

General Instruments Cleaning & Sterilization Guide

Reusable Instruments Instructions for Use

These instructions for use (IFU) are intended for reusable surgical instruments labelled with the FusionKraft™ name.

This cleaning and sterilization guide does not replace instrument-specific instructions for use already included with the instrument.

How Supplied

Instruments are packaged as non-sterile. Cleaning and sterilization of instruments must occur prior to use.

Limitations on Reprocessing

Repeated processing has minimal effect on the FusionKraft™ instruments. End of life is normally determined by wear and damage due to use.

Warnings

FusionKraft™ instruments shall be used in accordance with these Instructions for Use. Read all sections of this IFU prior to use. Improper use of these instruments may cause serious injury.

In addition, improper care and maintenance of the instruments may render the instruments unfit prior to patient use and may cause serious injury to the health care provider or the patient.

Cautions

If there are any variations between these Instructions for Use and either the facility's policies and / or the cleaning / sterilizing 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 sterilization of the FusionKraft™ instruments.

Use of an instrument for a task other than what it is intended for will usually result in a damaged or broken instrument.

Prior to use, inspect the instruments to ensure proper function and condition. Do not use the instruments if they do not satisfactorily perform their intended function or if they have physical damage.

Avoid mechanical shock or overstressing the instruments. Close distal ends prior to insertion or removal through cannulas.

Always use caution when inserting or removing the instruments through the cannula. Lateral pressure on the instrument during removal can damage the working tip, and / or shaft of the instrument.

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Be sure the tips are closed and the instrument is pulled straight out until completely clear of the cannula to avoid catching the valve assemblies in cannulas or dislodging the cannula.

Only the cleaning and sterilization processes which are defined within these Instructions for Use have been validated. Use only neutral pH (6-8) detergent solutions.

Pre-processing Instructions

Initiate cleaning of the instruments within 2 hours of use.

Transport the instruments via the institutions established transport procedure.

Remove excess gross soil / debris as soon as possible after use by rinsing or wiping the instrument.

All the instruments must be processed in the completely open position (i.e. jaws, catch etc.) to allow solution contact of all surfaces..

Note: that applicable instrument disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.

Manual Cleaning Process

Enzymatic / Neutral pH Detergent

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic/neutral pH detergent solution, utilizing drinking water with a temperature range of 27°C to 44°C (81°F to 111°F), as per manufacturer's instructions.
3. Place the instrument in the open / relaxed position with jaws / catch open. Completely immerse the instrument in the detergent solution and allow it to soak for a minimum of 3-5 minutes.

Actuate all movable parts during the initiation of the soak time.

4. Using a soft bristled brush, remove all visible soil / debris from the instrument.

Actuate the instrument while brushing, paying particular attention to the hinges, crevices and other difficult to clean areas.

Note: It is recommended that the detergent solution be changed when it becomes grossly contaminated (bloody and/or turbid).

5. Rinse the instrument by completely immersing it in treated water with a temperature range of 27°C to 44°C (81°F to 111°F), for a minimum of 30 seconds to remove any residual detergent and / or debris.
6. Dry the instrument with a clean, lint-free towel.
7. Visually examine each instrument for cleanliness.
8. If visible soil / debris remains, repeat cleaning procedure until the instrument is thoroughly clean.

FusionKraft™

Automatic Cleaning Process Enzymatic / Neutral pH Detergent

- Ensure all pre-processing instructions are followed prior to cleaning.
- Clean the instruments via the automatic cleaning parameters below.

Phase	Minimum Recirculation Time	Water Temperature	Detergent Type & Concentration (If Applicable)
Pre-Wash	15 Sec	Cold Drinking Water 1°C - 16°C (33°F - 60°F)	N/A
Enzyme Wash	60 Sec	Hot Drinking Water 43°C - 82°C (110°F - 179°F)	- Detergent: pH-neutral/enzymatic - Concentration: As per the Detergent Manufacturer's recommendations
Wash	120 Sec	Drinking Water 43°C - 82°C (110°F - 179°F)	- Detergent: pH-neutral cleanser - Concentration: As per the Detergent Manufacturer's recommendations
Rinse	15 Sec	Drinking Water 43°C - 82°C (110°F - 179°F)	N/A
Pure Rinse	10 Sec	Treated Water 43°C - 82°C (110°F - 179°F)	N/A
Drying	N/A	N/A	N/A

- If visible moisture is present dry the instrument with a clean, lint-free towel.
- Visually examine each instrument for cleanliness.
- If visible soil / debris remains, repeat cleaning procedure until the instrument is thoroughly clean.

Note: the final rinse step should be performed with treated water:purified, de-ionized, distilled or reverse osmosis.

If drinking water is used as part of the final rinse, ensure corrosion does not occur.

Inspection/Maintenance

Proper care and handling is essential for satisfactory performance of any FusionKraft™ surgical instruments.

The previous cautions should be taken to ensure long and trouble-free service from all FusionKraft™ surgical instruments. Inspect the instruments 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 instrument. Return instruments to an authorized repair service centre for repair or replacement.

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Before sterilizing, lubricate the instrument with instrument milk or a steam permeable / water soluble lubricant, following the lubricant manufacturer's instructions.

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

Packaging

Instruments can be loaded into dedicated packaging systems. Sterilization wrap material must be cleared for the applicable sterilization modality by the respective country's regulatory body. Use in accordance with packaging manufacturer's sterilization instructions being sure to protect jaws and the cutting edges from damage.

Sterilization

All the instruments must be processed in the completely open position (i.e. jaws, catch etc.) to allow sterilant contact of all surfaces. Note that applicable instrument disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.

All instruments with concave surfaces shall be configured so that water pooling does not occur.

Storage

After sterilization, the instruments should remain in sterilization packaging and be stored in a clean, dry environment.

Warranty

FusionKraft™ offers a 6 month Standard Warranty on every surgical instrument bearing the FusionKraft™ brand name (unless otherwise noted). Surgical instruments are guaranteed to be free of functional defects in workmanship and materials when used normally for its intended surgical purpose. Any FusionKraft™ instrument proving to be defective within the warranty period will be replaced or repaired at no cost to the customer.

Contact Information

Myra & Co.

#293, Ground Floor, Niti Khand - 2,
Indirapuram. Ghaziabad. Uttar Pradesh.
INDIA. PIN – 201010

Phone +91 120 6530330 (8 Lines)

Hotline +91 120 6401193

Mobile +91 99999 06920
+91 99711 16920

www.myraandcompany.in

For Domestic Enquiries:
customer.support@myraandcompany.in

For International Enquiries:
org@myraandcompany.in

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