.
13. If visible soil remains, repeat cleaning procedure.

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Figure 7

Figure 8
14. Before sterilizing, lubricate the device with instrument milk or a steam permeable / water soluble lubricant, following the lubricant manufacturer’s instructions. (Figure 9)

15. Let devices drip dry for three (3) minutes before packaging for sterilization.

Inspection/Maintenance
Proper care and handling is essential for satisfactory performance of any surgical device. The previous cautions should be taken to ensure long and trouble-free service from all your surgical devices. Inspect devices before each use for broken, cracked, tarnished surfaces, movement of hinges, and chipped or worn parts. If any of these conditions appear, do not use the device. Return devices to an authorized repair service center for repair or replacement.

Packaging
Devices can be loaded into dedicated packaging systems. Sterilization wrap material must be cleared for the applicable sterilization modality by your country’s regulatory body. Use in accordance with packaging manufacturer’s sterilization instructions.

Sterilization (Figure 10)
All devices must be processed in the completely open position (i.e. flushports open) to allow sterilant contact of all surfaces. The device must only be sterilized in the fully relaxed position, and the “protective/sterilization sleeve” must be located on the flexible, segmented portion of the instrument.

Parameters for Steam Sterilization (Autoclave)
Sterilization of instruments may be accomplished by steam autoclave. Time and temperature parameters required to steam sterilization vary according to type of sterilize, cycle design and packaging material. The following are the manufacturer’s guidelines for product sterilization. The use of “flash” sterilization is not recommended, as it will shorten the life of endoscopic instruments. Do not sterilize instruments at temperatures over 141°C (285°F) The Pretzel Retractors must only be sterilized in the fully relaxed position. The flush ports should be un-obstructed by luer cap. Before sterilization the “protective/sterilization sleeve” must be located on the flexible, segmented portion of the instrument. Failure to follow these instructions may significantly impair the life of the retractor.

Prevacuum Steam Sterilization Parameters
Preconditioning Pulses: 3
Temperature: 132°C (270°F)
Exposure Time: 4 minutes
Dry Time: 30 minutes
Sterilization Parameter: Wrapped (2 layer 1-ply)

Storage
After sterilization, instruments should remain in sterilization wrap and be stored in a clean, dry cabinet or storage case. Always store the retractor in its protective/sterilization sleeve. Note: Care must be taken to protect the flexible portion from damage, do not manually bend the segment string.

Operating Instructions
Instrument Insertion
1. Ensure instrument is cleaned and sterilized in accordance with cleaning and sterilization guidelines prior to use.
2. Insufflate the peritoneal cavity in the normal manner. Carefully guide the fully relaxed instrument through a laparoscopic port into the operating site. (Figure 11)

3. 3.a. For 5mm device (89-6132) rotate the actuation knob clockwise and form the pre-defined shape. Ensure that the tip of the retractor and the segments are always in the field of endoscopic vision during formation. DO NOT over-tighten the actuation knob. Once the retractor has assumed its actuated shape only rotate knob maximum of ¼ turn (90°) in clockwise direction. In the unlikely event of tissue becoming “snagged” between the segments relax the retractor, rotate slightly and re-activate. (Figure 12)

3.b. For 3mm device (89-6133) rotate the actuation knob clockwise until the pre-defined shape is achieved. Ensure that the tip of the retractor and the segments are always in the field of endoscopic vision during formation. A slipping clutch is included within the actuation knob to prevent over tightening. The actuation knob will slip and make an audible clinking when the correct unrestricted tension is achieved. (Figure 12)

4. When actuating in limited space, insert segment section A (Figure 1) of the flexible portion and actuate to approximately 90°. (Figure 13)
5. Insert the segment section B (Figure 1) and further actuate the instrument. Ensure that the tip remains approximately 2cm away from the port. (Figure 14)

6. Insert segment section C (Figure 1) and actuate the instrument until fully formed, ensure that all segments are inserted prior to forming. Take care to ensure the port does not bow during formation, if this occurs slacken the instrument and insert more segments. (Figure 15)

7. When using the retractor to move organs and tissue ensure that the shape and load is supported by the shaft of the device. Place the load on the orientation and shape as shown in the diagram. (Figure 16)

8. When instrument is in the position required, clamp to the operating table using an appropriate clamping instrument, such as the Snowden Pencer Fast Clamp system. Ensure the clamp is fixed to the shaft of the device. When clamping the 3mm device (89-6133) ensure the device is clamped onto the larger diameter area next to the handle. (Figure 1 and Figure 17)

9. DO NOT throw away the protective/sterilization tube.

Instrument Removal
1. Unclamp the instrument from the table and turn the actuation knob counter clockwise to the fully relaxed position. Ensure the direction of removal is in-line with the port.
2. Carefully withdraw the instrument from the port and place the instrument in the sterilization tube. If there is resistance during this process gently rotate the instrument during withdrawal. Do not repeatedly insert and withdraw the instrument as this may cause damage to the port and valve system.
3. Rinse the device from visible soil immediately after use or within a maximum of 2 hours.

Warranty
CareFusion offers a lifetime guarantee on every surgical device bearing the Snowden Pencer brand name (unless otherwise noted) to be free of functional defects in workmanship and materials when used normally for its intended surgical purpose. Any product which proves to be defective in material or workmanship will be repaired or replaced at our discretion. This guarantee does not cover damage to the instrument by overstress or mechanical shock. Repair, alteration or modification of any product by persons other than the manufacturer, or products subjected to misuse or abuse will result in immediate loss of guarantee. If instruments are damaged by accident or when used for a purpose other than originally intended, a repair charge will apply.

This device carries a lifetime warranty against manufacturer defects and a 1 year warranty against wear.

Repair Service
Regardless of age, if any Snowden Pencer device needs service, return it to an authorized repair service center. If the repair is covered under guarantee, it will be repaired or replaced at no charge when requested in writing. A nominal service charge will be made for repaired instruments outside the guarantee.

Note: Guarantee is void if instruments are repaired by any other repair service, subjected to abuse, or improperly reprocessed.

Note: All devices being returned for maintenance, repair, etc. must be cleaned and sterilized per these instructions for use prior to shipment.

Contact Information
For repair services and/or advice for use concerning this instrument, please contact your local CareFusion representative, or use the contact address below.

CareFusion
75 North Fairway Drive
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www.carefusion.com

For domestic inquiries email: GMB-VMueller-Cust-Support@carefusion.com
Other Resources: To learn more about sterilization practices and what is required of manufacturers and end users, visit www.aami.org, www.aorn.org or www.iso.org