8000 South Kolb Rd.
Tucson, AZ 85756

Ph: 800-528-1597
Fax: 520-885-1189

# WELLS JOHNSON

# REUSABLE CANNULAS AND ACCESSORIES

# INSTRUCTIONS FOR USE

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## Device Description

Wells Johnson Company cannulas and accessories are manual, reusable surgical instruments offered in various customizable specifications to meet customer requirements. Cannulas and accessories contain Stainless Steel, Aluminum and Delrin (acetal) Plastic. Metals are subject to damage and corrosion if improperly cared for. All plastics are subject to a normal ageing process, which can be accelerated by mechanical, chemical and thermal processes such as autoclaving.

## Intended Use

Wells Johnson Company reusable cannulas and accessories are used for instillation or aspiration of fluid to/from a targeted area of the body in general surgical procedures.

*Carefully read these instructions prior to using Wells Johnson Company cannulas and accessories. Keep them in a safe place for future reference.*

*Use instruments for their intended purpose only.*

## Intended Users

Cannulas and accessories should be used, handled and monitored in a health care setting by competent and qualified surgeons and medical professionals.

℞ Only *Federal (USA) law restricts this device to sale by or on the order of a physician.*

## Prior to use

Cannulas and accessories are shipped non-sterile and require processing prior to initial use and subsequent uses. A visual inspection of each instrument should be performed prior to use. It is the user's responsibility to ensure proper instrument function before use. See "Inspection and Care" section for between use inspection and overall care.

NON STERILE *Instruments are shipped and packaged non-sterile. Cleaning and sterilization must occur prior to use.*

*It is the responsibility of the user to inspect cannulas and accessories prior to use in surgery. If the instruments do not function properly or are damaged, do not use and discard.*

## Reprocessing Instructions

1. **Soak**
   - 1.1. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying of contaminants prior to cleaning. Immediately after each use, disconnect accessories (if needed, e.g. handles) from their connection interfaces and perform initial cleaning by wiping the device and remove excess debris with disposable cloth or non-shedding wipe.
     It is important to never hold instruments in a dry container, which allows blood and debris to dry onto device surfaces and makes cleaning more difficult**.**
   - 1.2. Place instruments in a basin or sink large enough to accommodate all instruments and prepare enzymatic cleanser for soaking in accordance with enzymatic cleanser manufacturer instructions. The recommended enzymatic cleaning solution is McKesson® Multi-Enzymatic Cleanser and is suitable for manual, automated and ultrasonic systems.
   - 1.3. Completely submerge all instruments in the enzymatic solution and soak for at least 10 minutes.
   - 1.4. Rinse each instrument free of debris and organic materials with lukewarm tap water, not exceeding 40°C.

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1.5. For instruments with lumens, use a 60ml syringe to completely flush each instrument at least 3 times from end to end and clear any debris inside the lumen, making sure there are no blockages and rinsing freely flows through each instrument. Visually inspect each instrument. Additional soak time may be necessary for hard to remove matter.
1.6. Make sure all the instruments are clean, non-greasy and unclogged.

⚠ *Cleaning and rinsing must take place immediately after use to minimize drying of soil and debris.*

⚠ *Always wear appropriate protective gear when performing cleaning procedures.*

**2. Manual Clean**

2.1. Remove the instruments from the enzymatic soak and rinse thoroughly, in lukewarm Tap Water not exceeding 40°C to remove debris loosened during soak.
2.2. Place the instruments back in the enzymatic cleaning solution to continue cleaning.
2.3. Brush the outside surfaces for at least 30 seconds immediately after withdrawal from solution until all visible contaminants have been removed.
2.4. Using a non-metal flexible cleaning brush, clean the inside lumen. Smaller diameter cannulas are included with a stylet to help clear the inner lumen of debris. These non-autoclavable stylets are for clearing debris only and should not be autoclaved.
The recommended flexible brushes are Wells Johnson Company Part #'s:

| Part Number | Size mm (cannula diameter) |
|---|---|
| 20-5230-00 | 4.0mm – 6.0mm |
| 20-5232-00 | 1.5mm – 3.0mm |
| 20-5231-00 | 7.0mm – 10mm |

⚠ *Using metal brushes to clean instruments can cause damage and should not be used.*

2.5. When cleaning the instruments, pay particular attention to surfaces and features that may be shielded from the brushing action. Additionally, pay careful attention to cannula ports/orifices as well as inside lumens and connection interfaces. Rinse for at least 3 minutes in running Tap Water not exceeding 40°C until all traces of cleaning solution are removed.
2.6. If necessary, use forceps or pickups to remove difficult debris in smaller areas. After the debris is removed, use a non-shedding wipe and wipe the outside surface where debris was removed.
2.7. Inspect each instrument. All parts should be checked for visible contaminants and/or distortion or damage. Particular attention should be paid to:

- Containment "traps" such as concave or mating surfaces.
- Recessed features (such as openings in the cannulas and accessories).
- All instruments (for any damage) **see "Inspection and Care" section.*

2.8. Remove instruments and drain enzymatic solution. Finish by thoroughly flushing the instruments at least 3 times with a syringe (volume 60ml) filled with Distilled Water, not exceeding 40°C.

**3. Ultrasonic Cleaning**

3.1. In an Ultrasonic Cleaner (bath) large enough to fully immerse all items, prepare enzymatic cleanser for Ultrasonic Cleaning (bath) in accordance with enzymatic cleanser manufacturer

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instructions. The recommended enzymatic solution is McKesson® Multi-Enzymatic Cleanser and is suitable for manual, automated and ultrasonic systems.

3.2. Place instruments into ultrasonic bath, completely submerged, for 10mins according to the Ultrasonic Cleaner (bath) manufacturer instructions.

3.3. Remove instruments from ultrasonic bath and thoroughly rinse with Distilled Water for 3 minutes.

3.4. Repeat steps 3.2 and 3.3 until no sign of debris, soil or enzymatic solution in the rinse stream.

**4. Drying**

4.1. Ensure all instruments are completely and properly clean.

4.2. Thoroughly and completely wipe any moisture from instruments using a clean, absorbent, and non-shedding towel, and let air-dry. Medical grade filtered compressed air may also be used.

4.3. Repeat step 4.2 as necessary until completely free of moisture.

**5. Packaging**

5.1. When completely dry, inspect each component for damage or signs of fatigue. If signs of damage or fatigue are identified, do not use and dispose.

⚠ *If signs of damage or fatigue are identified, do not use and dispose.*

5.2. Handles and instruments that contain plastic shall be packaged individually and disconnected from cannulas or metal interfaces prior to autoclaving. Failure to comply with this may result in damage to handles. Wells Johnson handles containing plastic (Delrin (acetal)) are:

| Part Number | Description |
|---|---|
| 20-0005-00 | Handle, Delrin, 1” |
| 20-0005-01 | Handle, Delrin, 5/8” |

5.3. The inspected devices should be terminally wrapped/pouched in accordance with ISO 11607.

**6. Sterilization**

Only the sterilization method below should be used; other sterilization methods are not permitted:

6.1. Instrument Sterilization Procedure

6.1.1. Cyle: Pre-Vacuum

6.1.2. Temperature: 132°C (270°F)

6.1.3. Exposure Time: 4 minutes

6.1.4. Dry Time: 20 - 30 minutes, depending on load size

⚠ *Immediate Use, “flash sterilization” is not permitted.*

**Storage**

Devices must be stored until subsequent use in suitable sterilization packaging according to the standards. The storage area must be dust-free, low microbiological contamination, dark and free of temperature fluctuations. Identify and store sterile products in accordance with ISO 11607.

**Inspection and Care**

Cannulas and Accessories require reprocessing for subsequent use according to the parameters in these Instructions for Use. Critical to this process is the inspection of instruments for signs of damage.

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The product life is normally determined by wear and damage due to use.

**1. Inspection Between Use**

These inspections shall be performed prior to sterilization to ensure compromised instruments are not placed in fields of use.

1.1. Visually inspect each instrument in totality for obvious signs of bends, fractures, cracks, dents, or irregularities.

1.2. Perform a pull-test on cannulas by holding the shaft of the cannula in one hand, and the handle/hub in the other hand. Gently apply a pulling force on the shaft. If the shaft moves in the handle/hub, do not use.

1.3. Using 5x magnifier to identify holes, cracks, fractures or irregularities specifically around cannula orifices and hub joint.

1.4. If signs of abnormalities are identified by either visual or magnification inspections, instruments must not be used and should be discarded according to facility and or applicable laws.

**2. Care**

The overall handling and care of cannulas and accessories must be observed to prevent and avoid physical damages. It is the user's responsibility to ensure proper handling, care and use, which includes observing and preventing the following causes of damage. Damage as a result of the following are non-warrantable.

2.1. Do not drop instruments on/in a hard surface or container.

2.1.1. Resulting damage:
Bent/broke cannula tip, bent/broke cannula shaft, shaft loose in handle/hub, dents, and connection interface damage.

2.2. Do not apply lateral stress, torque or lifting motions during use.

2.2.1. Resulting damage:
Bent/broke cannula tip, bent/broke cannula shaft, shaft loose in handle/hub, dents and connection interface damage.

2.3. Do not intentionally or unintentionally bend or manipulate cannula shaft

2.3.1. Resulting damage:
Bent/broke cannula tip, bent/broke cannula shaft, shaft loose in handle/hub, shaft fatigue leading to eventual breakage near handle/hub**.**

2.4. Do not force instruments into autoclave, ultrasonic bath, or any space for storage.

2.4.1. Resulting damage:
Bent/broke cannula tip, bent/broke cannula shaft, shaft loose in handle/hub, dents and connection interface damage.

2.5. Do not clean instruments with corrosive agents. i.e., oxidizing acids, alkaline solution, organic solvents, oxidizing agents, halogens, and aromatic/halogenated hydrocarbon, rinse acids, and acidic neutralizers.

2.5.1. Resulting damage:
Inadequate or prevented sterilization, corrosion to metal materials, damage to plastic materials, changes in appearance of cosmetics, and damage to hub joints.

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**Symbols Used**

| Symbol | Description |
|---|---|
|  | Symbol for: Manufacturer |
|  | Symbol for: Catalog or Part Number |
|  | Symbol for: Batch Code |
|  | Symbol for: Consult the Instructions for Use |
|  | Symbol for: Non-Sterile |
|  | Symbol for: Caution |
|  | Caution: Federal law restricts this device to sale by or on the order of a physician |
|  | Symbol for: Date of Manufacture |
|  | Symbol for: Unique Device Identifier |

**User Responsibility**

It is the responsibility of the re-processer/user to ensure that the reprocessing is accurately carried out with the equipment, materials and personnel to achieve the required results.

If the equipment, and materials for re-processing are not available as required by these Instruction for Use, the user/re-processer shall validate their process at their own risk.

It is the user's responsibility to ensure that cannulas and accessories are inspected and properly functioning prior to use.