

WELLS JOHNSON

Reusable Cannulas and Accessories

INSTRUCTIONS FOR USE

CAUTION: *Federal law restricts this device to sale by or on the order of a physician.*

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Device Description

Wells Johnson cannulas and accessories are manual, reusable surgical instruments offered in various sizes and configurations to meet customer requirements. The devices are manufactured from medical-grade stainless steel, aluminum, and/or Delrin (acetal) plastic, depending on the device configuration.

The devices are designed for repeated use when properly cleaned, inspected, and reprocessed in accordance with the instructions provided in this IFU. Improper cleaning, handling, chemical exposure, or thermal processing may damage the device, cause corrosion of metallic components, or accelerate degradation of plastic components and may adversely affect device performance.

CAUTION: *Carefully read these instructions before using Wells Johnson Cannulas and Accessories. Keep these instructions in a safe place for future reference.*

Intended Use

Wells Johnson Reusable Cannulas and Accessories are intended for use during liposuction procedures to facilitate the infiltration of fluids, aspiration of adipose tissue, and the transfer of adipose tissue for reinjection into targeted areas of the body.

Intended Users

Wells Johnson Reusable Cannulas and Accessories are intended to be used and handled in healthcare settings by qualified and trained healthcare professionals, such as licensed surgeons and operating room personnel.

Use Environment

Wells Johnson Reusable Cannulas and Accessories are intended for use in healthcare settings, including operating rooms and other clinical environments where liposuction procedures are performed.

Contraindications

No known contraindications.

Prior to Use

CAUTION: *Cannulas and Accessories are supplied non-sterile. Cleaning and sterilization must be performed before initial and each subsequent use.*

Before each use, visually inspect each instrument for signs of damage, excessive wear, corrosion, deformation, or contamination. Refer to the **Inspection and Care** section for detailed inspection and maintenance instructions.

CAUTION: *Do not use Cannulas and Accessories that show signs of damage, excessive wear, corrosion, deformation, or improper function. Remove damaged or non-functioning instruments from service and discard them in accordance with facility procedures and*

applicable regulations.

The user is responsible for ensuring that the instrument has been properly reprocessed and is suitable for use before the procedure.

Reprocessing Instructions

CAUTION: *Wear appropriate personal protective equipment (PPE) when cleaning and handling used instruments.*

1. Soak

CAUTION: *Begin cleaning within 30 minutes after use. Do not allow blood or other contaminants to dry on the instruments or hold instruments in a dry container.*

- 1.1. Within 30 minutes after use, disconnect accessories (e.g. handles) from connection interfaces. Remove excess debris from all surfaces using a disposable cloth or non-shedding wipe. Rinse with lukewarm water not exceeding 40 °C or temporarily cover the instruments with a cloth moistened with distilled or deionized water. Instruments should be cleaned within 30 minutes after use to minimize drying of contaminants before cleaning. Do not hold instruments in a dry container, as dried blood and debris may remain on device surfaces and make cleaning more difficult.
- 1.2. Place instruments in a basin or sink large enough to accommodate all instruments. Prepare a neutral pH enzymatic cleaning solution according to the enzymatic cleaner manufacturer's instructions. The recommended enzymatic cleaning solution is STERIS Prolystica 2X Concentrate Enzymatic Cleaner or a similar product suitable for manual and ultrasonic cleaning.
- 1.3. Completely submerge all instruments in the enzymatic solution and soak for at 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 60 mL syringe with enzymatic soak solution to completely flush each instrument at least three times from end to end. Ensure that all debris is removed and that the lumen is unobstructed, allowing the rinsing solution to flow freely through the instrument. Visually inspect each instrument and repeat steps 1.2 – 1.5 until all visible soil and debris have been removed.
- 1.6. Make sure all the instruments are visibly clean, free of grease, and free of obstructions.

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. Immediately after removing the instruments from the enzymatic cleaning solution, brush all external surfaces for at least 30 seconds or until all visible contaminants have been removed.
- 2.4. Using a non-metallic, flexible cleaning brush, clean the inside of each lumen. Smaller-diameter cannulas are supplied with a stylet to assist in clearing debris from the inner lumen. The stylets are non-autoclavable and are intended only for gently clearing debris. Do not autoclave or apply excessive force to the stylets.

The recommended flexible cleaning brushes are available from Wells Johnson under the following part numbers:

Part Number	Cannula Diameter
20-5232-00	1.5 mm – 3.0 mm
20-5230-00	4.0 mm – 6.0 mm
20-5231-00	7.0 mm – 10.0 mm

CAUTION: *Do not use metal-bristle brushes to clean instruments. Metal bristle may damage instrument surfaces and components.*

- 2.5. When cleaning the instruments, pay particular attention to surfaces and features that may be shielded from the brushing. Additionally, pay careful attention to cannula ports/orifices, lumens, and connection interfaces. Rinse under running tap water not exceeding 40 °C for at least 3 minutes or until all traces of cleaning solution have been removed.
- 2.6. If necessary, use forceps or pickups to remove difficult debris in smaller areas. After removing the debris, wipe the affected external surface with a non-shedding wipe.
- 2.7. Inspect each instrument to verify that all visible contaminants have been removed and that the instrument is free of distortion or damage. Pay particular attention to:
- Containment “traps,” such as concave or mating surfaces.
 - Recessed features, such as openings in cannulas and accessories.
 - Cannula ports/orifices, lumens, and connection interfaces.

If visible contamination remains, repeat the cleaning steps as necessary.

- 2.8. Remove instruments from the enzymatic cleaning solution and drain. Thoroughly flush each instrument at least three times using a 60 mL syringe 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 instruments, prepare a neutral pH enzymatic cleaning solution in accordance with the enzymatic cleaner manufacturer's instructions. The recommended enzymatic solution is STERIS Prolystica 2X Concentrate Enzymatic Presoak & Cleaner or similar product that is suitable for manual and ultrasonic cleaning.

- 3.2. Completely submerge the instruments in the ultrasonic bath and clean for 10 minutes in accordance with the ultrasonic cleaner manufacturer's instructions.
- 3.3. Remove instruments from the ultrasonic bath and thoroughly rinse with distilled or deionized water for 3 minutes.
- 3.4. Repeat steps 3.2 and 3.3 until no visible debris, soil, or enzymatic cleaning solution remains in the rinse water.

4. Drying

- 4.1. Ensure all instruments are completely and properly clean before drying.
- 4.2. Thoroughly dry all surfaces, joints, openings, channels, and lumens using a clean, absorbent, non-shedding towel. Medical-grade filtered compressed air may also be used to remove moisture from accessible areas, channels, and lumens.
- 4.3. Repeat step 4.2 as necessary until completely free of visible moisture.

5. Sterilization Packaging

- 5.1. When completely dry, inspect each component for damage, wear, or other conditions specified in the **Inspection and Care** section. Do not use any instrument that does not meet the specified inspection criteria. Dispose of instruments that are damaged or otherwise unsuitable for use in accordance with facility protocols and applicable regulatory requirements.
- 5.2. Handles and instruments containing plastic components must be packaged individually and disconnected from cannulas or metal components prior to autoclaving. This separation is intended to prevent heat transfer or contact that may result in damage to plastic parts. Wells Johnson handles containing Delrin (acetal) include:

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

- 5.3. The inspected and completely dried devices should be wrapped in accordance with ANSI/AAMI ST79 using sterilization packaging appropriate for steam sterilization.
- 5.4. Ensure the packaging provides adequate protection of the instruments and accessories from mechanical damage and allows effective penetration of the sterilization process.

6. Sterilization

Only the sterilization method and cycle parameters specified below have been validated for use with these devices. Do not use alternative sterilization methods or cycle parameters, as they may compromise device integrity, performance, or sterility.

Instrument Sterilization Procedure:

- Method: Moist Heat Sterilization according to ANSI/AAMI ST79
- Cycle: Pre-Vacuum
- Temperature: 132 °C (270 °F)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes

CAUTION: *Do not use immediate-use steam sterilization (“flash sterilization”). The validated sterilization cycle and sterilization packaging specified in this IFU must be followed.*

Storage of Sterilized Devices

Store sterilized devices in their intact sterilization packaging in a clean, dry, and environmentally controlled area that protects the devices and sterilization packaging from contamination and damage. Handle and store sterilized devices in accordance with ANSI/AAMI ST79.

CAUTION: *Inspect the sterilization packaging before use. Do not use the device if the sterilization packaging is torn, punctured, wet, opened, or otherwise compromised.*

Inspection and Care

Cannulas and Accessories must be cleaned and sterilized before each subsequent use in accordance with the procedures and parameters specified in these Instructions for Use. Thorough inspection before each use is essential to identify damage or wear that may affect device safety or performance.

The service life of reusable instruments is dependent on the frequency and conditions of use, handling, cleaning, sterilization, and inspection. Do not use an instrument that shows signs of damage, excessive wear, deformation, cracking, or other conditions that may affect its safe use.

1. Inspection Before Sterilization

Inspect each instrument after cleaning and drying and before packaging for sterilization. Inspection must be conducted to ensure that damaged or compromised instruments are not sterilized or returned to use.

- 1.1. Visually inspect each instrument thoroughly for bending, fractures, cracks, dents, loosened components, or other visible irregularities.
- 1.2. Perform a pull-test on each cannula by holding the cannula shaft of the in one hand, and the handle or hub in the other hand. Gently apply pulling force on the shaft. If the shaft moves within the handle or hub, do not use the cannula.
- 1.3. Using a 5x magnifier, carefully inspect the cannula orifices and hub-to-shaft joint for holes, cracks, fractures, or other irregularities.

- 1.4. If any damage, abnormality, or other condition that may affect the safe use or performance of the instrument is identified, do not use the instrument. Remove the instrument from service and dispose of it in accordance with facility procedures and applicable regulatory requirements.

CAUTION: *Do not package or sterilize instruments that do not pass the required inspection. Damaged or compromised instruments may fail during use and may result in patient or user injury.*

2. Care and Handling

Proper handling and care of cannulas and accessories are necessary to minimize damage during use, cleaning, sterilization, and storage. Handle instruments carefully and avoid the following conditions that may cause damage.

- 2.1. Do not drop instruments onto hard surfaces or into hard containers.
- 2.2. Do not apply lateral force, excessive torque, or lifting force to the instrument during use.
- 2.3. Do not intentionally bend, manipulate, or otherwise deform the cannula shaft.

CAUTION: *Excessive lateral force, bending, or manipulation may result in bent or broken cannula tips or shafts, loosening of the shaft from the handle or hub, damage to connection interfaces, or material fatigue that may result in eventual shaft breakage.*

- 2.4. Do not force instruments into autoclaves, ultrasonic cleaning baths, sterilization packaging, storage containers, or other spaces that are too small to accommodate the instrument without bending or compressing it.

CAUTION: *Forcing an instrument into a confined space may cause permanent deformation, bending, cracking, or damage to the cannula shaft, tip, handle, hub, or connection interfaces.*

- 2.5. Do not clean instruments with corrosive or incompatible cleaning agents. Avoid oxidizing acids, strongly alkaline solutions, organic solvents, oxidizing agents, halogens, aromatic or halogenated hydrocarbons, rinse acids, or acidic neutralizers unless specifically identified as compatible with the device.

CAUTION: *Use of incompatible cleaning agents may cause corrosion of metal components, degradation or damage to plastic materials, discoloration or surface changes, damage to hub joints, or other conditions that may compromise device integrity and performance.*

Symbols Used

Symbol	Title	Description	Standard
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021, 5.1.1
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1:2021, 5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021, 5.1.5

Symbol	Title	Description	Standard
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021, 5.4.3
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2021, 5.2.7
	Medical device	Indicates the item is a medical device	ISO 15223-1:2021, 5.7.7
	Prescription Only	Federal law restricts this device to sale by or on the order of a physician	FDA-recognized prescription-device designation under 21 CFR 801.109
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021, 5.7.10
	Quantity	Indicates the quantity of product contained in the labeled container.	None

User Responsibility

The user is responsible for ensuring that reprocessing is performed correctly using appropriate equipment, validated materials, and qualified personnel to achieve the intended results. If the equipment, materials, or processes specified in these Instructions for Use are not available, the user is responsible for validating any alternative equipment, materials, or processes before use.

Inspect cannulas and accessories before each use and confirm that they are in proper working condition.

Warranty

Cannulas are warranted from the date of invoice against defects in materials and workmanship for the lifetime of the cannula.

This warranty does not cover damage or failure resulting from misuse, abuse, improper handling, improper cleaning or reprocessing, use beyond the validated number of reuse cycles, unauthorized modification or repair, failure to follow the Instructions for Use, or normal wear and tear.

Customer Service and Technical Support

Report any product malfunction, adverse event, or complaint to Wells Johnson Customer Service or Technical Support:

Phone: +1 520-298-6069 or +1 800-528-1597

Email: customerservice@wellsgrp.com



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