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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 medical grade 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 intended for use in general surgical procedures to instill or aspirate fluids to or from targeted areas of the body.

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 are intended to be used, handled, and monitored in healthcare settings by qualified and trained medical professionals, such as licensed surgeons and operating room personnel.

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 must undergo full reprocessing including cleaning and sterilization prior to initial and subsequent use. A visual inspection of each instrument must be performed before use to check for signs of damage, wear, or contamination. It is the user's responsibility to ensure proper instrument function before use. For guidance on routine inspection and maintenance, refer to the "Inspection and Care" section.

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. Within 30 minutes after use, disconnect accessories (e.g. handles) from connection interfaces and remove excess debris on all surfaces with disposable cloth or non-shedding wipe and rinse with lukewarm water not exceeding 40 °C or temporarily cover with cloth moistened with Distilled or Deionized Water.
Instruments should be cleaned withing 30 minutes of use to minimize the potential for drying of contaminants prior to cleaning. 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 neutral PH enzymatic cleaner for soaking in accordance with enzymatic cleanser manufacturer instructions. The recommended enzymatic cleaning solution is STERIS® Prolystica® 2X

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Concentrate Enzymatic Cleaner or similar and is suitable for manual and automated ultrasonic systems.

1.3. Completely submerge all instruments in the enzymatic solution and soak for least 10 minutes or until visible soil has been removed.
1.4. Rinse each instrument free of debris and organic materials with lukewarm tap water, not exceeding 40 °C.
1.5. For instruments with lumens, use a 60ml syringe with enzymatic soak solution 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 and repeat steps 1.2 – 1.5 until visibly clear of soil or debris.
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 gently clearing debris only and should not be autoclaved or used forcefully. The recommended flexible brushes are Wells Johnson Company Part Numbers.

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

⚠ *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, 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) For guidance on routine inspection and maintenance, refer to the “Inspection and Care” section

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

3. Ultrasonic Cleaning

3.1. In an Ultrasonic Cleaner (bath) large enough to fully immerse all items, prepare neutral PH enzymatic cleanser for Ultrasonic Cleaning (bath) in accordance with enzymatic cleanser manufacturer instructions. The recommended enzymatic solution is STERIS® Prolystica® 2X Concentrate Enzymatic Cleaner or similar and is suitable for manual and automated 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 or Deionized 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. For guidance on routine inspection and maintenance, refer to the “Inspection and Care” section If any signs of damage, wear, or material fatigue are identified, do not use the instrument. Discard the instrument in accordance with facility protocols and applicable regulatory requirements.

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

5.2. Handles and instruments containing plastic must be packaged individually and disconnected from cannulas or metal components prior to autoclaving. Failure to follow this instruction may result in damage to the plastic components. 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 in accordance with ANSI/AAMI ST79.

5.4. Packaging should ensure sufficient protection of instruments, accessories and sterilization packaging from mechanical damage.

6. Sterilization

Only the sterilization method below is validated for use. The use of alternative sterilization methods is not permitted and may compromise device integrity or performance

6.1. Instrument Sterilization Procedure

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6.1.1.	Cycle:	Pre-Vacuum
6.1.2.	Temperature:	132 °C (270°F)
6.1.3.	Exposure Time:	4 minutes
6.1.4.	Dry Time:	30 minutes

⚠ *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, with 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 before each subsequent use according to the parameters in these Instructions for Use. A critical part of this process is the inspection of instruments for any signs of damage or wear.
Product life is typically limited by wear and damage sustained through normal use.

1. **Inspection Between Use**
   Inspections must be performed prior to packaging for sterilization to ensure compromised instruments are not placed in the sterile fields.

   1.1. Visually inspect each instrument thoroughly for obvious signs of bending, fractures, cracks, dents, or other 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 pulling force on the shaft. If the shaft moves in the handle/hub, do not use the cannula.

   1.3. Using a 5x magnifier, carefully inspect the cannula orifices hub joint for holes, cracks, fractures or other irregularities.

   1.4. If signs of abnormalities are identified during visual or magnified inspections, the instruments must not be used and should be discarded according to facility and applicable regulations.

2. **Care**
   Careful handling and maintenance of cannulas and accessories are necessary to minimize the risk of physical damage. It is the user's responsibility to ensure proper handling, care and use, which includes observing and preventing the following causes of damage. Damage resulting from the following causes is not covered under warranty.

   2.1. Do not drop instruments onto hard surfaces or into hard containers
   2.1.1. Resulting damage:
   Potential damage includes bent or broken cannula tips, bent or broken cannula shafts, loosened shafts in the handle or hub, dents, and damage to connection interfaces.

   2.2. Do not apply lateral stress, torque or lifting motions to the instrument during use.
   2.2.1. Resulting damage:
   Potential damage includes bent or broken cannula tips, bent or broken cannula shafts, loosened

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shafts in the handle or hub, dents, and damage to connection interfaces.

2.3. Do not intentionally or unintentionally bend or manipulate cannula shaft.
2.3.1. Resulting damage:
Bent or broken cannula tip, bent or broken cannula shaft, loosened shaft at the handle or hub and shaft fatigue that may lead to eventual breakage near handle/hub.

2.4. Do not force instruments into autoclaves, ultrasonic baths, or storage spaces.
2.4.1. Resulting damage:
Potential damage includes bent or broken cannula tips, bent or broken cannula shafts, loosened shafts at the handle or hub, dents, and damage to connection interfaces.

2.5. Do not clean instruments with corrosive agents. These may include oxidizing acids, alkaline solutions, organic solvents, oxidizing agents, halogens, and aromatic or halogenated hydrocarbons, rinse acids, or acidic neutralizers.
2.5.1. Resulting damage:
May result in compromised or ineffective sterilization, corrosion of metal components, damage to plastic materials, cosmetic discoloration or surface changes, , and damage to hub joints.

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 or user to ensure that the reprocessing is performed correctly using appropriate equipment, validated materials and qualified personnel to achieve the intended results.

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If the equipment and materials specified in these Instructions for Use are not available, the user or re-processer is responsible for validating any alternative process used, at their own risk.

It is the responsibility of the user to inspect cannulas and accessories and confirm their proper function before use.

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